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# Overview

UL has partnered with clients in a variety of industries for the past 30 years to provide training and services to build strong learning programs.

We currently maintain over 1,000 online e-learning courses that are written and reviewed by recognized subject matter experts, including the US FDA. In fact, more than one million industry professionals, have completed tens of millions of courses since 2003.

Courses are regularly updated to reflect the most current expectations and requirements of regulators and industry groups. Our global quality and compliance management methodology has resulted in measurable performance and compliance improvements. Our e-learning philosophy is based on Mastery Learning, which has been proven to improve retention and change behavior in adult learners through methods that include interaction with dynamic content and built-in assessments.

Should your organization have unique training requirements, you can rely on our Content Solutions team, which develops thousands of courses each year for our clients. Our team shares best practices as it relates to instructional design and multi-media, such as incorporating your organization's unique content and branding into our standard courses or new custom courses.

Courses are accessible on tablets and other mobile devices and can be translated into almost any language. Courses can be hosted independently on your own LMS, or you can take advantage of UL's industry standard LMS offerings. Learn more about UL's courses and additional solutions at [ulehss.com](http://ulehss.com).

## Selections:

**Libraries:** [Medical Device Catalog](#) |

## A Guide to ISO 13485 - The Quality Management System for Medical Devices

DEV50

This course serves as a guide to ISO 13485 – the international quality management system standard for medical devices. The requirements of the standard apply to the methods used in, and the facilities and controls used for, the design and development, production, installation, and servicing of medical devices. Topics in this course include: Quality Management System, Management's Role, Managing Resources, Planning, Design and Purchasing, Production, Monitoring and Analysis, and Improvement. This course also addresses specific aspects of ISO 13485 as it relates to the European Union (EU). After completing this course, learners will be able to recognize the specific requirements of ISO 13485 and apply them to specific situations.

**Languages Available:**

Chinese (Simplified)  
French (European)  
German  
Japanese  
Korean  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM,  
eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize the specific requirements of ISO 13485.

**Runtime:** 75

## A Guide to ISO 9001:2015 \_ Quality Management Systems Requirements

DEV61

This course serves as a guide to ISO 9001:2015 – the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization's ability to consistently provide products and services that meet customer satisfaction and applicable statutory and regulatory requirements. Topics in this course include: System and Process, Leadership, Planning, Support, Operation, Performance Evaluation, and Improvement. After completing this course, learners will be able to recognize the specific requirements of ISO 9001:2015 and identify management's role in implementation and maintenance of the standard. Learners will also be able to recognize the requirements for quality management system Clauses 4.7.10 and recognize how to ensure compliance with the standard.

**Languages Available:**

Chinese (Simplified)  
French (European)  
German  
Japanese  
Korean  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Medical Device Catalog
- FDA Inspections and Enforcement Library
- Medical Device GMPs Library

**Course Objectives:**

Recognize the specific requirements of ISO 9001:2015.;Identify management's role in implementation and maintenance of the standard.;Recognize requirements for quality management system Clauses 4.7.10;Recognize how to ensure compliance with the standard.

**Runtime:** 45

## A Step-by-Step Approach to Process Validation

PHDV79

Process validation is required by process control regulations for both drugs and medical devices. This course outlines the important tasks performed during each phase of the validation life cycle, as well as the information that should (and should not) be included in validation documents and why processes must be monitored once they are validated. Topics in this course include: Validation Life Cycle, Process Design, Process Qualification including IQ, OQ, PQ, Product Process Qualification, Change Control, and Documentation. After completing this course, you will be able to recognize the validation life cycle, process validation steps, and how the EU regulations differ from FDA requirements. You will also be able to identify validation principles that pertain to the medical device industry.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize the definition of process validation as it relates to pharmaceutical products and medical devices. ;Identify the steps involved in process validation. ;Identify how the process differs between FDA and EU regulatory agencies.

**Runtime:** 60

## A Tour of FDA

PHDV60

The Food and Drug Administration (FDA) touches the lives of virtually every American, every day. This course outlines the form and function of the FDA, its upper level structure, and its mission and goals. Topics in this course include: History and Scope of FDA, FDA Organization, Program Centers, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Veterinary Medicine, National Center for Toxicological Research, and Center for Tobacco Products.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize FDA's public health mission and how the Agency is organized to carry out its mission.;Recognize the history of FDA and the products that it regulates.;Recognize the work of FDA's program Centers and offices, and how the Agency enforces its regulations.

**Runtime:** 75

## A Tour of Health Canada

PHDV89

Health Canada touches the lives of virtually every Canadian; every day. This course introduces participants to Health Canada's mission and organization. After a brief introduction, the course will focus on the Health Products and Food Branch (HPFB) of Health Canada, which directly affects pharmaceutical manufacturers. Topics in this course include: Purpose, Organization, HPFB, TPD, BGTD, and HPFBI. After completing this course, learners will be able to identify the major branches of Health Canada, the HPFB, and its directorates. Learners will also be able to identify the unique roles and responsibilities of the three HPFB directorates that most directly affect the pharmaceutical industry.

**Format:** eLearning - SCORM, eLearning - EduFlex

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the major branches of Health Canada, the HPFB, and its directorates; Identify the unique roles and responsibilities of the three HPFB directorates that most directly affect the pharmaceutical industry.

**Runtime:** 30

## Access to Medical and Exposure Records for Employees (US)

PS5-100747

The law requires your employer to provide you with access to your medical and exposure records. Why should you care? How do you get access? Take this course to find out! This course is ideal for all employees.

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**                      **Topic/Industry:**

- Safety Catalog
  - EHS for Life Science - Basics Library
  - Medical Device Catalog
  - Pharmaceutical Catalog
- Awareness
  - Employment Liability

**Course Objectives:**

Why medical and exposure records are useful; How to access records; Your rights regarding records and access

**Runtime:** 5

## Accurate Company Records

ETHICS24

Companies have a legal obligation to create and retain records that accurately reflect their business transactions. Fraudulent reporting of books, records, or other written communication violates company policy and possibly the law. Topics in this course include: Laws and Regulations, Accurate Timely Records, Accurate Financial Records, and Records Management. After completing this course, learners will be able to recognize their role in recording every company transaction correctly, accurately, and on time. Learners will also be able to recognize the importance of proper management of company records.

**Format:** eLearning - EduFlex, eLearning - SCORM

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Recognize our legal obligation to create and retain records that accurately reflect our business transactions.;Recognize the importance of following internal controls to ensure accurate financial records.;Recognize company policies concerning management of company records, and obligations as an employee who is responsible for these records.

**Runtime:** 30

## Active Listening Skills

EHS02

Listening is one of the most important skills for success in life, but it is taken for granted by most people. This course describes how to improve active listening skills and gain an understanding of the significance of listening. Topics in this course include: Communication, Barriers, Benefits, Listening Levels, and Skills. After completing this course, learners will be able to identify the seven listening skills that can help increase productivity as well as improve the ability to work with others.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Spanish (Latin America)

**Format:** eLearning - EduFlex, eLearning - SCORM

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HR Compliance &amp; Risk Management Library</li></ul> | <ul style="list-style-type: none"><li>• Professional Development</li></ul> |

### Course Objectives:

Recognize how to improve your active listening skills and gain an understanding of the significance of listening. ;Identify the seven listening skills that can help you increase productivity as well as improve the ability to work with others.

**Runtime:** 45

## Administrative Roles of the Clinical Research Associate

GCP26

This course examines the administrative roles and responsibilities of the Clinical Research Associate (CRA) during specific on-site monitor visits conducted at the principal investigator location on behalf of a sponsor. Topics in this course include: Roles and Responsibilities, Monitoring Plan, PSSV and SIV, Source Documents, and Monitoring Functions. After completing this course, learners will be able to identify the general roles and responsibilities of a CRA, with recommended monitoring tasks to be completed at specified time intervals of an ongoing study.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the general roles and responsibilities of a CRA, with recommended monitoring tasks to be completed at specified time intervals of an ongoing study.

**Runtime:** 45

## Administrative Roles of the Clinical Research Coordinator

GCP27

This course describes the administrative roles and responsibilities of the Clinical Research Coordinator (CRC). The CRC is an individual who coordinates many aspects of a clinical trial at the investigative site. The CRC's tasks are formally delegated to them by the principal investigator (PI) and frequently involve both clinical duties (within their professional scope of practice) and coordination activities. Upon completion of this course, you will be able to identify the CRC role throughout a clinical trial, as well as recognize applicable Good Clinical Practice standards.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- Clinical Quality Manager

**Course Objectives:**

Identify the role of a CRC throughout a clinical trial, as well as recognize applicable Good Clinical Practice standards.

**Runtime:** 60



## Affirmative Action in the Workplace (For Employers)

LAV02

Today, federal laws make it illegal to discriminate against a job applicant or an employee because of the person's race, color, religion, sex, national origin, age, disability, or genetic information. This course addresses the essential features of affirmative action requirements for federal contractors. Topics in this course include discrimination laws, responsibilities of a federal contractor, and the equal opportunity clause. After completing this course, learners will be able to recognize Affirmative Action Plans (AAPs) and their role in aiding compliance with these anti-discrimination laws.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Topic/Industry:**

- HR Compliance & Risk Management

**Course Objectives:**

Recognize when affirmative action requirements for federal contractors are triggered and understand the structure of Affirmative Action Plans (AAPs). ;Recognize how federal contractors can stay in compliance with these anti-discrimination laws.

**Runtime:** 60

## Age Discrimination

LAV01

Age discrimination can be particularly challenging when an employer is reducing employee numbers or is managing an aging workforce. This course describes the federal legislation that prohibits age discrimination in the workplace. Topics in this course include: Legislation, Prohibited Practices, Claims, and Helpful Strategies. After completing this course, learners will be able to recognize provisions of the Age Discrimination in Employment Act (ADEA).

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Topic/Industry:**

- HR Compliance & Risk Management

**Course Objectives:**

Identify the provisions of the ADEA. ;Recognize a fair and equitable working environment for employees.

**Runtime:** 30

## Americans with Disabilities Act

LAV07

The course identifies who is classified as a disabled employee and how these employees are protected under the Americans with Disabilities Act (ADA). This course also discusses the concepts of reasonable accommodation and undue hardship as well as coverage for substance abuse. Topics in this course include: Disability, Legislation, Reasonable Accommodation, and Drugs and Alcohol. After completing this course, learners will be able to recognize who is classified as a disabled employee and how the ADA protects these individuals. Learners will also be able to recognize how to comply with the ADA reasonable accommodation requirement.

**Format:** eLearning - EduFlex, eLearning - SCORM

- | <b>Libraries:</b>  | <b>Topic/Industry:</b>  |
|--|---|
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HR Compliance &amp; Risk Management Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• HR Compliance &amp; Risk Management</li></ul> |

### Course Objectives:

Recognize who is classified as a disabled employee and how the ADA protects these individuals. ;Recognize how to comply with the ADA reasonable accommodation requirement.

**Runtime:** 30

## An Introduction to ISO 13485 - The Quality Management System for Medical Devices

DEV48

The international standard ISO 13485:2016 specifies the requirements for a quality management system that can be used by an organization in one or more stages of the life-cycle. ISO 13485 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. This course is the first of a two part series. Topics in this course include: ISO 13485:2016, Process Approach, Clauses 4-6, Clauses 7 and 8, and Preparation. This course also addresses specific aspects of ISO 13485 as it relates to the European Union (EU). After completing this course, learners will be able to recognize the requirements of ISO 13485.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

- | <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
|--|--|
| <ul style="list-style-type: none"><li>• Medical Device Catalog</li><li>• Medical Device GMPs Library</li></ul> | <ul style="list-style-type: none"><li>• QA/GMP Trainer</li></ul> |

### Course Objectives:

Recognize the difference between ISO 13485 and ISO 9001. ;Recognize the process approach of ISO 13485. ;Identify management's role in implementation and maintenance of ISO 13485 and recognize the requirements for quality management system Clauses 4-8 of ISO 13485:2016. ;Recognize how to ensure compliance with ISO 13485:2016.

**Runtime:** 60

### Languages Available:

Chinese (Simplified)  
French (European)  
German  
Japanese  
Korean  
Spanish (Spain)

## An Introduction to ISO 9001:2015 \_ The Quality Management System Requirements

DEV60

This course serves as an introduction to ISO 9001:2015 \_ the international quality management system requirements standard. This standard specifies requirements to demonstrate an organization's ability to consistently provide products and services which meet customer satisfaction and applicable statutory and regulatory requirements. However, requirements of this standard are generic and are intended to be applicable to any organization regardless of which products and services are provided. Topics in this course include: Scope, Principles, Certification, Auditing, and Resources. After completing this course, learners will be able to identify the quality management principles of the standard and be able to recognize considerations for selecting a certification body as well as appropriate preparations for certification audits.

**Languages Available:**  
Chinese (Simplified)  
French (European)  
German  
Japanese  
Korean  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM

### Libraries:

- Medical Device Catalog
- Medical Device GMPs Library

### Course Objectives:

Recognize the background and quality principles of the ISO 9001:2015 standard. ;Recognize advantages and applications of the ISO 9001:2015 standard.

**Runtime:** 45

## Antitrust Law and Competitor Relationships

LAV14

Federal antitrust laws are designed to ensure that the basic promise of a free market economy and effective competition is not undermined by unlawful manipulation or collusion between competitors. This course explains how antitrust legislation regulates contact between competitors, and what employers and employees can do to ensure that they are in compliance with US antitrust laws. Topics in this course include: Legislation, Sherman Act, Clayton Act, Federal Trade Commission (FTC), Illegal Agreements, Competitor Interactions, and Helpful Strategies. After completing this course, learners will be able to recognize the antitrust laws that govern competitor interactions as well as their application to everyday business situations.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

### Libraries:

### Topic/Industry:

- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Corporate Compliance

### Course Objectives:

Recognize the antitrust laws that govern competitor interactions as well as their application to everyday business situations.

**Runtime:** 45

## Application of GMPs to Analytical Laboratories

PHDV78

Compliance with current Good Manufacturing Practices (cGMP) requirements is essential in order to create products that have quality, purity, proper identity, strength, and are safe. All laboratory analysts must follow cGMPs in order to create effective products and comply with all quality standards. Topics in this course include: Laboratory Documents, Laboratory Practices, Raw Data, Method Validation, Calibration, Training, OOS, and Computer Systems. After completing this course, learners will be able to identify cGMP requirements as they apply to analytical laboratory practices.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify cGMP requirements as they apply to analytical laboratory practices. ;Recognize key concepts related to laboratory documents, raw data, and out-of-specification (OOS) test results, and the requirements for laboratory training.;Recognize laboratory calibration requirements, method validation, and computer systems for use in analytical laboratories.

**Runtime:** 45

## Applying Electrical Standards (US)

PS5-00262

Electrical standards do not just help you comply with the law, they keep you safe! You are already familiar with electrical terms and hazards. Take this course to learn about NFPA 70E and what it means for you. Stay compliant and stay safe! Ideal learners are people in all industries, particularly supervisors, electrical workers and safety managers.

**Format:** eLearning - Claro

**Libraries:**                      **Topic/Industry:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog
- General Safety and Manufacturing
- Health and Safety Management

**Course Objectives:**

Recognize the consequences of not following electrical standards;Recall the OSHA and consensus standards that apply to electrical work;Identify NFPA 70E training requirements for qualified and unqualified workers;Use NFPA 70E tables to determine safe approach boundaries, PPE categories for specific tasks and required PPE

**Runtime:** 25

**Languages Available:**  
French (Canadian) (PS5-102324)  
Spanish (Latin America) (PS5-102224)  
English

## Approach to Computerized Systems Validation and Compliance

PHDV103

This course describes an approach to the validation and compliance of computerized systems used in the manufacture of pharmaceuticals, biologicals, and medical devices that are required to meet FDA's regulations. It identifies ways to organize policies and procedures, and plans FDA expects a manufacturing company to establish. This course draws on current industry good practice. Though it also draws on FDA medical device guidance, this course is not intended to describe an approach to developing software that subsequently becomes part of a medical device. This is the second course in a series of four courses. Before taking this course, you should have successfully completed Requirements for Computerized Systems Validation and Compliance.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical

**Course Objectives:**

Identify the type of framework that is suitable for computerized systems validation and compliance. Recognize planning and reporting requirements. Recognize how a validation strategy is selected and the activities that are required to ensure ongoing compliance.

**Runtime:** 45

## Aspects of Regulatory History

GCP22

Regulatory standards for conducting clinical trials are in place to protect those conducting and participating in clinical trials. This course describes the regulatory requirements of the US Department of Health and Human Services (HHS), Food and Drug Administration (FDA), and the guidelines of the International Conference on Harmonisation (ICH) necessary to ensure proper and successful clinical trial execution. Topics in this course include: History, Organizations, Regulations, and Guidelines. After completing this course, learners will be able to recognize the impact of ICH guidelines on the industry from a global perspective.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the historical events that brought about the regulatory requirements for conducting clinical trials. Identify the standards, organizations, regulations, and guidelines that are involved when conducting clinical trials.

**Runtime:** 60

## Auditing of Computer System Validation to Ensure Data Integrity

DATA02

FDA inspectors and corporate auditors must be able to recognize the critical aspects of computerized systems and the documentation needed to demonstrate that they are validated. This course provides an approach to inspecting/auditing these systems and covers the detailed review of systems that automate part of the production process or part of a quality system. Topics in this course include: Data Integrity and Governance, Validation and the SDLC, Key Documentation Deliverables, Requirements, Design and Configuration, Implementation and Verification, and Maintenance. After completing this course, learners will be able to recognize validation activities and the maintenance of the validated state as it relates to data integrity. Prerequisites for this course include Introduction to Data Integrity and either the Computerized Systems Inspections in the Medical Device Industry or the QSIT 5 "The Production and Process Controls Subsystem" course.

**Languages Available:**  
Chinese (Simplified)  
French (European)  
German

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Data Integrity Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical

### Course Objectives:

Recognize the requirements for data integrity, validation activities, and documentation. Recognize an approach to inspecting computerized systems when a detailed review of those systems is needed.

**Runtime:** 60

## Australia Therapeutic Goods Administration (TGA) MDSAP Specific

MDSAP\_Australia

Japan's Ministry of Health, Labour and Welfare (MHLW) has specific requirements in all seven chapters in the Medical Device Single Audit Program (MDSAP).

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 15

## Australian Therapeutic Goods \_ Medical Device Regulations Overview

PHDV105

The EU has strict requirements for the manufacture and supply of medicinal products, which are defined in EU directives and GMP guides. To confirm that these requirements are being complied with, manufactures and suppliers are regularly inspected. If significant deficiencies are identified during inspections, the company may face sanctions and could even be barred from supplying product. Upon completion of this course, you will be able to identify the regulatory background regarding EU inspections, the expectations inspectors may have, and how to prepare for inspections.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device
- Pharmaceutical

**Course Objectives:**

Identify the regulatory basis and scope of inspections. Identify how inspections are performed. Identify how you should prepare for them.

**Runtime:** 45

## Basic Radiation Awareness

EHS05

The general public often thinks radiation exposure only occurs in areas displaying ?Caution: Radiation,? or ?Danger: Radiation? signs. Actually, in addition to exposure in certain work places, each of us is exposed to natural radiation each day of the year. Topics in this course include: Effects, Limits, Controls, Assessment, and Regulations. After completing this course, learners will be able recognize the types of natural and man-made (ionizing) radiation, where radiation originates, its health effects, principles of protection, and the components of an effective Radiation Protection Program.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device - Sales & Marketing Library
- Medical Device Catalog
- EHS Manager
- Sales Operations

**Course Objectives:**

Recognize the types of natural and man-made (ionizing) radiation.;Recognize where radiation originates.;Recognize the health effects of radiation.;Identify the principles of protection against radiation.;Identify the components of an effective Radiation Protection Program.

**Runtime:** 30

## Basics of Business Finance

EHS06

The purpose of corporate financial management is to get everyone pulling together to create value. No company can succeed if its people lack skills in managing its money and assets. This course describes the basics of business finance. Topics in this course include: Funding, Balance Sheet, Income and Cash Flow Statements, Ratios, Forecasting, and Common Language. After completing this course, learners will be able to recognize the fundamentals of corporate finance in simple, easy to understand terms. Learners will also be able to recognize how work activities can and do affect the financial health of an organization.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Course Objectives:**

Recognize the fundamentals of corporate finance in simple, easy to understand terms. Recognize how work activities can and do affect the financial health of an organization.

**Runtime:** 45

## Basics of Cleanroom Operations

Aseptic01

Cleanrooms play a major role in preventing product contamination and ensure product sterility and safety. This course describes the general principles and practices relevant to proper cleanroom operations. Topics in this course include: Cleanroom Design, Contamination Control, People and Materials, Validation, and Monitoring. After completing this course, you will be able to recognize how cleanrooms are designed, validated, and operated to ensure product sterility and safety of aseptically produced sterile products.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Aseptic Processing Library

**Course Objectives:**

Recognize how cleanrooms are designed, validated, and operated.

**Runtime:** 15

**Languages Available:**

Chinese (Simplified)  
French (European)  
German  
Japanese  
Spanish (Spain)



## Basics of Inspections: Beginning an Inspection

FDA38

This is the first of two courses designed to inform learners of the basic practices during an inspection of a food establishment. This course explores the preparation needed before an inspection and identifies pre-inspection issues. Topics in this course include: Preparation, Pre-inspection Issues, HACCP, Product Protection, Hazards, and Corrective Actions. After completing this course, learners will be able to identify the purpose of a Hazard Analysis Critical Control Point (HACCP) plan and recognize the purpose of corrective actions.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |   |   |
|---|---|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>  |
| <ul style="list-style-type: none"><li>• FDA Inspections and Enforcement Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Food Safety Manager</li></ul> |

### Course Objectives:

Identify how to prepare for an inspection.;Recognize how to properly deal with management and recognize initial observations you should make at the start of an inspection.;Identify the purpose of a Hazard Analysis Critical Control Point (HACCP) plan.;Recognize what to look for when searching for potential food contaminants.;Identify examples of chemical and physical hazards. ;Recognize the purpose of corrective actions.

**Runtime:** 45

## Basics of Inspections: Issues and Observations

FDA39

This is the second of two courses designed to inform the learner of the basic practices during an inspection of a food establishment. This course explores the issues and observations that must be examined during an inspection, including: processing equipment, employee practices, food storage/display, water supply and plumbing, and pest control. Topics in this course include: Employee Practices, Processing Equipment, Food Storage and Display, Cross-contamination, Water Supply, Food Sampling, Inspection Report, and Closing Conference. After completing this course, learners will be able to identify the unsatisfactory practices that lead to contaminated food. Learners will also be able to recognize proper sampling procedures. Lastly, learners will be able to identify what to include in an inspection report and how to conduct a closing conference at the conclusion of an inspection.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |   |   |
|---|---|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>  |
| <ul style="list-style-type: none"><li>• FDA Inspections and Enforcement Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Food Safety Manager</li></ul> |

### Course Objectives:

Identify the unsatisfactory practices that lead to contaminated food.;Recognize proper sampling procedures. ;Identify what to include in an inspection report.;Recognize how to conduct a closing conference at the conclusion of an inspection.

**Runtime:** 45

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## Basics of the AdvaMed Code

MDSM01

It is crucial for all Medical Technology companies to understand the guidelines of the Advanced Medical Technology Association (AdvaMed) Code and how they impact interactions with Health Care Professionals (HCPs). This course discusses the Basics of the AdvaMed Code. Topics in this course include: Code, Education and Business Meetings, Consulting, Evaluation and Demonstration Products, and Gifts and Meals. After completing this course, learners will be able to recognize how the AdvaMed Code guides interactions with HCPs.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device - Sales & Marketing Library
- Medical Device Catalog

**Course Objectives:**

Recognize how the AdvaMed Code guides your interactions with HCPs.

**Runtime:** 45

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## Batch Record Reviews

PHA53

Pharmaceutical batch records are essential to ensure that regulatory and product quality attributes are achieved. This course describes how to properly perform a batch record review. Topics in this course include: Regulations, Manufacturing Records, Packaging Records, Laboratory Records, and Issues and Deviations. After completing this course, learners will be able to identify the GMP and cGMP requirements for batch records and recognize how to maintain GMP and cGMP compliance throughout the review process. The regulatory requirements of FDA are addressed with reference also made to the requirements of the EU.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library

**Course Objectives:**

Recognize the definition of batch records and the purpose of reviews.;Recognize the key elements and reasons for organized batch records.;Identify the key components of batch records and the elements of compliance and completeness for batch records.

**Runtime:** 45

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## Best Practices: Modest Meals

ADVAMED-MINI-02

This course describes the best practices and requirements under the AdvaMed Code for providing modest meals to healthcare professionals as a part of medical device sales presentations.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device Catalog
- Medical Device - Sales & Marketing Library

**Course Objectives:**

Recognize the basic requirements for providing modest meals to healthcare professionals.

**Runtime:** 30

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## BIMO: Clinical Investigator

BIM004

This course focuses on the responsibilities of a Clinical Investigator (CI) who participates in clinical research involving unapproved test articles that are under FDA's jurisdiction. Topics in this course include: Purpose, Regulations, Managing Inspections, Develop a Strategy, Critical Elements, and FDA Options. After completing this course, learners will be able to recognize FDA's role in CI compliance and regulatory oversight. Learners will also be able to identify the responsibilities of CIs and recognize the regulations that apply to CIs.

**Format:** eLearning - EduFlex, eLearning - SCORM

- | <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
|---|--|
| <ul style="list-style-type: none"><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• FDA BIMO Course Library</li></ul> | <ul style="list-style-type: none"><li>• Clinical Quality Manager</li></ul> |

### Course Objectives:

Recognize FDA's role in CI compliance and regulatory oversight.;Identify the responsibilities of CIs.;Recognize the regulations that apply to CIs.;Identify the application of these regulations to assess CI compliance.

**Runtime:** 90

## BIMO: General Inspection Assignment Process

BIM002

This is the second in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Clinical Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo Bioequivalence inspections. This course provides an overview of the general inspection assignment process, site selection, background materials used in a BIMO inspection, and regulatory consequences of the BIMO program.

**Format:** eLearning - HIP2

- | <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
|---|--|
| <ul style="list-style-type: none"><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• FDA BIMO Course Library</li></ul> | <ul style="list-style-type: none"><li>• Clinical Quality Manager</li></ul> |

### Course Objectives:

Identify the general inspection assignment process. ;Recognize the site selection process and the background materials used in a BIMO inspection. ;Identify the regulatory consequences of the BIMO program.

**Runtime:** 60

## BIMO: In Vitro Bioequivalence Program Part I

BIM006

This course will introduce some brand name and generic drugs, explain the importance of bioavailability, and describe the underlying concept of bioequivalence for comparison of drug performance. This course will also discuss the implementation of the in vivo bioequivalence compliance program. Topics in this course include: Understanding Drugs, Drug Review Process, Bioavailability, Bioequivalence, Study Endpoints, and Implementation. After completing this course, learners will be able to recognize the distinction between brand name and generic drugs. Learners will also be able to identify the importance of bioavailability and recognize the underlying concept of bioequivalence for comparison of drug performance. In addition, learners will be able to recognize the implementation process of the in vivo bioequivalence compliance program.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Medical Device Catalog</li><li>• Pharmaceutical Catalog</li><li>• FDA BIMO Course Library</li></ul> | <ul style="list-style-type: none"><li>• Clinical Quality Manager</li></ul> |

### Course Objectives:

Recognize the distinction between brand name and generic drugs. Identify the importance of bioavailability and recognize the underlying concept of bioequivalence for comparison of drug performance. Recognize the implementation process of the in vivo bioequivalence compliance program.

**Runtime:** 60

## BIMO: In Vivo Bioequivalence Program Part II

BIM007

This course will introduce learners to the challenges of inspecting clinical and analytical facilities and the various technical terms commonly used in bioavailability and bioequivalence studies. Topics in this course include: Clinical Facility, Clinical Documents, Analytical Facility, Analytical Documents, and Analytical Method Validation. After completing this course, learners will be able to identify the challenges of inspecting clinical and analytical facilities, and recognize the various technical terms commonly used in bioavailability and bioequivalence studies.

**Languages Available:**  
Chinese (Simplified)  
English

**Format:** eLearning - EduFlex, eLearning - SCORM

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|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• FDA BIMO Course Library</li></ul> | <ul style="list-style-type: none"><li>• Clinical Quality Manager</li></ul> |

### Course Objectives:

Identify the challenges of inspecting clinical and analytical facilities. Recognize the various technical terms commonly used in bioavailability and bioequivalence studies.

**Runtime:** 60

## BIMO: Part 50 & 56 -- Institutional Review Boards (IRBs)

BIM003

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This is the third in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting clinical investigator, institutional review board (IRB), sponsor/monitor, and in vivo bioequivalence inspections. This course provides an overview of the regulations applicable to the protection of human subjects who participate in clinical research involving FDA-regulated test articles. Topics in this course include: Background, FDA Regulations, IRB Regulations, Informed Consent, Emergency Use, Special Considerations, and Investigator Perspective. After completing this course, learners will be able to recognize important details regarding the protection of human subjects and identify the IRB regulations applicable when conducting IRB inspections in the BIMO program.

**Format:** eLearning - HIP2

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• FDA BIMO Course Library</li></ul> | <ul style="list-style-type: none"><li>• Clinical Quality Manager</li></ul> |

**Course Objectives:**

Recognize important details regarding the protection of human subjects. ;Identify the IRB regulations applicable when conducting IRB inspections in the BIMO program.

**Runtime:** 90

## BIMO: Sponsor/Monitor Responsibilities

BIM005

This course focuses on the responsibilities of sponsors and;monitors of clinical research involving unapproved test articles under the jurisdiction;of FDA. Topics in this course include: Responsibilities, Applicable;Regulations, Compliance Program 7348.810, Strategy, Inspectional Elements, Additional;Elements, Potential Outcomes, and Regulatory Actions. After completing this;course, learners will be able to recognize the roles and responsibilities of;both sponsors and monitors in conducting clinical trials and use that knowledge;to conduct inspections successfully in the BIMO program.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• FDA BIMO Course Library</li></ul> | <ul style="list-style-type: none"><li>• Clinical Quality Manager</li></ul> |

**Course Objectives:**

Recognize the roles and responsibilities of both sponsors and monitors in conducting clinical trials and use that knowledge to conduct inspections successfully in the BIMO program.

**Runtime:** 90

## Bloodborne Pathogens (BBP)

If your job duties include even occasional contact with blood or other infectious materials, you are at risk for contracting potentially deadly, incurable diseases. Take this course to learn what bloodborne pathogens are and how you can protect yourself from them. Ideal learners include anyone who may be exposed to blood or other potentially infectious materials, including healthcare workers, custodians, maintenance staff, research personnel and construction workers.

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- General Safety and Manufacturing

### Content Suite:

- Advanced Safety Orientation for General Industry (IACET CEU=0.9)
- Advanced Safety Orientation for Managers and Supervisors in Construction (IACET CEU=2.7)
- OSHA 30: Construction Outreach Training Course (IACET CEU=3.0)
- OSHA 30: Construction Outreach Training Course (IACET CEU=3.0) (Actively Proctored)

### Course Objectives:

Know what bloodborne pathogens are;Recognize symptoms and treatments for hepatitis B, hepatitis C and the human immunodeficiency virus (HIV);Identify how bloodborne pathogens are transmitted;Remember to assume that all blood and other potentially infectious materials (OPIM) are contaminated and handle them accordingly;Recall safe handling procedures for blood and OPIM;Recall emergency procedures for blood or OPIM exposure

**Runtime:** 17

PS5-00282

### Languages Available:

- Chinese (Simplified) (PS5-101178)
- French (Canadian) (PS5-102325)
- French (European) (PS5-101175)
- German (PS5-101176)
- Italian (PS5-102443)
- Japanese (PS5-102442)
- Korean (PS5-102441)
- Portuguese (Brazil) (PS5-101177)
- Russian (PS5-102440)
- Spanish (Latin America) (PS5-100579)
- English

## Bloodborne Pathogens Awareness

PS5-102406

Contact with blood or other infectious materials puts you at risk for contracting potentially deadly, incurable diseases. Take this course to learn what bloodborne pathogens are, the risk they present, and general steps you should take to ensure your protection after potential exposure. This course is not intended to teach universal precautions. You need additional information, vaccinations/immunizations, and PPE to provide first aid or handle/clean up BBP and OPIM. Ideal learners include all workers.

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Awareness
- General Safety and Manufacturing

**Content Suite:**

- Working from Home Suite
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0) (Actively Proctored)

**Course Objectives:**

Know what bloodborne pathogens (BBPs) are;Recognize symptoms and treatments for hepatitis B, hepatitis C and human immunodeficiency virus (HIV);Identify how BBPs are transmitted;Remember to assume that all blood and other potentially infectious materials (OPIM) are contaminated;Recall emergency procedures to follow after a potential exposure to BBPs

**Runtime:** 8

## Brazil's Technical Regulations for Medical Devices: RDC 16/2013, 67/2009, and 23/2012

DEV63

This course discusses Brazil's technical regulations for medical devices, including RDC 16/2013 for Good Manufacturing Practices (GMPs) of Medical Devices and In Vitro Diagnostic Devices (IVDs), RDC 67/2009 for Technovigilance Requirements for Registration Holders, and RDC 23/2012 for Field Action Requirements. Topics in this course include: Background, Elements, and Applications. After completing this course, learners will be able to identify each of these regulations and recognize the practical actions to use in the normal course of business to ensure that the regulations are adhered to.

**Languages Available:**  
Portuguese (Brazil)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library

**Course Objectives:**

Identify each of the technical medical device regulations in Brazil.;Recognize practical actions to use in the normal course of business to ensure that the regulations are adhered to.

**Runtime:** 30

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## Building Customer Loyalty

EHS11

This course teaches the skills needed by employees at all levels of a company to create loyalty, and to impact the company's profitability in a positive way. Topics in this course include: Creating Loyalty, Words, Actions, Leadership, Turnoffs, and Rebuilding. After completing this course, learners will be able to recognize the skills needed to build customer loyalty. Learners will also be able to recognize the importance of customer loyalty to them personally as well as to the company.

**Format:** eLearning - EduFlex, eLearning - SCORM

- Libraries:**                      **Topic/Industry:**
- HR Compliance & Risk Management Library
  - HealthCare Catalog
  - Pharmaceutical Catalog
  - Medical Device Catalog

**Course Objectives:**

Recognize the skills needed to build customer loyalty. ;Recognize the importance of these skills personally as well as professionally.

**Runtime:** 45

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## Canadian Medical Device Regulations

DEV64

This course introduces the Canadian medical device regulations. This course identifies the scope and applicability of the Canadian Medical Devices Regulation (CMDR) that was last amended on February 13, 2017. Topics in this course include: Regulatory Agencies, Definition, Medical Device Licensing, Post Approval, and CMDR vs ISO 13485. After completing this course, learners will be able to identify the requirements to market devices in Canada.

**Format:** eLearning - EduFlex, eLearning - SCORM

- Libraries:**
- Global Regulatory Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
  - Medical Device GMPs Library

**Course Objectives:**

Recognize the general structure of CMDR and its requirements for the manufacture and distribution of medical devices to the Canadian market.;Identify the requirements to market devices in Canada.;Recognize the differences between CMDR and ISO 13485.

**Runtime:** 30



## Care and Handling of Drug Product Components, Labeling, Containers, and Closures

PHA41

It is crucial to understand and follow cGMP regulations related to components, labeling, containers, and closures of drug products. This course describes how to implement control handling and testing of drug products while meeting cGMP regulations. Topics in this course include: Receipt and Holding, Sampling, Vendor Certification, and Documentation. After completing this course, learners will be able to identify the proper procedures for the receipt, sampling, storage, testing, and record keeping of drug product components and containers and closures.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify the cGMP requirements for the receipt, identification, handling, storage, sampling, and testing of components, labeling, containers, and closures.

**Runtime:** 30

## CE Certification for Medical Devices

MDR03

This course describes information about compliance of medical devices in accordance with the European Medical Device Regulations (MDR). Topics in this course include: Classification and Conformity Routes, General Requirements, Design and Construction, Technical Documentation, Quality Management System (QMS), Device Information and Documentation, and Vigilance. After completing this course, learners will be able to recognize general requirements and harmonized standards for medical devices.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- Global Regulatory Library
- QA Auditor

**Course Objectives:**

Recognize general requirements and harmonized standards for medical devices. Identify significant legislative changes made to the directives. Recognize how to deal with the regulations proactively so certifications remain valid.

**Runtime:** 60

## CFDA Order No. 25 - Good Clinical Practices for Medical Devices

PHDV104

This course introduces the European Union's GMP requirements for computerised systems that are associated with the manufacture of medicinal products. Reference is also made to FDA expectations. This course covers requirements that govern the use of computerised systems as specified in regulations and guidance documents issued by the European Union.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify the requirements and definitions associated with the European Union's GMP regulations for computerised systems.;Recognise the requirements for the implementation of computerised systems, and for post implementation monitoring.;Recognise the measures taken to maintain data accuracy and security when using computerised systems.;Identify required control and security measures as well as the responsibilities management have for computerised systems.

**Runtime:** 60

## cGMP Refresher – Medical Device Quality System and Quality Culture

DEV65

This course is a reminder of the importance of a quality system and culture for medical device manufacturers. Topics in this course include: Subsystems of the QSR, Management Responsibility and Risk Management, and Developing a Quality Culture. After completing this course, learners will be able to identify the principal seven subsystems and objectives of the Quality System Regulation for medical devices. Learners will also be able to recognize how a robust quality culture can support the effective execution of Quality Systems.

**Format:** eLearning - EduFlex, eLearning - EduFlex - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device Catalog
- Medical Device GMPs Library
- Medical Device

**Course Objectives:**

Identify the principal seven subsystems and objectives of the Quality System Regulation for medical devices. Recognize how a robust quality culture can support the effective execution of Quality Systems.

**Languages Available:**

- Chinese (Simplified)
- English
- French (European)
- German
- Hebrew
- Japanese
- Portuguese (Portugal)
- Spanish (Spain)

## Change Control

PHA35

The control of change is very important in the regulated industries of drug products, biologics, and medical devices. Changes to processes, material, equipment, and people can have a direct impact on the quality, effectiveness, and safety of the product. This course presents the concept of change control by placing the learner in the role of a change control manager. Topics include key steps, change indicators, and notification of governing bodies. After completing this course, you will be able to identify what a change control consists of and recognize the basics of the change control model. You will also be able to recognize the importance of a change control. Lastly, you will be able to recognize the key elements of an effective change control system.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Global Regulatory Library
- QA/GMP Trainer

**Course Objectives:**

Identify what a change control consists of and recognize the basics of the change control model.;Recognize the importance of a change control.;Recognize the key elements of an effective change control system.

**Runtime:** 45

## Chapter 7 Process ? Purchasing

MDSAP07

Documentation is an essential part of Good Manufacturing Practice (GMP). This course provides an overview for manufacturers of pharmaceutical and biological products of the documents required and the controls that should be in place. The regulatory requirements of FDA are addressed with reference also made to the requirements of the EU. The course provides an introduction to staff at all levels and highlights the personal responsibility they have for ensuring documentation is followed and documentation is correct.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Global Regulatory Library
- MDSAP Library
- Medical Device Catalog
- Pharmaceutical

**Course Objectives:**

Recognize the importance of good documentation practices. Identify common forms of documentation used during the manufacturing process and the documentation practices you should follow.

**Runtime:** 45

## Cleanroom Cleaning, Sanitization, and Disinfection

In order to achieve safe and effective products, manufacturers of sterile product must employ various contamination control methods, such as cleaning, sanitization, and disinfection in the cleanroom. Topics in this course include: Contamination, Cleaning, Sanitization and Disinfection, and Additional Considerations. After completing this course, learners will be able to recognize why cleaning and sanitization are critical to contamination control in the cleanroom. Learners will also be able to identify the differences between cleaning, sanitizing, and disinfecting. Lastly, learners will be able to recognize proper basic cleaning procedures as well as critical parameters for effective sanitization.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

### Libraries:

- Pharmaceutical Catalog
- Medical Device Catalog
- Aseptic Processing Library

### Course Objectives:

Recognize why cleaning and sanitization are critical to contamination control in the cleanroom.;Identify the differences between cleaning, sanitizing, and disinfecting.;Recognize the proper basic cleaning procedures.;Recognize critical parameters for effective sanitization.

**Runtime:** 25

## Aseptic08

### Languages Available:

Chinese (Simplified)  
French (European)  
German  
Japanese  
Spanish (Spain)

## Clinical Trial Audits and Consequences of Non-Compliance

## GCP21

Sponsors can put measures in place in an attempt to dissuade researchers from being noncompliant, but those measures are only as effective as the personnel applying them. This course will provide a description of the clinical trial audit process and how audits help to ensure trials are conducted in accordance with regulatory requirements. Topics in this course include: Clinical Trial Audit, FDA Inspection, and Noncompliance. After completing this course, learners will be able to identify FDA standards for conducting and reporting clinical site inspections, as well as recognize FDA's system for classifying inspections and taking corrective action.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

### Libraries:

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Pharmaceutical
- Medical Device

### Course Objectives:

Identify the differences between a sponsor site audit and an FDA inspection.Recognize FDA standards for conducting and reporting clinical site inspections.Identify FDA's system for taking corrective actions.

**Runtime:** 30

## Code of Business Conduct

LAV15

All employees need to be aware of their companies Code of Business Conduct. This course describes the Code of Business Conduct and basic ethical principles and guidelines for conducting business with our partners, clients, and competitors. Topics in this course include: Obeying the Law, Conflicts of Interest, Gift Policies, Protected Information, and Ethical Conduct. After completing this course, learners will be able to identify the basic principles that make up the Code of Business Conduct.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• HR Compliance &amp; Risk Management Library</li><li>• Ethics &amp; Corporate Responsibility Library</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Identify the basic principles of our Code of Business Conduct and recognize how to apply those principles to your everyday business activities.

**Runtime:** 45

## Combination Products \_ cGMP Requirements

PHDV93

FDA has issued a regulation on the current good manufacturing practice (cGMP) requirements applicable to combination products in an effort to improve the consistency of the regulatory requirements and implementation. This course discusses cGMP requirements and FDA rules that relate to combination products. Topics in this course include: Background, Final Rule, Compliance, The Office of Combination Products, and Post-Approval Modifications. After completing this course, learners will be able to recognize the four different types of combination products and the scope of the regulation in 21 CFR Part 4. They will also be able to identify how to comply with each of the drug, device, and biological product provisions and handle post-marketing events.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Pharmaceutical GMPs Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• Medical Device GMPs Library</li></ul> | <ul style="list-style-type: none"><li>• QA/GMP Trainer</li></ul> |

### Course Objectives:

Identify the four different types of combination products.;Recognize the scope of the new regulation in 21 CFR Part 4, and each of the drug, device, and biological product rules. ;Identify the role of the Office of Combination Products (OCP). ;Recognize how post-marketing modifications are made and how to report post-marketing adverse events.

**Runtime:** 45

## Complaint Management for Medical Device Manufacturers

DEV46

It is very important for manufacturers to properly respond to reports of alleged medical device problems. This course covers the FDA regulations for reporting these problems. Topics include: Definition, System Elements, Complaint File, Investigation, MDR, and Complaint Analysis. After completing this course, you will be able to identify the primary elements in an effective complaint handling system; recognize how to document, evaluate, and investigate complaints; recognize complaints that must be reported under FDA regulations; and identify the importance of statistical techniques in analyzing complaint trends.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify the primary elements in an effective complaint handling system. ;Recognize how to document complaint information as required by FDA regulations and identify the basic requirements for complaint evaluation and investigation. ;Recognize the types of complaints that must be reported to FDA according to the Medical Device Reporting (MDR) regulations and identify the importance of using statistical techniques in analyzing complaint trends that may indicate potential quality problems.

**Runtime:** 60

**Languages Available:**

- Chinese (Simplified)
- French (European)
- German
- Japanese
- Korean
- Spanish (Spain)

## Computer Workstation Safety

EHS14

Computer workstations can be a source of nagging and debilitating Repetitive Stress Injuries (RSIs). This course addresses causes and symptoms of RSIs at computer workstations and ways to prevent those injuries. Topics in this course include: RSIs, Symptoms, Prevention, Exercises, and Laptop Safety. After completing this course, learners will be able to identify the symptoms of RSIs and find ways to stay healthy and prevent these injuries while working at a computer workstation.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
  - HR Compliance & Risk Management Library
  - HealthCare Catalog
  - Pharmaceutical Catalog
  - Medical Device Catalog
- EHS Manager
  - Corporate Compliance
  - HR Compliance & Risk Management

**Course Objectives:**

Identify common RSIs, their symptoms, their causes, and exercises and other safety measures that can help you prevent them.

**Runtime:** 45

**Languages Available:**

- Spanish (Latin America)

## Computerized Systems Inspections in the Medical Device Industry

DEV59

This course has been designed to assist FDA inspectors in recognizing the critical aspects of computerized systems in the medical device industry. This course explains how computerized systems are used in the medical device manufacturing process and provides an approach to inspecting these systems. Topics in this course include: Usage, Approach, and Focus. After completing this course, learners will be able to recognize where computerized systems are used in the medical device manufacturing process, recognize FDA's approach to inspecting computerized systems, and identify the levels of review that may be used and what comprises each level.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- Global Regulatory Library
- MDSAP Library
- QA/GMP Trainer

### Course Objectives:

Recognize where computerized systems are used in the medical device manufacturing process. Recognize FDA's approach to inspecting computerized systems. Identify the levels of review that may be used and what comprises each level.

**Runtime:** 30

### Languages Available:

Chinese (Simplified)  
French (European)  
German  
Japanese  
Korean  
Spanish (Spain)

## Conducting Annual Product Reviews

PHA45

This course identifies regulations for manufacturers conducting annual reviews of pharmaceutical products. Topics in this course include: APR Requirements, Benefits of APRs, APR Organization and Content, and Quality Metrics. After completing this course, learners will be able to recognize the benefits of conducting an Annual Product Report (APR), and how to organize an APR.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

### Course Objectives:

Recognize the benefits of conducting an APR.;Recognize how to organize an APR.;Identify the contents of an APR.

**Runtime:** 30

### Languages Available:

Chinese (Simplified)

## Confidentiality, Intellectual Property Protection, and Information Security

LAV19

Every day, employees may come into contact with information that must be protected. In order to preserve the confidentiality, integrity, and availability of this information, each employee must recognize information that is considered sensitive and be able to protect it. This course defines sensitive information, including intellectual property and trade secrets, and teaches employees how to protect it. Topics in this course include: Legal Protection, Company Protection, and Responses. After completing this course, learners will be able to identify what information is considered sensitive and how they can protect sensitive information and intellectual property, including how to respond to a request by a third party for this information.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HR Compliance &amp; Risk Management Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Recognize what information is considered sensitive and recognize if you are dealing with it. ;Identify the ways you can protect sensitive information and intellectual property, including how to respond to a request by a third party for this information.

**Runtime:** 30

## Confined Space Hazards Awareness

PS5-102385

If one of your co-workers passed out in a confined space, would you go in to rescue him? Can you be sure the air in the space is safe? This training will help you understand the risks associated with confined spaces. Do not take this information lightly. It can mean the difference between life and death! Ideal learners are all employees.

**Languages Available:**  
English

**Format:** eLearning - Claro

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Safety Catalog</li><li>• EHS for Life Science - Basics Library</li><li>• Medical Device Catalog</li><li>• Pharmaceutical Catalog</li></ul> | <ul style="list-style-type: none"><li>• Awareness</li><li>• General Safety and Manufacturing</li></ul> |

### Course Objectives:

Recognize a confined space;Explain the responsibilities of confined space authorized entrants, attendants and entry supervisors;Identify hazards associated with confined spaces

**Runtime:** 8



## Confined Spaces: Permit-Required

You may be able to enter an enclosed space, but could you get back out safely? If it is a permit-required confined space, you know there is a risk of a flammable, asphyxiating, corrosive or toxic atmosphere. This training will help you understand the hazards associated with confined spaces and the procedures your employer has in place to protect you and those around you. Do not take this information lightly. It can make the difference between life and death! Ideal learners are anyone who works in or around confined spaces.

**Format:** eLearning - Claro

- | <b>Libraries:</b>  | <b>Topic/Industry:</b>  |
|--|---|
| <ul style="list-style-type: none"><li>• Safety Catalog</li><li>• EHS for Life Science - Basics Library</li><li>• Medical Device Catalog</li><li>• Pharmaceutical Catalog</li></ul> | <ul style="list-style-type: none"><li>• General Safety and Manufacturing</li><li>• Health and Safety Management</li></ul> |

### Course Objectives:

List the differences between permit-required confined spaces and non-permit-required confined spaces; Identify the hazards associated with confined spaces; Recall the roles and responsibilities of the confined-space entry team; Identify what is required on an entry permit and other procedural safeguards when conducting a confined-space entry; Know how to respond to emergencies

**Runtime:** 45

## Courtroom Testimony

This course will introduce you to your role if you are called as an FDA witness, including grand jury, deposition, declaration, and courtroom testimony. Topics in this course include: Types of Testimony, Preparation, Conduct, On the Stand, and After Testimony. After completing this course, learners will be able to recognize the types of testimony, ways to prepare for testimony, the fundamental characteristics of appropriate courtroom conduct, and the components of effective testimony.

**Format:** eLearning - EduFlex, eLearning - SCORM

- | <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
|---|--|
| <ul style="list-style-type: none"><li>• FDA Inspections and Enforcement Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• QA/GMP Trainer</li></ul> |

### Course Objectives:

Recognize the types of testimony.; Recognize ways to prepare for testimony.; Recognize the fundamental characteristics of appropriate courtroom conduct.; Recognize the components of effective testimony.

**Runtime:** 30

## PS5-101280

**Languages Available:**  
Dutch (PS5-101529)  
Czech (PS5-101528)  
Chinese (Simplified) (PS5-102545)  
French (Canadian) (PS5-102630)  
French (European) (PS5-102547)  
German (PS5-101530)  
Italian (PS5-102551)  
Japanese (PS5-101531)  
Korean (PS5-102549)  
Polish (PS5-101532)  
Portuguese (Brazil) (PS5-102550)  
Russian (PS5-102548)  
Spanish (Latin America) (PS5-102546)  
Thai (PS5-101533)  
English

## FDA46

**Languages Available:**  
Chinese (Simplified)

## Data Integrity for Clinical Research Staff

Clinical research staff must be aware of the potential and inherent risks to data integrity. Topics in this course include: FDA Directions, Roles, and Errors. After completing this course, learners will be able to identify the role of clinical staff in maintaining data integrity, and identify various challenges to data integrity.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:** **Topic/Industry:**

- Data Integrity Library
- HealthCare Catalog
- Medical Device Catalog
- Pharmaceutical

**Course Objectives:**

Identify the role of clinical staff in data integrity. Recognize the importance of data integrity and various challenges to data integrity. Identify risks to data integrity.

**Runtime:** 20

**DATA05**

**Languages Available:**

Chinese (Simplified)  
French (European)  
German  
Spanish (Spain)

## Data Integrity for Quality Control Laboratories

To ensure the quality of raw materials, in-process materials, and finished goods, laboratory data integrity is of great importance in current Good Manufacturing Practices (cGMP) for the US Food and Drug Administration (FDA)-regulated industry. This course focuses on data integrity in the Quality Control (QC) laboratory. Topics in this course include: History, Strategies for Control, and Ethics. After completing this course, learners will be able to recognize potential strategies for maintaining data integrity and the consequences of noncompliance, and identify the types of data integrity issues found by FDA.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**

- Data Integrity Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Course Objectives:**

Recognize the history of data integrity. Identify the types of data integrity issues found by FDA. Recognize possible consequences of data integrity noncompliance. Identify possible strategies for remediation of data integrity issues. Recognize the effects of intentional and unintentional errors.

**Runtime:** 15

**DATA04**

**Languages Available:**

Chinese (Simplified)  
French (European)  
German  
Spanish (Spain)

## Data Integrity: The Role of Quality Assurance for Data Integrity

Clinical trial data integrity has traditionally been an integral part of quality assurance. This course describes quality assurance in the light of new data collection methods and procedures. Topics in this course include: Overall Approach to Quality, Quality Activities, and Documentation. After completing this course, learners will be able to identify the role of Quality Assurance in data integrity, and recognize regulatory compliance auditing and QMS auditing.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**

- Data Integrity Library
- HealthCare Catalog
- Medical Device Catalog

**Course Objectives:**

Recognize the definition and importance of a process approach to quality, and recognize activities that help maintain quality of data. Identify examples of deviations and nonconformances that must be recorded.

**Runtime:** 15

**DATA03**

**Languages Available:**

Chinese (Simplified)  
French (European)  
German  
Spanish (Spain)

## Defensive Driving - Small Vehicles

A split-second decision can change your life, especially when you are behind the wheel of a fast-moving, heavy vehicle. Take this course to refresh your memory about safe driving practices, particularly what you need to do before you drive, while you drive and in the event of an accident. Ideal learners are anyone who drives cars or small vehicles.

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Transportation Safety

### Content Suite:

- Advanced Safety Orientation for Managers and Supervisors in Construction (IACET CEU=2.7)
- OSHA 30: Construction Outreach Training Course (IACET CEU=3.0)
- OSHA 30: Construction Outreach Training Course (IACET CEU=3.0) (Actively Proctored)

### Course Objectives:

Know how to prepare to drive safely;Recall best practices for driving safely;Make safe driving choices in specific situations and conditions;Recall what to do in case of an accident

**Runtime:** 24

PS5-00264

### Languages Available:

Dutch (PS5-101314)  
Chinese (Simplified) (PS5-102455)  
French (Canadian) (PS5-102649)  
French (European) (PS5-102456)  
German (PS5-101315)  
Italian (PS5-102460)  
Japanese (PS5-102459)  
Korean (PS5-102614)  
Polish (PS5-101316)  
Portuguese (Brazil) (PS5-101317)  
Russian (PS5-102457)  
Spanish (Latin America) (PS5-100743)  
English

## Design Control Regulations for Medical Device Manufacturers

Manufacturers of medical devices are responsible for ensuring that the products they create follow the rules for design control. This course describes FDA design control regulations by providing basic information about the key procedures followed during the design and development of a product. Topics in this course include: Design and Development Plan, Design Input, Design Output, Design Review, Verification, Validation, Design Transfer, and Change Control. The design plan requires documentation of training, planning validation, design transfer and changes, formal review, a design history file, and human factors. After completing this course, learners will be able to recognize the purpose and scope of design control regulations and will also be able to identify the eight main aspects of design control and how they affect medical device manufacturers.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

### Libraries:

- Medical Device Catalog
- Medical Device GMPs Library

### Topic/Industry:

- QA/GMP Trainer

### Course Objectives:

Recognize the purpose and scope of design control regulations. Identify the eight main aspects of design control and how they affect medical device manufacturers.

**Runtime:** 90

DEV40

### Languages Available:

Chinese (Simplified)  
French (European)  
German  
Japanese  
Spanish (Spain)

## Destruction and Reconditioning

FDA33

This course discusses procedures and methods for destroying, reconditioning, and/or denaturing products that are in violation of the FD&C Act. Topics in this course include: Seized Articles, Detained Products, Voluntary Correction, Procedures, and Damage. After completing this course, learners will be able to identify the circumstances and procedures under which articles may be destroyed or reconditioned.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the circumstances and procedures under which articles may be destroyed or reconditioned.

**Runtime:** 45

## Discrimination and Harassment Free Workplace

ETHICS19

Each of us is responsible for our working environment. Every employee needs to understand the kind of behavior that fosters a positive and productive climate and the unacceptable behavior, such as discrimination and harassment which can negatively affect our workplace. This course addresses the laws and our company's policies related to discrimination, harassment, and diversity, and why they are important. Topics in this course include: Importance, Laws and Policies, Harassment, and Reporting Complaints. After completing this course, learners will be able to recognize how diversity is important to our company's success, the laws and policies that define discrimination and harassment, acceptable and unacceptable behavior, and the proper response to situations of discrimination and harassment.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Corporate Compliance

**Course Objectives:**

Recognize how diversity is important to our success.; Identify the laws and policies that define discrimination and harassment.; Recognize acceptable and unacceptable behavior so you can avoid situations that violate laws and policies.; Recognize a proper response to situations of discrimination and harassment.

**Runtime:** 45

## Documenting the Drug Development Process \_ ICH Q8(R2)

ICHreg03

This course explains FDA's guidance on a modern quality systems approach to pharmaceutical manufacturing. Topics in this course include: FDA's Approach, Quality Concepts, FDA Compliance, Quality System Model, Management Responsibilities, Resources, Manufacturing Operations, and Evaluation Activities. After completing this course, learners will be able to identify the guidance that FDA has provided on quality systems, the ways in which this supports cGMP compliance, and the ways in which the application of a quality systems approach encourages the use of modern quality management principles and promotes innovation and continuous improvement.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify FDA's guidance on modern quality systems and recognize how this can foster GMP compliance, innovation, and continuous improvement in the manufacture of pharmaceuticals.

**Runtime:** 60

## Documenting Validation Activities

PHA55

The process of validation in FDA-regulated industry is important to gain FDA acceptance. The key to successful validation is the understanding that validation must be documented. This course illustrates the process of documenting validation activities for FDA acceptance. Topics in this course include: Validation, Documents, Equipment, Materials, Process, and People. After completing this course, learners will be able to recognize FDA's definition of validation and identify the required components of the validation process.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Medical Device

**Course Objectives:**

Recognize FDA's definition of validation. Identify the requirements for cGMP compliant documentation of validation processes.

**Runtime:** 45

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## Doing Business with the US Government

ETHICS26

This course is designed to help learners understand how laws and company policies are applicable to your job. Topics in this course include: Obeying the Law; US Laws and Regulations; Employee Activities; Relationships with US Government Customers; Lobbying Activities; Relationships with Subcontractors, Suppliers, and Vendors; and Responsibilities and Reporting. After completing this course, learners will be able to identify potential violations of laws and policies that apply to US government contracts and recognize ways to find help.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Course Objectives:**

Identify potential violations of laws and policies that apply to US government contracts.;Recognize ways to find help.

**Runtime:** 30

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## Doing the Right Thing for Customers and Business Partners

ETHICS03

Businesses must be able to demonstrate that they can run their business with integrity and keep their promises. This course explores how to build strong relationships with our customers and business partners through trust, quality and service, privacy protection, and fair treatment. Topics in this course include: Earning Trust, Quality and Service, Protecting Privacy, and Fair Treatment. After completing this course, learners will be able to recognize how to build strong relationships with our customers and business partners.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

**Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Corporate Compliance

**Course Objectives:**

Recognize how to build strong relationships with our customers and business partners.;Identify our company's expectations for our relationships with customers and business partners. ;Recognize how to protect the privacy of our customers and business partners.

**Runtime:** 30

## Doing the Right Thing: Anti-bribery

ETHICS09

This course provides basic training on complying with laws prohibiting bribery, including the US Foreign Corrupt Practices Act (FCPA). Because of the special circumstances facing employees in the healthcare field, this course is focused on issues faced in interactions with healthcare professionals as well as government officials. Topics in this course include: Legal Foundation, Laws, and FCPA in Action. After completing this course, learners will be able to identify and navigate situations that may be perceived as bribery. Learners will also be able to recognize requirements of the FCPA.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- Libraries:**
- Ethics & Corporate Responsibility Library
  - HealthCare Catalog
  - Pharmaceutical Catalog
  - Medical Device Catalog
- Topic/Industry:**
- Corporate Compliance

### Course Objectives:

Identify and navigate situations that may be perceived as bribery. Recognize requirements of the US Foreign Corrupt Practices Act (FCPA). Identify the steps to take if you find yourself in a difficult situation.

**Runtime:** 30

## Dos and Don'ts of Aseptic Environments

Aseptic07

This course introduces best practices for aseptic technique and behavior for use with conventional cleanroom Aseptic Processing Library. Topics in this course include: Dos and Don'ts (including Personnel Requirements, Gowning and Gloves, Cleanroom Integrity, Behavior, Critical Area Interactions, and Culture). After completing this course, learners will be able to recognize best practice aseptic behaviors and techniques as well as specific examples of what to do and what not to do in the cleanroom.

**Languages Available:**  
French (European)  
German  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

- Libraries:**
- Pharmaceutical Catalog
  - Medical Device Catalog
  - Aseptic Processing Library

### Course Objectives:

Recognize best practice aseptic behaviors and techniques. Recognize specific examples of what to do and what not to do in the cleanroom.

**Runtime:** 15



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## Effectively Responding to FDA 483s and Warning Letters

PHDV70

No company wants to receive an FDA 483 or Warning Letter for adverse findings after an FDA inspection, but it does happen. This course explains the basic principles of FDA 483s and the use of Warning Letters to provide feedback on compliance concerns. Topics in this course include: FDA 483, Response, Warning Letter, Response Process, and Avoiding Mistakes. After completing this course, learners will be able to describe key aspects of written responses to both FDA 483s and Warning Letters, and recognize the importance of both of these documents.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize the basic principles of FDA 483s and the use of Warning Letters. ;Recognize the significance of both these documents. ;Identify the key aspects of written responses to both FDA 483s and Warning Letters.

**Runtime:** 45

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## Egress and Emergency Action Plans Awareness (US)

PS5-01423

**Languages Available:**  
English

Each year, more than 200 deaths and 5,000 injuries result from fires and explosions in the workplace. The National Fire Protection Association reported over 115,000 non-residential structural fires in a recent year, accounting for \$2.4 billion in direct property damage. Those are the losses due to fires, but there are other hazardous situations that can threaten a worker's life and limb. These include severe weather, medical emergencies, chemical release, and bomb threats. We can't completely eliminate dangerous workplace situations, but we can reduce the number of associated injuries and deaths attributable to these incidents. This course will focus on two important aspects of this effort: egress and emergency action plans.

**Format:** eLearning - Claro**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Awareness
- General Safety and Manufacturing

**Content Suite:**

- Advanced Safety Orientation for General Industry (IACET CEU=0.9)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0) (Actively Proctored)
- OSHA 10: General Industry Outreach Training Course (High-Tech/Semiconductor) (IACET CEU=1.0)

**Course Objectives:**

Identify the components of an exit route, the fundamental requirements of egress, the detailed elements of egress and the core elements of emergency action plans

**Runtime:** 14

## E-Mail and Corporate Communications

ETHICS20

E-mail remains the predominant form of communication in the business world, with estimates ranging in excess of 100 billion e-mails sent and received daily. This course illustrates the use of e-mail in the workplace, including several hot-button issues, such as an employee's expectation of privacy, and electronically transmitted computer viruses. Topics in this course include: How E-mail Works, E-mail Use, and Privacy and Security. After completing this course, learners will be able to recognize the consequences of sending or forwarding an inappropriate e-mail attachment or message.

**Format:** eLearning - EduFlex, eLearning - SCORM**Libraries:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Topic/Industry:**

- Corporate Compliance

**Course Objectives:**

Recognize what happens when e-mails are sent and received. ;Identify e-mail privacy and security issues and the dangers of viruses.

**Runtime:** 30

## Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations

FDA64

This course introduces the definition and principles of quality risk management (QRM) and the basic steps of a typical QRM process. Topics in this course include: QRM Process, Tools, and Applying QRM. After completing this course, learners will be able to identify the methodology and tools used in a risk management process.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Global Regulatory Library
- QA/GMP Trainer

**Course Objectives:**

Identify the methodology and tools used in a risk management process.;Recognize the operational areas where risk tools can be used to increase quality in pharmaceutical and biologics manufacturing.

**Runtime:** 60

## Environmental Control and Monitoring

PHDV87

It is important for all personnel involved in the manufacturing of sterile products and medical devices to understand how to maintain the quality of the cleanroom environment through environmental control and monitoring. This course examines regulatory requirements for environmental control and monitoring and how to prevent particulate and microbiological contamination of sterile products and devices. Topics in this course include: Purpose, Control, Monitoring, Documentation, and Prevention. After completing this course, learners will be able to recognize the methods of environmental control and monitoring, and identify how to prevent contamination.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Medical Device
- Pharmaceutical

**Course Objectives:**

Recognize the definition of environmental control and environmental monitoring.Recognize how cleanrooms are classified according to International Organization for Standardization (ISO) standards and what operations are typically carried out in various classifications.Identify the methods for environmental control and monitoring in cleanrooms and what your company's written program should include.Recognize how to prevent viable and non-viable particulate contamination.

**Runtime:** 30

## Essentials of an Effective Calibration Program

PHDV75

Injuries, fatalities, or major class action suits filed against the manufacturer can result when products are produced with out-of-calibration equipment. This course identifies the essentials of an effective calibration program. This course contains references to both U.S. and EU regulations. Topics in this course include the four aspects of calibration, calibration standards, regulatory requirements, and calibration procedures. After completing this course, learners will be able to recognize the reasons for calibration and the requirements and standards of effective calibration programs.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Medical Device
- Pharmaceutical

**Course Objectives:**

Identify the essentials of an effective calibration program. Identify what calibration standards are and the regulatory requirements needed for calibration. Recognize what procedures are needed for calibration.

**Runtime:** 30

## Ethical Review Boards

GCP14

This course addresses the role, responsibilities, and regulatory requirements of Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) in protecting the rights and welfare of human research subjects. Topics in this course include: Development, Membership/Procedures, Review and Approval, Post-Approval Responsibilities, Vulnerable Subjects, Noncompliance, and Compliance Resources. After completing this course, learners will be able to recognize their obligations in relation to the IRB/IEC and the policies and procedures that were developed to protect and safeguard research subjects.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the key events that helped establish the ethical review system. ;Recognize the membership requirements of an IRB/IEC and the procedures these groups must follow with regard to approval of clinical research. ;Identify the additional protections put in place for various types of vulnerable subjects. ;Identify how FDA will enforce noncompliance to established regulations for IRB/IECs.

**Runtime:** 60

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## Ethics as the Foundation to Clinical Research

GCP10

All clinical research personnel confront ethical decisions. This course reviews the principles and methods that exist to ensure that the rights and welfare of human subjects are protected. Topics in this course include: Ethical Documents, Decision-Making Process, Emerging Trends, and Considering the Ethical Dilemma. After completing this course, learners will be able to recognize the ethical components of historical clinical research guidelines, the definition of clinical equipoise and its importance in clinical trials, and one systematic approach to ethical decision-making.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the ethical components of the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, the International Conference on Harmonisation Good Clinical Practice Guideline, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects. ;Recognize the definition of clinical equipoise and its importance in clinical trials. ;Recognize one systematic approach to ethical decision-making.

**Runtime:** 45

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## EU Directives and Inspection Readiness

PHDV96

In many organizations today, electronic records and electronic signatures are becoming more common. This course identifies how to implement Part 11 and what it means in terms of FDA's enforcement policy for 21 CFR Part 11, Electronic Records; Electronic Signatures. Topics in this course include: Meeting Expectations, Records, Security, Electronic Signatures, System Documentation, and Audit Trails. After completing this course, learners will be able to recognize how to apply Part 11 regulations to your company's systems and records in accordance with FDA's expectations.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device Catalog
  - Pharmaceutical Catalog
  - FDA Inspections and Enforcement Library
- QA/GMP Trainer

**Course Objectives:**

Recognize how to apply Part 11 regulations to your company's systems and records in accordance with FDA's expectations. ;Identify what records are considered Part 11 records. ;Identify how system documentation is controlled.

**Runtime:** 60

## EU In Vitro Diagnostic Regulations (IVDR)

MDR02

This course describes information about the compliance of the in vitro diagnostic medical devices in accordance with the European In Vitro Diagnostic Medical Device Regulations (IVDR). Topics in this course include: Definitions, Regulatory Requirements, Conformity Assessments and Performance Studies, and EU Portal and Surveillance. After completing this course, learners will be able to recognize essential requirements and harmonized standards for in vitro diagnostic medical devices.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- Global Regulatory Library
- QA Auditor

**Course Objectives:**

Recognize essential requirements and harmonized standards for in vitro diagnostic medical devices. Identify significant legislative changes made to the regulations. Recognize how to deal with the regulations proactively so certifications remain valid.

**Runtime:** 45

## EU Medical Device Regulation (MDR)

MDR01

This course describes basic information concerning the European Medical Device Regulation and the CE marking of medical devices. Topics in this course include: History, Definitions, Approach, Quality System, and General Classifications and Rules. After completing this course, learners will be able to identify the basic components of the EU Medical Device Regulation (MDR).

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- Global Regulatory Library
- QA Auditor

**Course Objectives:**

Identify the basic components of the EU Medical Device Regulation. Recognize the definitions and classifications that describe the devices that fall under this regulation. Identify other directives and regulations that might apply to medical devices sold in EU countries.

**Runtime:** 45

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## European Union Clinical Trials Directive

GCP16

The European Union (EU) Clinical Trials Regulation covers clinical trials in the EU and sets forth requirements of investigators, sponsors, EU Member States? Competent Authorities, and others responsible for clinical trial regulation. Topics in this course include: Requirements and Responsibilities, Overall Authorization, Modifications and Amendments, IMPs, and Adverse Events. After completing this course, learners will be able to identify the principal elements of the EU Clinical Trials and Good Clinical Practice Directives.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the principal elements of the EU Clinical Trials Regulation and Good Clinical Practice Directive.

**Runtime:** 60

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## European Union GMP Requirements

PHA78

If you are involved with the manufacture of medicinal products you must comply with Good Manufacturing Practice (GMP) requirements. This course explains the European Union's (EU) GMP regulations and guidelines. Topics in this course include: Pharmaceutical Quality Systems, Staff, Premises and Equipment, Documentation, Production, Quality Control Department, and Controls. After completing this course, learners will be able to identify the EU's basic GMP regulations and recognize how to comply with these requirements.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Pharmaceutical Catalog
- Global Regulatory Library
- Medical Device Catalog
- Medical Device GMPs Library

**Course Objectives:**

- Identify the EU's basic GMP regulations and recognise how you comply with these requirements.

**Runtime:** 45

## European Union Good Distribution Practices for Medicinal Products

PHA77

This course describes the Good Distribution Practices (GDPs) required by the European Union (EU). The EU's recommended practices are similar to requirements in the US and many other countries. The controls to maintain the quality and integrity of medicinal products as they are distributed from manufacturer to patient are explained in this course. Because modern supply chains are often complex, the responsibilities of all organisations involved with wholesale activities — including storage, transport, purchase, and supply — are detailed. The controls required to prevent falsified or fake drug products including fake active pharmaceutical ingredients (APIs) from entering the supply chain are also addressed.

**Languages Available:**  
French (European)  
German  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM

### Libraries:

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library

### Course Objectives:

? Identify participating regulatory agencies. ;? Identify the rights of clinical trial subjects and the responsibilities of investigators, sponsors, the administrative department, and the ethics committee. ;? Recognize the documentation and reporting requirements for clinical trials.;

**Runtime:** 60

## Evidence and Proof

FDA22

FDA takes action based on information collected and developed by investigational and analytical personnel. FDA's ability to perform its function is based on the quality and care used in collecting and preserving information. Information is evidence; obtaining it properly is a vital portion of FDA's law enforcement work. This course explores forms of evidence and proof. Topics in this course include: Physical Evidence, Photographic Evidence, Written Evidence, Testimony, Elements of Proof, and FDA Actions. After completing this course, learners will be able to recognize the processes involved in gathering evidence and proof, and identify the circumstances under which both can be used.

**Languages Available:**  
Chinese (Simplified)  
French (European)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

### Libraries:

### Topic/Industry:

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

### Course Objectives:

Recognize the processes involved in gather evidence and proof. ;Identify the circumstances under which both evidence and proof can be used.

**Runtime:** 45

## Failure Investigations for Medical Device Manufacturers

DEV45

Handling medical device failures can be significant in a company's ability to maintain a state of control in operations and prevent future failures. This course will explore what a failure is, the regulatory and practical aspects of investigations, and the elements that make these investigations effective. Topics in this course include: Product Failure, Investigations, Root Cause, CAPA, Follow-up, and Documentation. After completing this course, learners should be able to recognize the basic definition of failures, identify when a failure investigation should occur, and the documentation required.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- QA Auditor

**Course Objectives:**

Recognize the basic definition of failures. ;Identify when a failure investigation should occur and the documentation required.;Identify the basic elements of a comprehensive failure investigation and the steps for management review and follow-up.

**Runtime:** 30

## Fair Labor Standards Act (FLSA) and Equal Pay Act (EPA)

LAV03

The Fair Labor Standards Act (FLSA) is a federal law that establishes;minimum wage, overtime pay, recordkeeping, and youth employment standards. The;Equal Pay Act (EPA) is a federal law that requires men and women in the same;workplace to receive equal pay for equal work.This course provides an overview of the FLSA and EPA with a;concentration on employer concerns. It also covers important distinctions;between exempt and non-exempt employees and between employees and independent;contractors. Topics in this course include: FLSA, Minimum Wage, Overtime, Exempt;Employees, Contractors, Compensatory Time, Child Labor, Nursing Mothers, and;Equal Pay Act (EPA). After completing this course, learners will be able to;recognize the significant aspects and exemptions of both the FLSA and EPA.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- HR Compliance & Risk Management

**Course Objectives:**

Recognize the significant aspects of the Fair Labor Standards Act and the Equal Pay Act. ;Recognize the important exemptions specified by the FLSA and EPA that affect employers and many employees who are salaried, work in a specialized industry, or are classified as independent contractors.

**Runtime:** 45





## Fall Protection

Each year, many workers are hurt or killed as a result of falls in the workplace. Falls are usually complex events that involve a variety of factors. This training will cover systems and procedures designed to prevent falls off, onto or through working levels and to protect workers from being struck by falling objects. Ideal learners include all workers.

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- General Safety and Manufacturing
- Construction

**Content Suite:**

- Advanced Safety Orientation for Construction Industry (IACET CEU=0.9)
- Advanced Safety Orientation for Managers and Supervisors in Construction (IACET CEU=2.7)
- Advanced Safety Orientation for General Industry (IACET CEU=0.9)

**Course Objectives:**

Identify common fall hazards;Recognize the types of equipment and methods that provide fall protection;List the components of a personal fall protection system;Recognize the importance of inspecting fall protection equipment;Recall important information about fall rescue plans

**Runtime:** 48

## FDA 483s: Inspectional Observations

This course is designed to familiarize FDA staff with the important aspects of the FDA 483. Topics in this course include: FDA 483, Objectionable Conditions, Reportable Conditions, Essentials, and Annotation. After completing this course, you will recognize the purpose of issuing an FDA 483. You will be able to identify what kinds of inspectional observations are included on an FDA 483, when that form is issued to the inspected firm, and how to annotate it during the discussion with management.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog

**Topic/Industry:**

- QA Auditor

**Course Objectives:**

Recognize the purpose of issuing an FDA 483. ;Identify what kinds of inspectional observations are included on an FDA 483, when it is issued to the inspected firm, and how to annotate it during the discussion with management.

**Runtime:** 45

## PS5-00556

**Languages Available:**

- Dutch (PS5-101330)
- Czech (PS5-101329)
- Chinese (Simplified) (PS5-100518)
- German (PS5-101331)
- Hungarian (PS5-102367)
- Japanese (PS5-101332)
- Polish (PS5-101333)
- Portuguese (Brazil) (PS5-102512)
- Russian (PS5-102510)
- Spanish (Latin America) (PS5-100516)
- Thai (PS5-101334)
- French (Canadian) (PS5-103012)
- English
- French (European) (PS5-102509)
- Italian (PS5-102513)
- Korean (PS5-102511)

## FDA30

**Languages Available:**

- Chinese (Simplified)
- German
- Japanese

## FDA Establishment Inspection (EI)

FDA32

FDA performs approximately 15,000 establishment inspections (EIs) per year. Topics in this course include: FDA Authority, Preparation, Initiating Inspection, Refusals, Observation, Evidence, and Concluding an Inspection. After completing this course, learners will be able to recognize the procedures to prepare for, conduct, and conclude inspections.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

**Course Objectives:**

Identify the statutory authority for establishment inspections.;Recognize the procedures to prepare for, conduct, and conclude inspections.

**Runtime:** 60

## FDA Establishment Inspection Report Writing

FDA26

Establishment inspection reports (EIRs) are written reports that create a record of an inspection of a regulated firm. This course illustrates the purpose of the establishment inspection report (EIR), and what should be included in an EIR. Topics in this course include: FDA Required Standards, Parts of an EIR, Readability, and Additional Formats. After completing this course, learners will be able to identify the purpose and multiple uses of the EIR, recognize the items to be included in the EIR, recognize ways to make the report more readable, and identify multiple formats of the EIR.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

**Course Objectives:**

Identify the purpose and multiple uses of the EIR. ;Recognize the items to be included in the EIR. ;Recognize ways to make the report more readable. ;Identify multiple formats of the EIR.

**Runtime:** 30

## FDA Good Guidance Practices (GGPs)

FDA21

This course on FDA Good Guidance Practices (GGPs) explains which Agency documents are considered guidance documents. It also explains why we have GGPs, their legal effect, how they are developed, and GGP implementation. Topics in this course include: Purpose and Scope, Implementation, Issuing Guidance, and Legal Effects. After completing this course, learners will be able to describe the history, development, issuance, and use of Agency guidance. Learners will also be able to recognize how and why GGPs were established.

**Languages Available:**  
Chinese (Simplified)  
French (European)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA Auditor

**Course Objectives:**

Recognize the history, development, issuance, and use of Agency guidance.;Recognize why GGPs were established.

**Runtime:** 30

## FDA Training and Qualification Requirements

PHA67

Effective personnel training and qualification can produce a competent workforce, which can lead to a reduction of errors/deviations, customer complaints, regulatory risk, and operational costs. This course addresses the measures required to stay in compliance with FDA regulations, and the requirements needed to implement an effective training and qualification program. This course also discusses specific responsibilities of personnel, records that need to be maintained, and how to measure training and qualification. Topics in this course include: Responsibilities, System Requirements, Training Specifics, Qualification Specifics, and Metrics. After completing this course, learners will be able to identify FDA's requirements for personnel training and qualification, responsibilities of personnel, and how to measure training and qualification.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify FDA requirements for personnel training and qualification, responsibilities of personnel, and how to measure training and qualification.

**Runtime:** 45

## Field Examinations

FDA28

**Languages Available:**  
Chinese (Simplified)

Field examinations help to ensure the safety, purity, and compliance of products released for public use. For imported products, field exams help to determine legal admissibility. This course is designed to familiarize individuals with the ?what, why, and when? of conducting examinations of products while performing inspections, sample collections, or surveillance activities. Topics in this course include: Scope, Indicators, Equipment, and Conduct. After completing this course, learners will be able to recognize the basics of field examinations. In addition, learners will also be able to identify the types of field examinations, the equipment commonly used during field examinations, and ways to conduct these examinations.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

**Course Objectives:**

Recognize the purpose of field examinations. ;Recognize when field examinations are conducted. ;Identify some of the equipment commonly used for field exams and how those examinations are conducted.

**Runtime:** 45

## Financial Disclosure by Clinical Investigators

GCP24

This course provides a summary of Title 21 of the Code of Federal Regulations (CFR) Part 54 entitled "Financial Disclosure by Clinical Investigators." This course discusses which financial arrangements must be disclosed, as well as investigator and sponsor responsibilities when disclosing financial information. Topics in this course include: Requirements, Responsibilities, and FDA Evaluation. After completing this course, learners will be able to identify the types of financial arrangements that must be disclosed and recognize how FDA evaluates the submitted financial information and the actions they may take if it is inadequate.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical
- Medical Device

**Course Objectives:**

Recognize the types of financial arrangements that must be disclosed and the requirements for proper financial disclosure for covered clinical studies. Recognize the responsibilities of the applicant (or sponsor) and the clinical investigator. Identify how FDA evaluates the submitted financial information and the actions they may take if it is inadequate.

**Runtime:** 45



## Fire Extinguisher Safety

If you were confronted with a fire in your workplace, would you know whether to fight or flee? If you decide to fight the fire, do you know what to do? Take this course to learn when to fight or flee a fire and how to choose and use fire extinguishers. Knowing what to do can save lives! Ideal learners include all employees.

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- General Safety and Manufacturing

**Content Suite:**

- Advanced Safety Orientation for General Industry (IACET CEU=0.9)

**Course Objectives:**

Decide when to fight or flee a fire;Recall the three elements needed to start and sustain a fire;Choose the appropriate fire extinguishers for different types of fires;Recall how to use the PASS method to operate fire extinguishers;Recall general guidelines about how to inspect and maintain fire extinguishers;Identify best practices for hands-on fire extinguisher training

**Runtime:** 15

**PS5-00246**

**Languages Available:**

- Dutch (PS5-101274)
- Czech (PS5-101273)
- Chinese (Simplified) (PS5-102516)
- French (European) (PS5-101275)
- German (PS5-101276)
- Italian (PS5-102521)
- Japanese (PS5-102520)
- Korean (PS5-102519)
- Polish (PS5-101277)
- Portuguese (Brazil) (PS5-101278)
- Russian (PS5-102518)
- Spanish (Latin America) (PS5-100564)
- Thai (PS5-101279)
- English
- French (Canadian) (PS5-102334)

## Fire Prevention

Fire is a terrible way to die or be injured. You cannot assume that having a fire department keeps you safe. Most workplace fires are completely preventable. Take this course to find out how to reduce the risk of fires in your workplace. Ideal learners are all employees.

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- General Safety and Manufacturing

**Content Suite:**

- Advanced Safety Orientation for General Industry (IACET CEU=0.9)

**Course Objectives:**

Know the four components needed to start and sustain a fire;Recognize the leading causes of fires in the workplace;Recall common workplace fire prevention tools and practices;Recall typical procedures for fire drills and evacuations

**Runtime:** 20

**PS5-00271**

**Languages Available:**

- Dutch (PS5-101094)
- Czech (PS5-101093)
- Chinese (Simplified) (PS5-101100)
- French (Canadian) (PS5-102698)
- German (PS5-101096)
- Japanese (PS5-101097)
- Polish (PS5-101098)
- Portuguese (Brazil) (PS5-101099)
- Thai (PS5-101102)
- English



## First Aid - Basics

Incidents requiring first aid can happen anywhere and at any time. The first response to such an incident is the most important. First aid given at the scene can improve the chances of survival and recovery of a victim. This course presents ways to respond to basic first aid situations until the emergency medical services (EMS) personnel arrive. Ideal learners are all employees.

**Format:** eLearning - Claro

<b>Libraries:</b>	<b>Topic/Industry:</b>
<ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul>	<ul style="list-style-type: none"> <li>• Health and Wellness</li> <li>• Construction</li> </ul>

### Course Objectives:

Explain when you might be held accountable for a victim's outcome; Assess scenes and victims before providing first aid; Provide valuable information to emergency medical services (EMS); Recall guidelines about when and how to move victims; Recall basic first aid techniques for the treatment of breathing emergencies, choking, severe bleeding, shock, fractures, sprains, strains and burns

**Runtime:** 37

## PS5-100989

### Languages Available:

Dutch (PS5-101479)  
Czech (PS5-101478)  
Chinese (Simplified) (PS5-101477)  
French (European) (PS5-101480)  
German (PS5-101481)  
Italian (PS5-102603)  
Japanese (PS5-101482)  
Korean (PS5-101587)  
Polish (PS5-101483)  
Portuguese (Brazil) (PS5-101484)  
Russian (PS5-102602)  
Spanish (Latin America) (PS5-101485)  
Thai (PS5-101486)  
English

## First Aid - Medical Emergencies

Injuries, both on and off the job, represent a significant health problem. The outcome of injuries depends on not only the severity of the injury, but also on the rendering of first aid care. Prompt, properly administered first aid care can mean the difference between life and death. This course will cover a variety of emergency scenarios and the appropriate first aid care. Ideal learners are all employees.

**Format:** eLearning - Claro

<b>Libraries:</b>	<b>Topic/Industry:</b>
<ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul>	<ul style="list-style-type: none"> <li>• Health and Wellness</li> <li>• Construction</li> </ul>

### Course Objectives:

Sudden illness (such as fainting, seizures, asthma attacks, heart attacks, diabetic emergencies, stroke, and severe allergic reactions); Poisoning; Stings and bites; Heat and cold-related illnesses

**Runtime:** 33

## PS5-100991

### Languages Available:

Dutch (PS5-101135)  
Czech (PS5-101113)  
Chinese (Simplified) (PS5-101112)  
French (European) (PS5-101115)  
German (PS5-101116)  
Japanese (PS5-101117)  
Polish (PS5-101118)  
Portuguese (Brazil) (PS5-101119)  
Spanish (Latin America) (PS5-101120)  
Thai (PS5-101121)  
English

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## Food and Drug Law: Criminal Acts Violations

FDA04

This course will describe several felony criminal statutes available for use by FDA that are not part of Title 21 of the USC. These are statutes that have been used in the past and are most likely to be used for felony violations associated with Title 21 criminal prosecutions. Topics in this course include Definition, False Statements, Mail and Wire Fraud, Justice Obstruction, Conspiracy, Aiding and Abetting, and Intent. After completing this course, learners will be able to recognize what constitutes as criminal felony behavior and the means by which FDA proves criminal intent. Learners will also be able to identify specific elements of proof for the statutes covered in this course.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

**Course Objectives:**

Recognize what constitutes as criminal felony behavior and the means by which FDA proves criminal intent; Identify specific elements of proof for the statutes covered in this course

**Runtime:** 45

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## Food and Drug Law: FDA Jurisdictions

FDA01

This course introduces the legal jurisdiction of FDA and the responsibilities and limits assigned by Congress to FDA. Topics in this course include Jurisdiction History, Responsibilities, Foods, Drugs, Devices, Cosmetics, and Jurisdiction Limits. After completing this course, learners will be able to recognize the scope and limits of FDA jurisdiction. Learners will also recognize how products are regulated within the different industries.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

**Course Objectives:**

Recognize the scope and limits of FDA jurisdiction; Recognize how products are regulated within the different industries

**Runtime:** 45

## Food and Drug Law: Imports and Exports

FDA05

This course is a general introduction to Chapter 8 of the Federal Food, Drug, and Cosmetic (FD&C) Act, which addresses Imports and Exports. Topics in this course include Imports, Exports, Primary Agencies, Other Agencies, Importers, Samples, Violative Samples, and Preventing Violations. After completing this course, learners will be able to recognize the definition of imports and exports and recognize various imported and exported products. Learners will also be able to identify the roles agencies play in the import and export of FDA regulated products, as well as non-government parties involved in the import process. Finally, learners will be able to recognize how FDA determines that a sample is in violation of the FD&C Act and prevents violative products from entering the US. This course is not intended to provide detailed legal guidance to any party.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - SCORM, eLearning - EduFlex

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

### Course Objectives:

Recognize the definition of imports and exports and recognize various imported and exported products; Identify the roles agencies play in the import and export of FDA regulated products, as well as non-government parties involved in the import process; Recognize how FDA determines that a sample is in violation of the FD&C Act and prevents violative products from entering the US

**Runtime:** 60

## Food and Drug Law: Judicial Actions

FDA03

This course will address the types of judicial actions, both;criminal and civil, that are available to FDA as part of its law enforcement;armory in the event it encounters suspected violations of the Food, Drug, and;Cosmetic (FD&C) Act. Topics in this course include: Judicial System, Law;Enforcement, The Laws, Criminal Penalties, and Civil Penalties. After;completing this course, learners will be able to identify how FDA is empowered;to take judicial action, identify the laws enforced by FDA, identify the entities;that enforce federal law, and recognize what criminal and civil penalties may;be imposed for violations of the FD&C Act and related laws. Prerequisites for;this course are FDA01 \_ Food and Drug;Law: FDA Jurisdictions and FDA02 ?;Food and Drug Law: Prohibited Actions.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

### Course Objectives:

Identify how FDA is empowered to take judicial action. ;Identify the laws enforced by FDA. ;Identify the entities that enforce federal law. ;Recognize what criminal and civil penalties may be imposed for violations of the FD&C Act and related laws.

**Runtime:** 45



## Food and Drug Law: Prohibited Actions

FDA02

The FD&C Act specifically describes what actions are violations and who will be held accountable for those actions. This course discusses prohibited actions under that law. Topics in this course include: Common Violations, Consequences, Responsibility, and Defining Cases. After completing this course, learners will be able to recognize the specific acts that are prohibited under the FD&C Act. Learners will also be able to identify the most commonly violated acts and recognize how FDA determines who is responsible. Finally, learners will be able to identify major cases that establish consequences for violating prohibited acts, and recognize what these consequences may be.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

**Course Objectives:**

Recognize the specific acts that are prohibited under the FD&C Act; Identify the most commonly violated acts; Recognize how FDA determines who is responsible; Identify major cases that establish consequences for violating prohibited acts and recognize what these consequences may be.

**Runtime:** 45

## GCP/ICH Obligations of Sponsors and Monitors

GCP04

This course describes sponsor and monitor requirements and responsibilities for the conduct of clinical trials in support of new drug and biologics applications. Topics in this course include: Sponsor's Role, Research Team, Investigators, Prestudy Site Visit (PSV), Other Visits, and Monitoring Activities. After completing this course, learners will be able to recognize the roles and responsibilities of sponsors and monitors during clinical trials.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the roles and responsibilities of sponsors and monitors in clinical trials; Identify regulatory requirements, the types of personnel selected to run the trial, elements of sponsor-investigator interaction, types of site and monitoring visits, and the extent of the regulations that burden the sponsor's monitoring responsibilities in the process of new product development.

**Runtime:** 45

## GCP/ICH Obligations of Sponsors, Monitors, and Investigators

GCP01

This course addresses the GCP obligations of sponsors, monitors, and investigators as described in the ICH GCP Guideline. Topics in this course include: Definitions, Protecting Subjects, Sponsor, Monitor, Investigator, and Overall Responsibilities. After completing this course, learners will be able to identify the specific obligations of sponsors, monitors, investigators, and their staff for executing clinical trials.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- | <b>Libraries:</b>   | <b>Topic/Industry:</b>  |
|---|---|
| <ul style="list-style-type: none"><li>• Clinical: Medical Device Library</li><li>• Clinical: Pharmaceutical Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Pharmaceutical</li><li>• Medical Device</li></ul> |

### Course Objectives:

Identify the specific obligations of sponsors, monitors, investigators, and their staff for executing clinical trials.

**Runtime:** 45

## General Data Protection Regulation

DP01

This course covers the European Union's (EU's) General Data Protection Regulation (GDPR), which is a harmonized data privacy law across Europe. Topics in this course include: General Provisions and Principles, Rights of the Data Subject, Data Processors and Controllers, and Other Considerations. After completing this course, learners will be able to recognize the general provisions of the GDPR, and identify data subject rights under the Regulation. Learners will also be able to identify controller and processor obligations related to data privacy and security.

### Languages Available:

French (European)  
German  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- | <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
|--|--|
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• HealthCare Catalog</li></ul> | <ul style="list-style-type: none"><li>• All Industries</li></ul> |

### Course Objectives:

Recognize general provisions of the GDPR. Identify data subject rights under the Regulation. Identify controller and processor obligations related to data privacy and data security.

**Runtime:** 30

## Global Fair Competition Laws

Fair competition laws help to preserve a level competitive playing field for companies. This course covers the basic principles and laws governing fair competition. Topics in this course include: Definitions, Horizontal Agreements, Vertical Agreements, Other Key Considerations, Laws, EU Law \_ General Considerations, and EU Law \_ Specific Considerations. After completing this course, learners will be able to recognize the principles and laws that ensure fair competition globally.

**Format:** eLearning - EduFlex, eLearning - SCORM

- | <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
|--|--|
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Recognize the types of agreements that have the potential to restrict competition.;Identify the fair competition laws that govern and often prohibit use of those agreements.;Recognize guidelines for conducting business within the constraints of global fair competition laws.

**Runtime:** 60

## ETHICS22

**Languages Available:**  
Chinese (Simplified)  
French (European)  
German  
Italian  
Japanese  
Portuguese (Brazil)  
Spanish (Spain)

## Global Regulatory Library Strategy and Planning Process

This course discusses creating the strategy and planning documents that help companies align the development of new products with the regulatory submission process for those products. Along with the regulatory plan, a company's regulatory strategy describes the overall regulatory approach and the specific tactical steps required to meet regulatory objectives for the product. Topics in this course include: Purpose, Strategy Elements, and Plan Elements. After completing this course, learners will be able to identify the elements of a regulatory strategy and plan that can meet your company's development needs while meeting regulatory submission requirements for a variety of regulatory environments.

**Format:** eLearning - EduFlex, eLearning - SCORM

- | <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
|---|--|
| <ul style="list-style-type: none"><li>• Global Regulatory Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• Medical Device GMPs Library</li></ul> | <ul style="list-style-type: none"><li>• QA/GMP Trainer</li></ul> |

### Course Objectives:

Identify the elements of a regulatory strategy and plan that can meet your company's development needs while meeting regulatory submission requirements for a variety of regulatory environments.

**Runtime:** 45

## DEV54

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

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## GMP Principles for Batch Records

PHA60

This course explains the Good Manufacturing Practices associated with batch records. Topics in this course include: Record Requirements, Manufacturing Records, Packaging Records, Deviations, and Batch Record Review. After completing this course, learners will be able to identify the regulatory requirements for batch records and recognize how to properly create and maintain batch records.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
  - Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify regulatory requirements and responsibilities for completing batch records.;Recognize documentation elements that are required in manufacturing and packaging records.;Recognize what deviations are and how to correct and document them.

**Runtime:** 45

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## GMP Principles of SOPs

PHA64

Working within SOPs is critical to making high-quality products that comply with FDA regulations. This course describes the basic GMP principles involved in creating SOPs. Topics include the contents of an SOP, the proper procedure for changing an SOP, and appropriate use of an SOP. After completing this course, you will be able to identify what SOPs are, what their purpose is, and how they are structured. You will be able to recognize how to handle changes to SOPs, as well as how SOPs are used in the workplace.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify what SOPs are, what their purpose is, and how they are structured.;Recognize how to handle changes to SOPs as well as how SOPs are used in the workplace.

**Runtime:** 45

## GMP Updates: Supply Chain Quality and Emerging Compliance Concerns

PHDV92

Supply chain activities provide the natural resources and raw materials that manufacturers transform into a finished product. This course describes why supply chain quality has evolved as a critical concern in the medical device and pharmaceutical industries and what manufacturers can do to better manage supply chain quality. Topics in this course include: Challenges, Responses, and Company Improvements. After completing this course, learners will be able to recognize how regulators are responding to supplier quality concerns and identify what manufacturers can do to better manage supply chain quality.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

### Course Objectives:

Recognize the critical concerns of supply chain quality in the medical device and pharmaceutical industries. ;Identify the challenges manufacturers of finished pharmaceutical and medical device products face. ;Recognize how regulators are responding to quality concerns and identify what manufacturers can do to better manage supply chain quality.

**Runtime:** 45

## Good Clinical Practices (GCPs) for New Product Investigations

PHA36

This course describes the general requirements of Good Clinical Practice (GCP) for new product investigations for the protection of human subjects, as well as information regarding the concepts, individuals, and groups involved with them. Topics in this course include: Clinical Trial Process, Clinical Trial Team, Specific GCP Requirements, and Documentation Requirements. After completing this course, learners will be able to recognize the basic concepts and key elements of GCP, including documentation, purpose, subject protection, and regulatory authority requirements.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

### Course Objectives:

Recognize the basic concepts and key elements of GCP, including documentation, purpose, subject protection, and regulatory authority requirements.

**Runtime:** 30

## Good Documentation Practices for Medical Device Manufacturers

DEV56

This course presents the critical importance of creating and maintaining good documents for medical device manufacturers. Learners will identify the stages of the Documentation Life Cycle, recognize important types of documents, recognize how documentation is controlled, identify the important requirements of electronic recordkeeping, and recognize best practices for recording and correcting data.

**Format:** eLearning - SCORM\*, eLearning - EduFlex

**Libraries:**

- Medical Device GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Runtime:** 60

**Languages Available:**

- Chinese (Simplified)
- French (European)
- German
- Japanese
- Spanish (Latin America)

## Good Laboratory Practices (GLPs)

PHDV62

Nonclinical laboratory studies are one of the first steps taken in bringing a new drug, device, or biologic to the marketplace, so it is important that practices are in place to ensure the reliability of the study and the safety and efficacy of the product. This course gives the learner an introduction to Good Laboratory Practice (GLP) Regulations and their application to nonclinical animal safety and toxicology studies. Topics in this course include: GLP Guidance, Personnel, Protocol, Documentation, and Inspections. After completing this course, learners will be able to recognize the general characteristics of GLPs and identify how they apply to nonclinical studies.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

**Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- QA Auditor

**Course Objectives:**

Recognize the general characteristics of GLPs; Recognize how GLPs apply to nonclinical studies

**Runtime:** 60

## Gowning for Sterile Manufacturing

PHA63

Because of the importance of preventing contamination in finished sterilized pharmaceuticals or medical devices, anyone involved in the production of these products must have a basic knowledge of sanitization and sterilization, the microbiological principles involved, and the importance of proper gowning and working in cleanrooms. This course covers requirements of the European Union (EU) and FDA. Topics in this course include Regulations, Contaminants, and Gowning Procedures. After completing this course, you will be able to identify the sources and types of contamination in a manufacturing environment, recognize the importance of health issues and personal hygiene, and identify the staged entry and use of cleanrooms. You will also be able to recognize important practices and procedures for proper gowning. Before taking this course, make sure you have completed Principles of Aseptic Processing and Principles of Sterilization.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical Library
- Pharmaceutical GMPs Library
- Global Regulatory Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical Library
- Medical Device

**Course Objectives:**

Identify the sources and types of contamination in a manufacturing environment. Recognize the importance of health issues and personal hygiene. Recognize the staged entry and use of cleanrooms. Identify important practices and procedures for proper gowning.

**Runtime:** 30

## Guidelines of Workplace Safety

EHS53

This course explains how both employees and employers uphold safety in the workplace. Topics in this course include: Causes of Accidents, Accidents and Prevention, Hazards in the Workplace, Employer Role, and Your Role. After completing this course, learners will be able to recognize potential workplace accidents and hazards that may be prevented in order to maintain workplace safety.

**Languages Available:**  
Spanish (Latin America)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- EHS Manager
- HR Compliance & Risk Management Library
- Corporate Compliance
- HealthCare Catalog
- HR Compliance & Risk Management
- Pharmaceutical Catalog
- Medical Device Catalog

**Course Objectives:**

Recognize potential workplace accidents and hazards.;Recognize the roles of the employer and employee in maintaining workplace safety.

**Runtime:** 45

## GxPs

Regulated Good Practices (GxPs) apply to the development, clinical testing, and manufacture of drugs, biological products, and medical devices to ensure their safety, efficacy, and security. This course discusses the manner in which regulatory authorities oversee the drug, biologic, and device development and manufacturing processes using GxP regulations. Topics in this course include: Practices and Process, GLPs, GCPs, and GMPs. After completing this course, learners will be able to identify what practices comprise the GxP regulations. Learners will also be able to recognize how these practices relate to each step in the development and manufacture of new drugs, biologics, and medical devices.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize what practices comprise the GxP regulations; Recognize how these practices relate to each step in the development and manufacture of new drugs, biologics, and medical devices

**Runtime:** 45

PHDV61

**Languages Available:**

Chinese (Simplified)  
French (European)  
Japanese

## Handling a Product Recall

This course defines product recalls and explains their impact on the manufacturer, FDA's requirements and enforcement when dealing with a product recall, and the basic steps for handling a recall. Topics include: Procedures, Roles, Effects, and Communication. After completing this course, learners will be able to recognize the definition of ?product recall?, the impact of a product recall on a manufacturer, and FDA's requirements and enforcement authorities when dealing with a product recall. Learners will also be able to identify the basic steps for handling a recall.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize the definition of ?product recall?;Recognize when a product recall is required;Recognize the impact of a product recall on a manufacturer;Recognize FDA's requirements and enforcement authorities when dealing with a product recall. ;Identify the basic steps for handling a recall.

**Runtime:** 30

PHDV64



## Harassment Avoidance Training for California

LAV22

Supervisors and managers must take all complaints and incidents of sexual harassment seriously and should respond quickly and appropriately. This course describes the different types of sexual harassment that can occur in the workplace and how to prevent, monitor, and report these events if they occur. Topics in this course include: Laws and Policies, Types of Sexual Harassment, Prevention and Monitoring, Enforcement, Reporting Harassment, Investigating Harassment, and Retaliation. After completing this course, learners will be able to recognize what actions constitute harassment in the workplace.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Topic/Industry:**

- Corporate Compliance

**Course Objectives:**

Identify company policies that prohibit sexual harassment. ;Recognize what constitutes harassment and how to apply the laws and company policies to help prevent harassment. ;Identify ways to report harassment.

**Runtime:** 120

## Hazard Communication (US)

PS5-00206

Workers are exposed to hazardous chemical products every day. This poses serious problems for exposed workers and their employers. Hazard Communication (HazCom) training is designed to provide workers with the information they need to recognize and avoid hazardous chemicals. This course will introduce learners to everything from the content of the HazCom Standard to how to use Safety Data Sheets (SDSs) and chemical labels to prepare for hazards or react to exposures. Ideal learners are employees who work with or around hazardous chemicals.

**Format:** eLearning - Claro

**Languages Available:**  
Spanish (Latin America) (PS5-102163)  
English

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- General Safety and Manufacturing

### Content Suite:

- OSHA 10: Construction Industry Outreach Training Course (IACET CEU=1.0) (Actively Proctored)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0) (Actively Proctored)
- OSHA 10: Construction Industry Outreach Training Course (IACET CEU=1.0)

### Course Objectives:

State the purpose of the HazCom Standard;Recognize who is covered by the HazCom Standard;State the four basic parts of the HazCom Standard;Identify physical and health hazards of chemicals ;List what items should be included in a hazardous chemical inventory;Recognize what should be included in the written hazard communication program;Recognize the information contained in a Safety Data Sheet (SDS) and how it is used and maintained in the workplace;Identify where and how hazard warning labels must be used;List the elements of the HazCom Standard training program

**Runtime:** 26

## HAZMAT Transportation - Part 1 - The Hazardous Materials Table (US)

PS5-00576

Because of the risks and dangers associated with shipping hazardous materials, the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration and its supporting agencies regulate the transport of these materials within the US and ensure we comply with the Hazardous Materials Regulations (or the HMR).

**Languages Available:**  
English

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Transportation Safety

### Content Suite:

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

### Course Objectives:

Identify proper shipping names; Know how to decipher the codes within the HMT; Utilize Appendices A and B of the HMT to determine which materials qualify as a hazardous substance or marine pollutant

**Runtime:** 28

## HAZMAT Transportation - Part 2 - Shipping Papers (US)

PS5-00250

Shippers are responsible for documenting information about hazardous materials before offering them for transport. This module covers the components of a properly prepared shipping paper.

**Languages Available:**  
English

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Transportation Safety

### Content Suite:

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

### Course Objectives:

Identify the information required on shipping papers; Recognize the correct entries for the shipping and basic descriptions; Identify shipping paper and certification exceptions; Select the appropriate retention requirements for shipping papers

**Runtime:** 23

## HAZMAT Transportation - Part 3 - Packaging (US)

PS5-00578

If given the task of packaging or inspecting and accepting hazardous materials for transportation, could you do so in compliance with HMR (Hazardous Materials Regulations) packaging requirements? Your employer wants to make sure you can, since the DOT and its designated agencies regulate the packaging and transportation of hazardous materials. These agencies also have the authority to inspect hazardous materials packages and fine or penalize you as well as your employer for any HMR violations. Module 3 covers general packaging requirements.

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Transportation Safety

**Content Suite:**

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

**Course Objectives:**

Identify the packaging requirements and exceptions for hazardous materials;Determine which types of packages and materials are forbidden from transportation;Recall the requirements for reusing packaging, as well as for transporting leaking or damaged packages and empty packaging

**Runtime:** 27

## HAZMAT Transportation - Part 4 - Marking (US)

PS5-00580

This series of Hazardous Materials Transportation e-Lessons provides general awareness training for the U.S. Department of Transportation (USDOT) Hazardous Materials Regulations. Module 4 covers the marking and labeling of hazardous materials.

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Transportation Safety

**Content Suite:**

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

**Course Objectives:**

Explore how to mark bulk and non-bulk packages;Detail special provisions and exceptions in marking certain types of hazardous materials and packaging;Identify general marking requirements;Describe special provisions for marking hazardous materials;Determine when exceptions apply to marking hazardous materials

**Runtime:** 23

## HAZMAT Transportation - Part 5 - Labeling and Placarding (US)

PS5-00581

This series of Hazardous Materials Transportation e-Lessons provides general awareness training for the U.S. Department of Transportation (USDOT) Hazardous Materials Regulations. Module 5 covers Placarding.

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Transportation Safety

**Content Suite:**

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

**Course Objectives:**

Identify the general requirements for affixing labels and placards to hazardous material (HAZMAT) shipments; Determine when exceptions to these requirements apply as well as when modifications can be made to labels and placards; Use the labeling and placarding tables to select the appropriate labels and placard for hazardous materials

**Runtime:** 29

## HAZMAT Transportation - Part 6a - Carrier Requirements - Highway (US)

PS5-00582

This series of Hazardous Materials Transportation e-Lessons provides general awareness training for the U.S. Department of Transportation's (USDOT) Hazardous Materials Regulations. Module 6 is composed of four parts: Module 6a covers Highway Carrier Requirements.

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Transportation Safety

**Content Suite:**

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

**Course Objectives:**

Identify the general Highway Carrier Requirements; Determine segregation requirements for hazardous materials; Select the appropriate methods of loading, unloading and transporting hazardous materials

**Runtime:** 22

## HAZMAT Transportation - Part 6b - Carrier Requirements - Air (US)

PS5-00583

When it comes to transporting hazardous materials by air, Part 175 of the Hazardous Materials Regulations or HMR provides air carriers with the specific requirements they need to accept, handle and transport hazardous materials.

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Transportation Safety

**Content Suite:**

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

**Course Objectives:**

Recognize how shippers and carriers must work together to comply with HMR requirements; Identify which hazardous materials are authorized for air transportation; Determine the quantity limitation, stowage and segregation requirements for transporting hazardous materials aboard passenger and cargo aircraft

**Runtime:** 30

## HAZMAT Transportation - Part 6c - Carrier Requirements - Rail (US)

PS5-00584

The DOT (Department of Transportation) identifies requirements for transporting hazardous materials by rail in Part 174 of the HMR (Hazardous Materials Regulations).

**Languages Available:**  
English

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Transportation Safety

**Content Suite:**

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

**Course Objectives:**

Recall the documentation, inspection and movement requirements for hazardous materials by rail; Identify proper HAZMAT handling and loading requirements; Determine how to segregate hazardous materials and position rail cars containing these materials

**Runtime:** 21

## HAZMAT Transportation - Part 6d - Carrier Requirements - Water (IMDG) (US)

PS5-00585

In this module, we will focus on the actions we can take to protect our waters and marine life when transporting hazardous materials by any type of vessel or ship.

Languages Available:  
English

Format: eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Transportation Safety

### Content Suite:

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

### Course Objectives:

Determine who is responsible for preparing HAZMAT packages, shipping documentation and the vessel for transportation; Select the stowage location of hazardous materials according to the segregation restrictions; Identify the appropriate handling, loading, unloading and inspection requirements for hazardous materials

Runtime: 28

## HAZMAT Transportation - Part 7 - Security Awareness (US)

PS5-00223

Hazardous materials are vulnerable when they are in transit. Imagine what would happen if criminals or terrorists were able to obtain dangerous chemicals and materials! Take this course to find out what you can do to prevent that from happening. Ideal learners include people who work at companies involved in the packaging, shipment, transportation and distribution of hazardous materials.

Languages Available:  
English

Format: eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Transportation Safety

### Content Suite:

- Commercial Drivers Suite (IACET CEU=0.4)
- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- HazMat Transportation Suite (US) (IACET CEU=0.4)
- HazMat Transportation, Parts 1-7 (US)

### Course Objectives:

Recall security requirements for people who handle hazardous materials; Identify potential targets for hazardous material terrorism; Identify potential threats of hazardous material terrorism; Recognize the key factors that go into planning a safe route for hazardous materials transportation; Recognize ways to prevent hazardous materials from getting into the wrong hands; Use security checklists to identify and resolve security vulnerabilities

Runtime: 27

## HAZMAT Transportation Awareness (US)

PS5-00575

In the United States, we ship millions of tons of hazardous materials (HAZMAT) every day. These materials can be poisonous, toxic, flammable, explosive or corrosive by nature. Take this course to learn basic information about how to identify and safely handle hazardous materials, all while complying with federal laws and regulations. This course may be taken for general familiarization and is also ideal for employees who are involved in shipping, packaging or transporting hazardous materials.

**Languages Available:**  
 Spanish (Latin America) (PS5-102359)  
 English

**Format:** eLearning - Claro

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• Awareness</li> <li>• Transportation Safety</li> </ul> |

### Course Objectives:

What hazardous materials and associated risks are;How they are transported;How they are regulated;What responsibilities employers, handlers, shippers and carriers have

**Runtime:** 10

## Health Canada - MDSAP Country-Specific Tasks

MDSAP\_Canada

This course provides an overview of the chapter structure of MDSAP.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

- Libraries:**
- Pharmaceutical Catalog
  - MDSAP Library
  - Medical Device Catalog

**Runtime:** 15

## Hearing Conservation

PS5-00267

Did you know that most noise-related hearing loss is completely preventable? In this course you will learn about the noise risks in your workplace and what you need to do to protect your hearing. Ideal learners include all employees who work with noisy tools or equipment or in loud environments.

**Languages Available:**  
 Dutch (PS5-101244)  
 Czech (PS5-101243)  
 Chinese (Simplified) (PS5-100586)  
 French (Canadian) (PS5-102862)  
 French (European) (PS5-102564)  
 German (PS5-101245)  
 Italian (PS5-102568)  
 Japanese (PS5-102567)  
 Korean (PS5-102566)  
 Polish (PS5-101246)  
 Portuguese (Brazil) (PS5-101247)  
 Russian (PS5-102565)  
 Spanish (Latin America) (PS5-100522)  
 Thai (PS5-101248)  
 English

**Format:** eLearning - Claro

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• General Safety and Manufacturing</li> </ul> <p><b>Content Suite:</b></p> <ul style="list-style-type: none"> <li>• Advanced Safety Orientation for Managers and Supervisors in Construction (IACET CEU=2.7)</li> </ul> |

### Course Objectives:

Recognize the effects of noise on hearing;Recall the components of a hearing conservation program;Compare the advantages and disadvantages of various types of hearing protection;Know how to use and care for hearing protection

**Runtime:** 20



## High Purity Water Systems

PHDV82

Because water quality can directly impact product quality, GMP regulations require that water receive the same scrutiny, monitoring, and control as any other critical raw material used in manufacturing processes. This course describes the typical uses of water in pharmaceutical and medical device manufacturing. Topics in this course include: Types of Water, Quality Determination, WFI System, Monitoring Process, Monitoring Approaches, System Problems, and Solutions. After completing this course, learners will be able to recognize water types used in manufacturing, monitoring processes, and solutions to problems within high purity water systems.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

### Course Objectives:

Identify the typical uses of water in pharmaceutical and medical device manufacturing. ;Recognize the general process for producing high quality water.;Recognize various approaches for monitoring a water system. ;Recognize possible methods of solving water system problems.

**Runtime:** 60

## HIPAA -- The Impact On Clinical Research

GCP05

Congress enacted the Health Insurance Portability and Accountability Act (HIPAA) to protect patient privacy and confidentiality. This course explains the history of HIPAA implementation, legal entities involved in HIPAA oversight and compliance, and the impact HIPAA has on clinical research in the United States. Topics in this course include: Privacy Requirements, PHI, Waivers, Current Regulations, Limited Data Sets, Exceptions and Enforcement, and Future Clinical Research. After completing this course, learners will be able to identify penalties for violations of HIPAA Privacy requirements.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

### Course Objectives:

Identify who is required to comply with HIPAA Privacy Rules. ;Recognize the roles of an institutional review board (IRB) and a privacy board (PB). ;Identify the penalties for violations of HIPAA Privacy requirements.

**Runtime:** 45

## HIPAA: General Awareness

HIPAA01

This course is designed to provide all employees and associates with an in-depth overview of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy, security, and data standardization requirements from a health plan perspective. This course describes the updated requirements that were included in the Health Information Technology for Economic and Clinical Health Act (HITECH), which was signed into law February 2009. Topics in this course include: Privacy Standards, Security Standards, Data Standardization, and Enforcement. After completing this course, learners will be able to identify HIPAA regulations and ways to keep members' PHI secure.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- | <b>Libraries:</b>  | <b>Topic/Industry:</b>  |
|--|---|
| <ul style="list-style-type: none"><li>• HIPAA Library</li><li>• Medical Device - Sales &amp; Marketing Library</li><li>• Pharmaceutical - Sales &amp; Marketing Library</li><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• QA/GMP Trainer</li><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Identify the goals of HIPAA and its Administrative Simplification provisions. ;Identify the entities that are covered under the law and recognize how the law is enforced.;Identify the key privacy and security requirements that apply to the use and disclosure of protected health information (PHI).

**Runtime:** 60

## Hiring and Firing

LAV04

Hiring is an important factor in creating a solid workforce, and firing is a tool to ensure productivity. This course provides techniques for making good hiring decisions, terminating employees in a consistent and fair manner, and avoiding lawsuits resulting from the hiring and firing process. Topics in this course include: Regulations, Hiring, Interviewing, Testing, and Firing. After completing this course, learners should recognize several tools that will assist in the hiring and firing processes. Learners will also identify how to handle difficult employee situations.

**Format:** eLearning - EduFlex, eLearning - SCORM

- | <b>Libraries:</b>  | <b>Topic/Industry:</b>  |
|--|---|
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HR Compliance &amp; Risk Management Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• HR Compliance &amp; Risk Management</li></ul> |

### Course Objectives:

Recognize several tools that will assist in the hiring and firing processes;Identify how to handle difficult employee situations.

**Runtime:** 30

## ICH Q7: Resources and Materials Management

ICHreg02

This is the second in a series of courses designed to instruct on Good Manufacturing Practices (GMPs) for Active Pharmaceutical Ingredients (APIs), as set out by the ICH Q7 Guideline. This course covers qualifications for personnel, requirements for buildings used in API manufacturing, considerations for API manufacturing equipment, and materials management. Learners should have a working knowledge of current GMPs for drug products as set out in CFR 21 Parts 210 and 211. Learners should also have a basic understanding of chemical and biological processes used in the manufacture of Active Pharmaceutical Ingredients. Learners should have completed the course ICH Q7: Introduction and Quality Management.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
  - Global Regulatory Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the general requirements for qualification of API manufacturing personnel. ;Identify the requirements for buildings and facilities as well as API manufacturing equipment. ;Recognize materials management and warehousing and distribution procedures.

**Runtime:** 60

## Implementing an Equipment Qualification Program

PHDV88

A well-developed and established equipment qualification program allows a company to meet current GMP requirements and save operational costs at the same time. This course provides an overview of the equipment qualification requirements, for the US and European Union, that apply to the pharmaceutical, biotechnology, and medical device industries. Topics in this course include: Protocol, Design, Installation, Operation, Performance, and Legacy Equipment. After completing this course, learners will be able to identify the steps in successful implementation of an equipment qualification program.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify the importance of equipment qualification. ;Recognize the GMP requirements for equipment qualification.

**Runtime:** 45

## Import Operations 1: Background

FDA37

The first in a series of three courses, this course introduces FDA's import program and the laws applied to products offered for entry into the US and products intended for export from the US. Topics in this course include: Enforcement Approaches, Importers vs. Domestic, FD&C Act, 21 CFR, 19 CFR, 18 USC, and Resources. After completing this course, learners will be able to recognize how FDA ensures that imported products meet US public health standards. Learners will also be able to identify the differences between the regulation of domestic and imported products, the regulations that apply to imported products, and how the FD&C Act, the Code of Federal Regulations, and the United States Code address imports.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

### Course Objectives:

Recognize how FDA ensures that imported products meet US public Health standards.;Recognize differences between the regulation of domestic and imported products.;Identify the regulations that apply to imported products.;Recognize how the FD&C Act, the Code of Federal Regulations, and the United States Code address imports.

**Runtime:** 75

## Import Operations 2: The Process

FDA42

The second in a series of three, this course addresses FDA import and export programs, procedures, and policies and introduces the process followed during import proceedings. This course concentrates on how FDA regulates products pre-entry, types of entries, how FDA makes decisions about entries, and the resources available to assist with entry decisions. Topics in this course include: Pre-Entry, Food Safety, Entries, Entry Decisions, Resources, Examination, Analysis, Admissibility, and Enforcement. After completing this course, learners will be able to recognize the approaches and processes FDA uses to determine whether or not an import entry is in compliance with current import regulations.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

### Course Objectives:

Identify pre-entry activities, types of entries, and evaluation of entries. ;Recognize types of import resources, examinations of products and evaluations of documentary evidence, and analysis of samples.;Identify the resources available to assist in making admissibility decisions. ;Recognize the import operations process and FDA enforcement actions.

**Runtime:** 75

## Import Operations 3: Other Activities

FDA43

This course continues discussion on import operations. Topics in this course include: Filers, Sharing Information, Exports, Export Certificates, and Shared Responsibility. After completing this course, learners will be able to recognize how import filers participate in OASIS; how FDA identifies and removes violative imports from the US market; how FDA regulates exports; and what other agencies share responsibilities for imports with FDA. Learners will also be able to recognize the different types of export certificates and their significance.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize how import filers participate in OASIS. ;Recognize how FDA identifies and removes violative imports from the US market.;Identify how FDA regulates exports.;Identify what other agencies share responsibilities for imports with FDA.;Recognize the different types of export certificates and their significance.

**Runtime:** 45

## Improving Productivity

EHS49

Mastering productivity skills will make employees more valuable, and their work more satisfying. This course identifies basic skills for setting goals, prioritizing tasks, and managing time. This course also illustrates how to avoid time-wasters, delegate appropriately, and make efficient decisions. Topics in this course include: Productivity, Values, Becoming a Goal Getter, Planning, Time Wasters, Delegating, Individual Decisions, Group Decisions, Networking, and Teamwork. After completing this course, learners will be able to recognize the basic skills for setting goals, prioritizing tasks, and managing time.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Professional Development

**Course Objectives:**

Recognize skills for setting goals.;Identify how to prioritize tasks.;Recognize how to manage time efficiently.

**Runtime:** 30

## Industrial Ergonomics

PS5-00291

Jobs in an industrial environment can be physically demanding. Preventing work-related musculoskeletal problems rests on an ergonomically sound work environment, good work practices and employee awareness. This course will introduce common risk factors and methods to prevent musculoskeletal injury. Ideal learners include all industrial employees.

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- General Safety and Manufacturing

**Content Suite:**

- AES Ergonomic Improvement Specialist (IACET CEU=0.2)

**Languages Available:**  
Dutch (PS5-101166)  
Czech (PS5-101165)  
Chinese (Simplified) (PS5-101172)  
French (Canadian) (PS5-102669)  
French (European) (PS5-101167)  
German (PS5-101168)  
Japanese (PS5-101169)  
Polish (PS5-101170)  
Portuguese (Brazil) (PS5-101171)  
Spanish (Latin America) (PS5-101173)  
Thai (PS5-101174)  
English

**Course Objectives:**

Identify the signs and symptoms of musculoskeletal disorders;Recognize workplace risk factors for musculoskeletal disorders;Identify general methods for controlling these risk factors

**Runtime:** 24

## Informed Consent

GCP13

The informed consent document and process are designed to serve as an ethical framework for safeguarding the rights and well-being of research participants. This course explains informed consent regulations and guidelines, the informed consent process, and the roles and responsibilities of clinical research professionals. Topics in this course include: Foundational Documents, Consent Document, Types, Exceptions, Pediatric Research, Managing Consent, and Verifying. After completing this course, learners will be able to identify key historical events that led to the current informed consent regulations and guidelines and will also be able to recognize the informed consent process as well as its documentation requirements.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Pharmaceutical
- Medical Device

**Course Objectives:**

Identify key historical events that led to the current informed consent regulations and guidelines. Recognize the informed consent process as well as its documentation requirements.

**Runtime:** 75

## Interviewing Techniques

FDA27

Interviews are an important part of virtually every operation performed by FDA investigators and analysts. This course identifies effective interviewing techniques and traits of an effective interviewer. Topics in this course include: FDA Interviewers, Preparation, Interviewees, Interviewer Traits, Effective Questions, and Nonverbal Behavior. After completing this course, learners will be able to recognize the fundamentals of conducting an effective interview. Learners will be able to identify the traits of a successful interviewer and the importance of appropriate interpersonal skills. Learners will also be able to identify appropriate questioning techniques to use in an interview.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA Auditor

**Course Objectives:**

Recognize the fundamentals of conducting an effective interview.;Identify the traits of a successful interviewer.;Recognize the importance of appropriate interpersonal skills.;Identify appropriate questioning techniques to use in an interview.

**Runtime:** 45

## Introduction to Data Integrity

DATA01

This course provides foundational knowledge of the concepts of Data Integrity and quality. Topics in this course include: Regulatory Requirements, International Standards, Ensuring Data Integrity, and Evaluation and Review. After completing this course, learners will be able to identify requirements that help maintain Data Integrity and quality.

**Languages Available:**  
Chinese (Simplified)  
French (European)  
German  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Data Integrity Library
- QA Auditor
- QA/GMP Trainer

**Course Objectives:**

Recognize the definition of Data Integrity as it pertains to a pharmaceuticals manufacturing environment.;Identify regulatory requirements for Data Integrity in a pharmaceuticals manufacturing environment.;Identify what steps must be taken to ensure Data Integrity in a pharmaceuticals manufacturing environment.

**Runtime:** 30

## Introduction to GMPs

PHA38

Current Good Manufacturing Practices (cGMPs) are specific requirements that ensure safe manufacturing of pharmaceutical products and medical devices. This course describes the importance, purpose, and enforcement of cGMPs by FDA. Topics in this course include: History, Procedures, Documentation, Pharmaceutical Quality System, Responsibilities, and FDA Inspections. After completing this course, learners will be able to recognize basic cGMP requirements and identify the roles and responsibilities of pharmaceutical and medical device manufacturing employees.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Course Objectives:**

Recognize cGMPs and their importance to the pharmaceutical and medical device manufacturing industry. Identify basic cGMP requirements and the roles and responsibilities for compliance. Recognize how FDA enforces cGMP regulations.

**Runtime:** 45

## Introduction to the Medical Device Single Audit Program (MDSAP Library)

DEV62

In many industries today, the use of electronic records and signatures is becoming more common. This course explains the purpose of 21 CFR Part 11. Topics in this course include: Records Requirements, Records Security, Electronic Signatures, Signature Controls, and FDA Enforcement. After completing this course, learners will be able to recognize how to properly implement and use an electronic record or signature. FDA requirements for computerized systems that generate electronic records ensure that they and any electronic signatures applied to them are trustworthy, reliable, and traceable to the person(s), events, and actions taken to generate the records.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device Catalog
- Pharmaceutical Catalog
- FDA Inspections and Enforcement Library
- Pharmaceutical GMPs Library

**Course Objectives:**

Identify the regulatory requirements for electronic records and electronic signatures. ;Recognize FDA expectations for compliance.

**Runtime:** 30

**Languages Available:**

- French (Canadian)
- French (European)
- German
- Japanese
- Portuguese (Brazil)
- Spanish (Spain)



## Ionizing Radiation

PS5-01286

Although radiation offers many benefits, exposure to it can also threaten our health and the quality of our environment. We cannot eliminate radiation, but this training shows how we can reduce our risk by controlling our exposure to it. Ideal learners include for workers whose job duties require them to work or spend time in any portion of an area where harmful radiation may be present.

**Languages Available:**  
Spanish (Latin America) (PS5-102781)  
English

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- General Safety and Manufacturing

### Content Suite:

- HAZWOPER 8-Hr Supplemental Training  
29 CFR 1910.120/29 CFR 1926.65 (IACET CEU=0.3)
- HAZWOPER 8-Hr Refresher Training 29 CFR 1910.120/29 CFR 1926.65 (IACET CEU=0.8)

### Course Objectives:

Define ionizing radiation;Identify types and sources of ionizing radiation;Recognize the risks and health effects of exposure to radiation;Describe basic practices to maintain radiation exposures "as low as reasonably achievable";Recall measures used to control radiation doses in the workplace;Recognize what to do in the event of an emergency involving ionizing radiation

**Runtime:** 27

## ISO 14155: Clinical Investigation of Medical Devices for Human Subjects — Good Clinical Practice

GCP30

ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices as required in national, regional, and international Health Authorities (HA). This course is intended to be an overview of Good Clinical Practices (GCPs) as outlined in ISO 14155. Topics in this course include: Summary of GCP Principles, Ethical Considerations, CIP, IB, Informed Consent, and Other Documents. After completing this course, learners will be able to identify the specific requirements of ISO 14155. Learners will also be able to identify ways to assess safety, clinical performance, and effectiveness of investigational medical devices.

**Languages Available:**  
Chinese (Simplified)  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

### Libraries:

- Clinical: Medical Device Library
- Medical Device Catalog

### Topic/Industry:

- QA/GMP Trainer

### Course Objectives:

Identify the specific requirements of ISO 14155. ;Identify ways to assess safety, clinical performance, and effectiveness of investigational medical devices.

**Runtime:** 60

## ISO 14155: Obligations of Sponsors and Monitors

GCP20

ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices as required in national, regional, and international Health Authorities (HA). This course covers the basic obligations of sponsors and monitors, including a review of informed consent processes and forms. Topics in this course include: Sponsors, Monitors, and Informed Consent. After completing this course, learners will be able to identify the roles and responsibilities of sponsors and clinical monitors. Learners will also be able to identify specific requirements around informed consent under ISO 14155.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Clinical: Medical Device Library</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• QA/GMP Trainer</li></ul> |

### Course Objectives:

Identify the roles and responsibilities of sponsors and clinical monitors. ;Identify specific requirements around informed consent under ISO 14155.

**Runtime:** 60

## ISO 14971: Risk Management for Medical Devices

DEV55

This course illustrates the application of risk management;activities for medical device product safety through implementing the ISO 14971;International Standard for Risk Management. Topics in this course include: Overview;;Definitions, General Requirements, Risk Assessment, Risk Control, Risk in;Context, Risk Management File, and Tools. After completing this course;;learners will be able to recognize how to apply risk management activities for;medical device product safety.

**Format:** eLearning - EduFlex, eLearning - SCORM

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Medical Device Catalog</li><li>• Medical Device GMPs Library</li></ul> | <ul style="list-style-type: none"><li>• QA/GMP Trainer</li></ul> |

### Course Objectives:

Recognize Risk Management's role towards medical devices product safety.;Identify the elements of the risk management process.;Recognize the purpose and content for the Risk Management plan and report. ;Identify tools that may be applicable to use in the Risk Management Process. ;Recognize Risk Management tasks that are applied at various stages of the product lifecycle.

**Runtime:** 60

## Isolators for Aseptic Processing Library

This course describes critical operating principles for the successful operation of an isolator for Aseptic Processing Library. Topics in this course include: Prepare, Leak Test, Decontaminate, Setup, Operate, Monitor, Clean, and Maintain. After completing this course, learners will be able to recognize the major process steps for isolator processing.

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

### Libraries:

- Pharmaceutical Catalog
- Medical Device Catalog
- Aseptic Processing Library

### Course Objectives:

Identify the key benefits of isolators for Aseptic Processing Library.;Recognize the major process steps for isolator processing.;Identify the purpose and mechanism of the isolator decontamination process including critical process parameters.;Recognize the importance of proper glove use and aseptic technique in the isolator.;Identify methods for moving materials into and out of isolators.;Recognize the environmental monitoring techniques applicable to isolators.

**Runtime:** 25

## Aseptic04

### Languages Available:

French (European)  
German  
Spanish (Spain)

## Japan Therapeutic Goods Administration (TGA) MDSAP Specific

## MDSAP\_Japan

This course describes the tasks in the first chapter of the Medical Device Single Audit Program (MDSAP), which verifies that top management ensures that an adequate and effective quality management system (QMS) has been established and maintained.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

### Libraries:

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 15

## Japanese Medical Device and Pharmaceutical Regulations

## PHDV94

The course introduces the Japanese medical device;regulations. This course explores the scope and applicability of Japan's new;Act on Medical Devices (PMD Act). Topics in this course include: History,;Agencies, Approval Process, PMD vs ISO 13485, and Labeling. After completing;this course, learners will be able to recognize the general structure of PMD;and its requirements for the manufacture and distribution of medical devices to;the Japanese market.

**Format:** eLearning - EduFlex, eLearning - SCORM

### Libraries:

### Topic/Industry:

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

### Course Objectives:

Recognize the general structure of PMD and its requirements for the manufacture and distribution of medical devices to the Japanese market.;Identify specific elements of the regulations to incorporate into management reviews and internal audits.

**Runtime:** 30

## Key Concepts of Process Validation

PHDV77

Production problems can result in high scrap rates, product failures, customer dissatisfaction, and even death of a user. This course identifies the key concepts in the regulatory requirements for the validation of manufacturing processes. Topics in this course include: Requirements and Procedures, Process Design, Verification and Validation, Installation and Operational Qualification, and Continued Verification and Revalidation. After completing this course, learners will be able to identify recognize important aspects of process validation and identify the components of the validation life cycle.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify applicable regulatory requirements. ;Recognize important aspects of process validation. ;Identify the components of the validation life cycle.

**Runtime:** 60

## Lab Safety

PS5-100555

A laboratory safety program depends on participation and cooperation from every employee. This course describes common hazards associated with laboratory environments and introduces ways to control and limit chemical exposure. Ideal learners are any employees who work in a laboratory environment.

**Format:** eLearning - Claro

**Libraries:**                      **Topic/Industry:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Laboratory Safety
- Content Suite:
  - Laboratory Safety Training Suite (IACET CEU=0.3)

**Course Objectives:**

Identify the most common routes of chemical exposure in a laboratory setting;Identify common hazards found in the laboratory environment;Identify control methods that reduce chemical exposure;Recall general rules of lab safety;Know appropriate responses to various emergencies such as exposure, spills and fire;Identify proper handling, storage and disposal methods of hazardous chemicals

**Runtime:** 21

**Languages Available:**  
 Chinese (Simplified) (PS5-102908)  
 Spanish (Latin America) (PS5-102912)  
 Japanese (PS5-102909)  
 French (Canadian) (PS5-102907)  
 Portuguese (Brazil) (PS5-102910)  
 English

## Laboratory Specimens for Clinical Research

GCP25

This course will introduce you to regulations and guidelines that oversee the process of laboratory sample collection and shipping of human specimens for clinical research use in the United States. Topics in this course include: Clinical Laboratories, CLIA Certification, Site Responsibility and Documentation, Medical Waste Disposal, and Packaging and Transport of Specimens. After completing this course, learners will be able to identify the rules and regulations that apply to laboratory samples. In addition, learners will also be able to recognize how a sponsor utilizes the services of a central laboratory and how a principal investigator utilizes a local laboratory. Finally, learners will be able to identify the sponsor and investigator site responsibilities for collection of specimens, as well as specimen packaging for shipping.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the rules and regulations that apply to laboratory samples.;Recognize how a sponsor utilizes the services of a central laboratory and how a principal investigator utilizes a local laboratory.;Identify the sponsor and investigator site responsibilities for collection of specimens, as well as specimen packaging for shipping.

**Runtime:** 45

## Lockout/Tagout (LOTO)

PS5-101282

Would you stick your hand into a machine and hope no one turns it on? You can guarantee the machine stays off by locking and tagging it out. Failure to lock out machinery before servicing it is a major cause of injury and death. These deaths and injuries can be prevented by establishing and following an effective lockout/tagout program. Ideal learners are all employees.

**Format:** eLearning - Claro

**Libraries:**                      **Topic/Industry:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog
- General Safety and Manufacturing
- **Content Suite:**
  - Advanced Safety Orientation for General Industry (IACET CEU=0.9)
  - Advanced Safety Orientation for Managers and Supervisors in Construction (IACET CEU=2.7)

**Course Objectives:**

Explain the purpose of lockout/tagout;List the different forms of hazardous energy to which you may be exposed;Identify what activities are covered by lockout/tagout;Describe the three elements of an Energy Control Program;Recognize the types of lockout/tagout devices;Explain who is required to lock out or tag out;List the steps for attaching and removing locks and tags;Discuss periodic inspections of lockout/tagout;Understand the training requirements for lockout/tagout

**Runtime:** 32

**Languages Available:**

- Dutch (PS5-101708)
- Czech (PS5-101707)
- Chinese (Simplified) (PS5-102525)
- French (Canadian) (PS5-102330)
- French (European) (PS5-102527)
- German (PS5-101709)
- Hungarian (PS5-102363)
- Italian (PS5-102532)
- Japanese (PS5-102530)
- Korean (PS5-102529)
- Polish (PS5-101710)
- Portuguese (Brazil) (PS5-102531)
- Russian (PS5-102528)
- Spanish (Latin America) (PS5-102526)
- Thai (PS5-101711)
- English



## Lockout/Tagout (LOTO) Awareness

PS5-102281

Energy powers machines and industrial systems. Lockout/tagout procedures neutralize hazardous energy and prevent equipment startup during servicing, maintenance and installation activities. Take this course to learn how lockout/tagout helps ensure workplace safety. Ideal learners are personnel working where lockout/tagout occurs. Those who work under lockout protections also benefit from refresher information provided in this course.

**Languages Available:**  
English

**Format:** eLearning - Claro

- |   |   |
|---|---|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>  |
| <ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• Awareness</li> <li>• General Safety and Manufacturing</li> </ul> |

### Course Objectives:

Identify lockout/tagout responsibilities;Recognize different forms of hazardous energy;Recognize types of lockout/tagout devices;Recall best practices for attaching and removing locks and tags

**Runtime:** 10

## Making Meetings Work I: Purpose and Preparation

EHS60

This course explores ways to assess the effectiveness of meetings and skills to enhance the meeting process. Topics in this course include: Purpose, Meeting Costs, Key Steps, and Prepare. After completing this course, learners will be able to recognize how to lead meetings, accomplish goals, and follow up to ensure success.

**Format:** eLearning - EduFlex, eLearning - SCORM

- |   |   |
|---|---|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>  |
| <ul style="list-style-type: none"> <li>• HR Compliance &amp; Risk Management Library</li> <li>• HealthCare Catalog</li> <li>• Pharmaceutical Catalog</li> <li>• Medical Device Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• HR Compliance &amp; Risk Management</li> </ul> |

### Course Objectives:

Recognize how to lead meetings;Recognize how to accomplish goals;Recognize follow-up techniques to ensure success.

**Runtime:** 30



## Making Meetings Work II: Leadership

EHS61

The success of any meeting is largely determined by the leadership skills of the key participants. This course discusses the leadership skills necessary to conduct successful meetings. Topics in this course include: Start, Lead, Goals, Common Problems, Conflict, and Finish. After completing this course, learners will be able to recognize how to effectively set up, kickoff, conclude, and follow up a meeting. Learners should take Making Meetings Work I: Purpose and Preparation prior to taking this training.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- HR Compliance & Risk Management

**Course Objectives:**

Recognize how to effectively set up, kickoff, conclude, and follow up a meeting.

**Runtime:** 45

## Managing Conflict

EHS62

As workforce numbers shrink, and individuals are called to interact more intensely with fewer people, the ability to manage conflict effectively becomes more important. This course identifies appropriate responses to conflict. Topics in this course include: Conflict Resolution Styles, Selecting Styles, Collaboration Guidelines, and Application. After completing this course, learners will be able to successfully approach and resolve conflict in the workplace.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Professional Development

**Course Objectives:**

Recognize the five different styles used to handle conflict. Identify how to approach and resolve conflict successfully in the workplace.

**Runtime:** 45

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## Managing Job Stress

EHS63

Stress is a major factor in employee attendance, work performance, and Equal Employment Opportunity Commission (EEOC) claims. This course provides participants with an opportunity to assess their stress level at work and learn strategies for coping with that stress. Topics in this course include: Definition, Stressors, Positive Stress, Hassles, Outlook, and Visualization. After completing this course, learners will be able to identify their stress level at work. Learners will also be able to recognize strategies for coping with different problems in the workplace.

**Format:** eLearning - EduFlex, eLearning - SCORM

- Libraries:**                      **Topic/Industry:**
- HR Compliance & Risk Management Library
  - HealthCare Catalog
  - Pharmaceutical Catalog
  - Medical Device Catalog

**Course Objectives:**

Identify your stress level at work ; Recognize strategies for coping with different problems in the workplace.

**Runtime:** 30

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## Managing Transition to Teams

EHS64

This course will help team leaders and team members to understand the process of moving from a hierarchical structure and mindset to a more team-oriented approach. Topics in this course include: Differences, Model, Transition, Vision, Coaching, and Example. After completing this course, learners will be able to recognize how to transition successfully from a top-down management approach to one in which team members work together to achieve greater results than could be achieved individually.

**Format:** eLearning - EduFlex, eLearning - SCORM

- Libraries:**                      **Topic/Industry:**
- HR Compliance & Risk Management Library
  - HealthCare Catalog
  - Pharmaceutical Catalog
  - Medical Device Catalog

**Course Objectives:**

Recognize how to transition successfully from a top-down management approach to one in which team members work together to achieve greater results than could be achieved individually.

**Runtime:** 30



## Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code) and Similar State-Level Requirements

MDSM03

The Massachusetts Pharmaceutical and Medical Device;Manufacturer Conduct Regulation (Mass. Code) imposes a number of restrictions;on pharmaceutical and medical device manufacturing companies? (including;distributors?) interactions with healthcare practitioners. The Mass. Code is intended;to benefit patients, enhance the practice of medicine, and ensure that the;relationship between pharmaceutical or medical device manufacturers and;healthcare practitioners does not interfere with the independent judgment of;healthcare practitioners. This course;provides an introduction to the Mass. Code. Topics in this course include: Scope;;Data; Contracts, Audits, and Meals; Education, Conferences, and Meetings; Other;Payments, and Disclosure of Payments. After completing this course, learners;will be able to recognize the;provisions of the Mass. Code, 105 CMR 970.000, how to comply with new;restrictions, and what some of the critical differences are between the Mass.;Code and the AdvaMed and PhRMA Codes of Ethics.

**Format:** eLearning - EduFlex, eLearning - SCORM

- Libraries:**                      **Topic/Industry:**
- Medical Device - Sales & Marketing Library
  - Medical Device Catalog
  - Corporate Compliance

### Course Objectives:

Recognize the provisions of the Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Regulation (Mass. Code), 105 CMR 970.000.;Recognize how to comply with the new restrictions and what some of the critical differences are between the Mass. Code and the AdvaMed and PhRMA Codes of Ethics.

**Runtime:** 45

## MDR Regulation 1: Overview and General Provisions

FDA63

FDA Investigators, compliance officers, medical device manufacturers, user facilities, and importers need to be aware of the Medical Device Reporting (MDR) regulation and its provisions. This course describes the key characteristics of the MDR regulation and its preamble as well as the key terms used in the MDR regulation. Topics in this course include: Origin, Device and Modernization Amendments, Characteristics, , and Application. After completing this course, learners will be able to identify the key characteristics of the MDR regulation and its preamble as well as the key terms used in the MDR regulation. Also, you will be able recognize to whom the MDR regulation applies and who is exempt from the regulation.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

- Libraries:**                      **Topic/Industry:**
- FDA Inspections and Enforcement Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
  - QA/GMP Trainer

### Course Objectives:

Identify the key characteristics of the MDR regulation and its preamble as well as the key terms used in the MDR regulation. ;Recognize to whom the MDR regulation applies and who is exempt from the regulation.

**Runtime:** 60

## MDR Regulation 2: Device User Facility, Importer, and Manufacturer Reporting Requirements

FDA65

Medical device manufacturers, user facilities, and importers need to identify and monitor significant adverse events involving medical devices. This course describes important terms crucial to understanding the Medical Device Reporting (MDR) regulation and its requirements as they relate to user facilities, importers, and manufacturers. Topics in this course include: User Facilities, Importers, Manufacturers, and Event Files. After completing this course, learners will be able to identify the requirements for electronic MDR submission, MDR procedures, and event files.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize important terms crucial to the device user facility requirements of the MDR regulation. ;Identify the MDR requirements as they relate to user facilities, importers, and manufacturers. ;Identify the requirements for MDR procedures and event files.

**Runtime:** 60

## MDR Regulation 3: Requirements for Individual Adverse Event Reports

FDA66

FDA investigators, compliance officers, medical device manufacturers, user facilities and importers need to know how to document and submit adverse event reports in a timely fashion. This course identifies the proper forms and timelines for reporting adverse events. Topics in this course include: Reporting, MEDWATCH, Deadlines, Codes, and Exceptions. After completing this course, learners will be able to recognize the proper forms and timeframes necessary for adverse event reporting and identify when it is not necessary to file a report.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify how user facilities, importers, and manufacturers report adverse events. ;Recognize the proper forms to use to report adverse events, as well as the timeframes for reporting. ;Identify when it is not necessary to report an event.

**Runtime:** 60

## MDSAP Chapter 1 ? Process: Management

MDSAP01

This course covers MDSAP Chapter 4, including linkages, considerations, and best practices for each task within that chapter. Topics in this course include: Purpose, Task 1, and Task 2.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 45

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## MDSAP Chapter 3 - Process: Measurement, Analysis, and Improvement

MDSAP03

This course covers the first 15 tasks of Chapter 6 of the Medical Device Single Audit Program (MDSAP) - Production and Service Controls.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 45

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## MDSAP Chapter 6: Process - Production and Service Controls ? Part 1

MDSAP06\_01

This course covers the practical application of risk management principles, published in “Guidance for Industry: Q9 Quality Risk Management”, through case studies applied to process design and manufacturing. Topics in this course include: Risk Assessment, Risk Control, Review and Communication, Validation Case Study, and Change Control Case Study. After completing this course, learners will be able to recognize risk management principles for the pharmaceutical industry and the tools that can be used to reduce patient risk and ensure quality throughout a product’s lifecycle.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

**Topic/Industry:**

- Pharmaceutical Catalog
- Pharmaceutical GMPs Library
- Medical Device Catalog
- MDSAP Library

- Pharmaceutical

**Course Objectives:**

Recognize FDA’s guidance on risk management and the potential uses and benefits for our industry as a whole.

**Runtime:** 45

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## MDSAP Chapter 6: Process - Production and Service Controls ? Part 2

MDSAP05

Chapter 7 in the Medical Device Single Audit Program (MDSAP) verifies that the manufacturer’s processes ensure that products (e.g., components, materials and services provided by suppliers, including contractors and consultants) are in conformance with specified purchase requirements, including QMS requirements.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 45

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## MDSAP Chapter 6: Process - Production and Service Controls ? Part 2

MDSAP06\_02

Any failure of a batch or its components to meet any of its specifications must be thoroughly investigated, whether or not the batch has already been distributed. This course describes the process of evaluating and using corrective and preventative actions (CAPA) systems and tools that align with an organization's methods and processes, so the Quality Assurance (QA) team can successfully determine which actions must be made to prevent future issues. Topics in this course include: CAPA Programs, Data Monitoring and Review, Analysis, and CAPA Software Tools. After completing this course, learners will be able to recognize the steps involved in the CAPA program. PHA40 Corrective and Preventive Actions is a prerequisite to this course and must be completed before taking this course.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Pharmaceutical GMPs Library
- Medical Device Catalog
- MDSAP Library
- QA/GMP Trainer

**Course Objectives:**

Recognize the tools available that can help achieve an effective corrective and preventive actions (CAPA) process.

**Runtime:** 45

## Media Fills for Aseptic Processing Library

Aseptic06

Media fills allow manufacturers to evaluate if their aseptic processes are capable of reliably producing sterile products that are free from contamination and are safe and effective for patients. This course describes the process of designing and executing media fills. Topics in this course include: Purpose and Design, Study Considerations, Execution, and Monitoring and Results. After completing this course, learners will be able to recognize the purpose of a media fill. Learners will also be able to identify the elements to consider while designing a media fill.

**Languages Available:**

French (European)  
German  
Spanish (Spain)

**Format:** eLearning (Editable) - CREATE, eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Aseptic Processing Library

**Course Objectives:**

Recognize the purpose of a media fill.;Identify the elements to consider while designing a media fill.;Recognize what occurs after the execution of a media fill.

**Runtime:** 25

## Medical Device Filings: 510(k), PMA, and IDE

DEV53

This course describes the premarket approval and notification processes for medical devices in the US. Topics in this course include: FDA Authority, Classification, Premarket Notification, Premarket Approval, IDE, and Compliance. After completing this course, learners will be able to identify the essential elements of the 510(k), premarket approval (PMA), and Investigational Device Exemption (IDE) filing processes for medical devices under FDA.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify the essential elements of the 510(k), premarket approval (PMA), and Investigational Device Exemption (IDE) filing processes for medical devices under FDA.

**Runtime:** 45

## Medical Device Packaging, Labeling, and Distribution

DEV41

Mistakes or mix-ups in the critical areas of product packaging, labeling, and distribution can pose a danger to the consumer. This course provides you with information on current packaging and labeling requirements specified by the Quality System Regulation. A basic understanding of quality system regulations for medical device and equipment manufacturers (21 CFR 820), quality control procedures, and quality principles are prerequisites for this course. Topics in this course include: Importance of Labeling, Packaging, Label Control, and Distribution. After completing this course, learners will be able to recognize the requirements for packaging, labeling, and distribution of medical devices 21 CFR 820.120-160.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize the requirements for the packaging, labeling, and distribution of medical devices.

**Runtime:** 60

## Medical Device Safety Reporting

GCP19

This course explores the process by which US and European regulatory agencies ensure the safety of medical devices used in medical facilities and homes every day by following up on adverse events. Topics in this course include: Adverse Events, Premarket Reporting, Marketed Devices, and Reports. After completing this course, learners will be able to identify the regulatory requirements in the medical device clinical trial and postmarketing environments as well as recognize device safety monitoring and reporting efforts in the US and Europe.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the regulatory requirements in the medical device clinical trial and postmarketing environments.;Recognize device safety monitoring and reporting efforts in the US and Europe.

**Runtime:** 60

## Meeting GMP Training Requirements

PHDV76

In order to produce products that are pure, safe, effective, and in compliance with FDA regulations, it is necessary to understand the nature of GMP Training Requirements. GMP regulations are very clear as to what training is required. This interactive program introduces you to these training requirements and asks you to apply them to actual FDA-regulated industry situations. Upon completion of this course, you will be able to discuss the requirements and different types of training specified in GMPs. You will also be able to discuss several varied approaches to training and understand the advantages and disadvantages of each. Finally, you will understand the more technical aspects of training, why each is important to GMP compliance, and identify examples of achieving training compliance.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library

**Course Objectives:**

Identify cGMP training requirements as well as other important cGMP training issues, such as types of training, approaches to training, trainer qualifications, training verification, and communication.

**Runtime:** 30

## National Patient Safety Goals: HCIR Credentialing

MDSM07

This course focuses on best practices and safety goals for healthcare industry representatives (HCIRs). Topics in this course include: Definition, HCIR Program, What to Know, and Policies and Procedures. After completing this course, learners will be able to recognize the role and value of standardized credentialing training for HCIRs and the five substantive training areas recommended for HCIRs. Learners will also be able to recognize how this training advances the goals of safety, quality of care, confidentiality, and compliance with applicable regulatory guidelines.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Medical Device - Sales & Marketing Library
- Medical Device Catalog

**Course Objectives:**

Recognize standardized credentialing training for HCIRs. ;Recognize the five substantive training areas recommended for HCIRs. ;Recognize how this training advances the goals of safety, quality of care, confidentiality, and compliance with applicable regulatory guidelines.

**Runtime:** 30

## Obligations of Investigators in Conducting Medical Device Trials

GCP03

This course addresses the requirements for conducting clinical trials for investigational premarket medical devices. It provides an overview of the clinical investigator's general and specific obligations to protect human subjects while providing valid data that sponsors may submit to regulatory authorities for approval. This course also introduces documentation and reporting requirements, the inspection process, and the consequences for failure to comply with good clinical practice. It concludes with suggestions for improving compliance.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the requirements for conducting medical device research including following a protocol, safety and reporting standards, and documentation requirements. ;Identify recommended procedures to follow during a regulatory authority inspection. ;Recognize the consequences of noncompliance.

**Runtime:** 90

## Office Safety

EHS65

Hidden dangers lurk in every corner of a workplace. With potential hazards ranging from fire to personal injury, knowing how to identify hazards and avoid accidents can keep everyone safe in the office. This course identifies common hazards that may be present in your office and how to avoid such hazards. Topics in this course include: Emergency Action Plan, Hazard Identification, Safe Work Practices, Office Equipment, Walking Surfaces, Good Housekeeping, and Workplace Violence. After completing this course, learners will be able to describe an action plan, identify potential hazards in the workplace, and recognize methods of hazard avoidance.

**Languages Available:**  
Spanish (Latin America)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Corporate Compliance
- HR Compliance & Risk Management
- EHS Manager

**Course Objectives:**

Recognize safe work practices that will help you identify and remove hazards that can lead to accidents. ;Recognize how to interpret and follow written emergency action plans. ;Identify the different types of hazards and recognize how to use office equipment safely. ;Recognize how to behave safely on slippery walking surfaces and how to use proper lifting techniques. ;Recognize and prevent violence in the workplace.

**Runtime:** 60

## Office Safety

Although accidents involving office personnel generally occur less frequently than mishaps to industrial workers, they do still occur and can result in serious injuries and even death. Office safety is the responsibility of everyone. You must understand what you can do to stay safe on the job, and you need to be aware of how to correct unsafe conditions. This course provides the information you need to work safer in your office environment. Ideal learners include office workers.

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- General Safety and Manufacturing

**Content Suite:**

- Working from Home Suite

**Course Objectives:**

Common office hazards;Emergency response plan;Prevention techniques;Injury reporting process;Workplace security

**Runtime:** 27

**PS5-00290****Languages Available:**

- Dutch (PS5-101434)
- Czech (PS5-101435)
- Chinese (Simplified) (PS5-101588)
- French (Canadian) (PS5-100566)
- German (PS5-101436)
- Polish (PS5-101438)
- Portuguese (Brazil) (PS5-101439)
- Spanish (Latin America)
- Thai (PS5-101440)
- English

## OIG Compliance Program Guidance for Medical Device Manufacturers -- Field Force

**OIG03**

This course identifies practices that present a potential risk of liability for medical device manufacturers under the three major risk areas identified in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Topics in this course include: Risk Areas, Problematic Areas, Consulting Agreements, Truthful and Non-Misleading Product Promotion, and Discounting Arrangements. After completing this course, learners will be able to identify risk areas in medical device promotion as well as OIG Guidance for navigating these risks successfully.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**

- Medical Device - Sales & Marketing Library
- Medical Device Catalog

**Topic/Industry:**

- Corporate Compliance

**Course Objectives:**

Recognize the portions of the OIG Guidance that relate to the activities of sales representatives. ;Identify OIG risk areas and permissible and impermissible benefits under the federal Anti-Kickback Statute. ;Recognize the guidelines for discounts to customers, grants and charitable contributions, consulting arrangements, product support services, off-label marketing, and discounting arrangements. ;Recognize what types of activities are \_ and are not \_ permitted under these laws and our company policies.

**Runtime:** 45



## Orientation to GMP Compliance

PHDV73

Because FDA GMP regulations have a direct impact on how you do your job, you need insight on how they are applied and interpreted. This course illustrates how the Food, Drug, and Cosmetic Act is tied to Title 21 of the Code of Federal Regulations and how Good Manufacturing Practices (GMPs) are key elements in those regulations. Topics include key definitions, GMP focus areas, interpretation of GMPs, and enforcement actions. After completing this course, you will be able to recognize GMP regulations, basic GMP requirements, your roles and responsibilities for compliance, and the ways FDA enforces GMP regulations.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device
- Pharmaceutical

**Course Objectives:**

Recognize regulations and their importance to your industry. Identify basic GMP requirements and your roles and responsibilities for compliance. Recognize how FDA enforces GMP regulations.

**Runtime:** 45

## Overcoming Negativity in the Workplace

EHS95

This course is designed to help learners manage and solve interpersonal conflicts at work or away from work. Topics in this course include: Viewpoints and Approaches, Evaluation, Changing Thoughts, Listening, and Application. After completing this course, learners will be able to identify the approaches and skills required to solve problems. Learners will also be able to recognize how to overcome negativity in the workplace.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- HR Compliance & Risk Management
- Corporate Compliance

**Course Objectives:**

Identify the approaches and skills required to solve problems. Recognize how to overcome negativity in the workplace.

**Runtime:** 30

## Overhead and Gantry Crane Safety

PS5-00953

Anyone who works with cranes knows not to underestimate the daily risk of collapse, electrical accidents, falls and other serious incidents. The power that makes overhead, gantry and similar cranes so useful also makes them dangerous. By properly maintaining and operating the cranes with which you work, you can protect yourself and your co-workers. Ideal learners are crane operators and their supervisors.

**Format:** eLearning - Claro

<b>Libraries:</b>	<b>Topic/Industry:</b>	<b>Languages Available:</b> Dutch (PS5-101638) Czech (PS5-101637) German (PS5-101639) Japanese (PS5-101640) Polish (PS5-101641) Spanish (Latin America) (PS5-102253) Thai (PS5-101642) English
<ul style="list-style-type: none"><li>• Safety Catalog</li><li>• EHS for Life Science - Basics Library</li><li>• Medical Device Catalog</li><li>• Pharmaceutical Catalog</li></ul>	<ul style="list-style-type: none"><li>• General Safety and Manufacturing</li></ul> <b>Content Suite:</b> <ul style="list-style-type: none"><li>• Crane Safety and Basic Rigging Training Suite (IACET CEU=0.3)</li></ul>	

### Course Objectives:

Identify the crane components you need to formally inspect and the frequency at which you need to inspect them; Recall safe crane operating procedures; Recognize safe and unsafe crane components and working conditions

**Runtime:** 25

## Overview of FDA's Bioresearch Monitoring Program

BIMO01

This is the first in a series of courses that provide an overview of FDA's Bioresearch Monitoring (BIMO) program and the methods and techniques used in conducting and reporting Nonclinical Laboratory, Clinical, Investigator, Institutional Review Board (IRB), Sponsor/Monitor, and in vivo; Bioequivalence inspections. This course provides an overview and historical perspective of FDA's BIMO program. Topics in this course include: Purpose and History, BIMO Terminology, Research and Marketing Permits, Regulatory Expectation, and Implementation. After completing this course, learners will be able to recognize the historical perspective and regulatory basis of the BIMO program. Learners will also be able to identify the definitions of common BIMO terms and recognize how FDA implements the BIMO program.

**Format:** eLearning - EduFlex, eLearning - SCORM

<b>Libraries:</b>	<b>Topic/Industry:</b>
<ul style="list-style-type: none"><li>• Clinical: Medical Device Library</li><li>• Clinical: Pharmaceutical Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• FDA BIMO Course Library</li></ul>	<ul style="list-style-type: none"><li>• Clinical Quality Manager</li></ul>

### Course Objectives:

Recognize the historical perspective and regulatory basis of the BIMO program.; Identify the definitions of common BIMO terms and recognize how FDA implements the BIMO program.

**Runtime:** 60

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## Overview of the Clinical Research Process

GCP11

Clinical research is the testing of experimental drugs, biologics, and medical devices in humans. This course describes the clinical research process for those who are involved in any aspect of the development, research, marketing, or sales of new drugs, biologics, and devices. Topics in this course include: Regulations, GCP, Documents, Phases, Timelines and Costs, and Final Stages. After completing this course, learners will be able to recognize the nonclinical and clinical components of new product development.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical
- Medical Device
- Medical Device

**Course Objectives:**

Identify what is entailed in the research process for new drug, biologic, and device products, including the documents submitted in order to gain marketing approval. Recognize the nonclinical and clinical components of new product development. Identify the importance of the US Code of Federal Regulations (CFR), European Union (EU) Directives/Regulations, and the International Conference on Harmonisation (ICH) guidelines and ways good clinical practices (GCPs) are reflected in each of these documents.

**Runtime:** 45

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## Overview of the Medical Device Single Audit Program (MDSAP) Chapter Structure

MDSAP00

Chapter 3 in the Medical Device Single Audit Program (MDSAP) verifies that the manufacturer's processes ensure that information related to products, processes, or the QMS is collected and analyzed to identify actual and potential product, process, or quality system nonconformities. This course covers Chapter 3 of the MDSAP.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 45

## Part 11: Electronic Records and Signatures -- Application

FDA61

This course introduces developers and those individuals involved in validation of analytical methods to the regulatory requirements for the validation of analytical laboratory procedures. Topics in this course include: Validation Characteristics, Specificity, Linearity and Range, Accuracy and Precision, Detection/Quantitation, Robustness, and Revalidation. After completing this course, learners will be able to identify applicable regulatory requirements and recognize the important aspects of analytical methods validation, including the data that must be generated.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Global Regulatory Library
- QA/GMP Trainer

**Course Objectives:**

Identify applicable regulatory requirements.;Recognize the important aspects of analytical methods validation, including the data that must be generated.

**Runtime:** 45

**Languages Available:**

Chinese (Simplified)  
French (European)  
Japanese  
Korean

## Part 11: Electronic Records; Electronic Signatures

FDA31

This course provides an overview of Postmarketing Adverse Drug Experience (PADE) regulations, guidance, inspectional candidate selection, inspectional techniques, and regulatory actions to enhance the field investigator's knowledge. Topics in this course include: Reporting, FAERS, Types of ADE Reports, ADE Team, Inspecting, and Compliance. After completing this course, learners will be able to recognize how to perform the inspectional activities necessary to monitor industry's surveillance, receipt, evaluation, and submission of adverse drug experience information to FDA.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the role of the Postmarketing Adverse Drug Experience Reporting Compliance Program in monitoring and enforcing the drug safety reporting regulations.;Recognize when the pharmaceutical industry is complying with its adverse drug experience reporting responsibilities. ;Recognize how to perform the inspectional activities necessary to monitor industry's surveillance, receipt, evaluation, and submission of adverse drug experience information to FDA. ;Identify the regulations and guidance documents that are the foundation of the inspectional program.

**Runtime:** 60

**Languages Available:**

Chinese (Simplified)  
French (European)  
Japanese  
Korean

## Personal Leadership Power

EHS66

This course presents information about the definition of leadership, how to increase your PLP, and how to apply PLP to increase the productivity of your company. Topics in this course include: Leaders, Key Traits, Barriers, Personal Leadership Power (PLP), Five Principles, Developing Your PLP, and Workplace PLP. After completing this course, learners should be able to identify and apply the five principles involved in increasing and effectively using PLP for themselves and for their organizations.

**Format:** eLearning - SCORM, eLearning - EduFlex

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|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Ethics &amp; Corporate Responsibility Library</li> <li>• HR Compliance &amp; Risk Management Library</li> <li>• HealthCare Catalog</li> <li>• Pharmaceutical Catalog</li> <li>• Medical Device Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• Professional Development</li> </ul> |

**Course Objectives:**

Identify and apply the five principles involved in increasing and effectively using PLP for yourself and for your organization.

**Runtime:** 45

## Personal Protective Equipment (PPE) Overview

PS5-00286

Workplaces can be very dangerous and unpredictable places with loud noises, falling objects, flying sparks, toxic chemicals, whirling blades and belts, you name it. So what is one way to keep yourself safe? By wearing personal protective equipment, commonly known as PPE, you can protect yourself against hazards and reduce your chances of getting hurt or even killed.

**Format:** eLearning - Claro

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• General Safety and Manufacturing</li> </ul>                                 |
|   | <b>Content Suite:</b>  |
|   | <ul style="list-style-type: none"> <li>• Advanced Safety Orientation for General Industry (IACET CEU=0.9)</li> </ul> |

**Languages Available:**  
 Chinese (Simplified) (PS5-102500)  
 French (Canadian) (PS5-102660)  
 French (European) (PS5-102502)  
 German (PS5-102504)  
 Italian (PS5-102507)  
 Japanese (PS5-102506)  
 Korean (PS5-102505)  
 Portuguese (Brazil) (PS5-102508)  
 Russian (PS5-102503)  
 Spanish (Latin America) (PS5-102501)  
 English

**Course Objectives:**

Identify different types of PPE; Select the appropriate PPE for the hazards present; Recognize the principles of proper PPE use, care and maintenance

**Runtime:** 32

## Pharmaceutical and Medical Device Supplier Quality Management

PHDV85

A growing list of unsafe, counterfeit, contaminated, and defective products has emphasized the need for increased supplier quality management. This course discusses the regulations and standards for supply chain integrity. Topics in this course include: Origin, New Regulations, ICH Q10, Supplier Quality Agreements, and FDA vs EMA. After completing this course, learners will be able to recognize regulations and guidances, identify critical supplier quality agreements and audits, and recognize the differences between U.S. FDA and EMA approaches to supplier quality.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library

**Course Objectives:**

Identify regulator concerns about supply chain quality;Recognize new regulations and guidances coming into effect.;Identify critical supplier quality agreements and audits.;Recognize the differences between U.S. FDA and EMA approaches to supplier quality.

**Runtime:** 30

## Pharmaceutical Risk Management: Picking the Right CAPA Tools

PHA73

Any failure of a batch or its components to meet any of its specifications must be thoroughly investigated, whether or not the batch has already been distributed. This course describes the process of evaluating and using corrective and preventative actions (CAPA) systems and tools that align with an organization's methods and processes, so the Quality Assurance (QA) team can successfully determine which actions must be made to prevent future issues. Topics in this course include: CAPA Programs, Data Monitoring and Review, Analysis, and CAPA Software Tools. After completing this course, learners will be able to recognize the steps involved in the CAPA program. PHA70 Corrective and Preventive Actions is a prerequisite to this course and must be completed before taking this course.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Global Regulatory Library
- Medical Device Catalog

**Course Objectives:**

Recognize the tools available that can help achieve an effective corrective and preventive actions (CAPA) process.

**Runtime:** 30

## Physical and Network Security

ETHICS21

Information security is critical for any business. This course identifies the types of assets that are at risk, outlines methods to protect them, and examines how every employee can develop a security mindset. Topics in this course include: The Security Mindset, Physical Security, Virtual Data Security, Use of the Internet, and Proprietary Information. After completing this course, learners will be able to recognize security risks to physical and virtual assets, identify their responsibilities for protecting all of these resources, and recognize requirements and guidelines for maintaining physical and network security.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Recognize security risks to our company's physical and virtual assets.;Identify your responsibilities for protecting all of these resources.;;Recognize requirements and guidelines for maintaining physical and network security.

**Runtime:** 45

## Physician Payment Sunshine Act

PHSM11

After completing this course, you will be able to recognize the meaning and purpose of the Physician Payment Sunshine Act. You will also be able to recognize key terms and phrases, such as, "applicable manufacturers," "covered drug, device, biological, or medical supply," "covered recipient," and "payments or other transfers of value." Lastly, you will be able to identify what needs to be reported, when it will be reported, how it will be reported, and the penalties for any failure to properly report.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |   |   |
|---|---|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>  |
| <ul style="list-style-type: none"><li>• Medical Device - Sales &amp; Marketing Library</li><li>• Pharmaceutical - Sales &amp; Marketing Library</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Pharmaceutical</li><li>• Medical Device</li></ul> |

### Course Objectives:

Recognize the meaning and purpose of the Physician Payment Sunshine Act. Recognize the definition of key terms and phrases, such as, "applicable manufacturers," "covered drug, device, biological, or medical supply," "covered recipient," and "payments or other transfers of value." Identify what needs to be reported, when it will be reported, how it will be reported, and the penalties for any failure to properly report.

## Powered Industrial Trucks Module 1 - Introduction to Powered Industrial Trucks

PS5-00607

Powered industrial trucks like forklifts, motorized pallet jacks, tuggers, tow motors and other powered equipment are used every day to lift and move equipment or materials. Every year, powered industrial trucks are involved in tens of thousands of accidents and injuries, some of which are fatal. If you are going to operate a powered industrial truck, you need to be trained and tested to make sure you know how to do it safely. Module 1 is an introduction to powered industrial trucks and their safe operation. Ideal learners are employees who operate powered industrial trucks.

**Format:** eLearning - Claro

<b>Libraries:</b>	<b>Topic/Industry:</b>
<ul style="list-style-type: none"><li>• Safety Catalog</li><li>• EHS for Life Science - Basics Library</li><li>• Medical Device Catalog</li><li>• Pharmaceutical Catalog</li></ul>	<ul style="list-style-type: none"><li>• General Safety and Manufacturing</li></ul>
	<b>Content Suite:</b>
	<ul style="list-style-type: none"><li>• Powered Industrial Trucks (PIT), Modules 1-3</li></ul>

**Languages Available:**  
Dutch (PS5-101680)  
Czech (PS5-101679)  
Chinese (Simplified) (PS5-101678)  
French (Canadian) (PS5-102734)  
German (PS5-101681)  
Japanese (PS5-101682)  
Polish (PS5-101683)  
Portuguese (Brazil) (PS5-101684)  
Spanish (Latin America) (PS5-01163)  
Thai (PS5-101685)  
English

### Course Objectives:

Define what a powered industrial truck is;Recognize classes and types of powered industrial trucks;Explain the importance of using data plates and markings to find capacity information;Identify operator safety responsibilities;Recall general safety rules about pre-operation safety, traveling and stopping

**Runtime:** 19

## Powered Industrial Trucks Module 2 - Pre-Operation Inspection and Maintenance

PS5-00771

Powered industrial trucks like forklifts, motorized pallet jacks, tuggers, tow motors and other powered equipment are used every day to lift and move equipment or materials. According to the U.S. Bureau of Labor Statistics, every year powered industrial trucks are involved in approximately 68,400 accidents, 34,000 injuries and 85 fatalities. Because of this high risk of injury and even death while operating a powered industrial truck, OSHA regulates their operation. This course covers OSHA-required information that needs to be communicated to operators during the classroom portion of their training. Module 2 covers pre-use inspections, maintenance and refueling/recharging.

**Format:** eLearning - Claro

<b>Libraries:</b>	<b>Topic/Industry:</b>
<ul style="list-style-type: none"><li>• Safety Catalog</li><li>• EHS for Life Science - Basics Library</li><li>• Medical Device Catalog</li><li>• Pharmaceutical Catalog</li></ul>	<ul style="list-style-type: none"><li>• General Safety and Manufacturing</li></ul>
	<b>Content Suite:</b>
	<ul style="list-style-type: none"><li>• Powered Industrial Trucks (PIT), Modules 1-3</li></ul>

**Languages Available:**  
Dutch (PS5-101756)  
Czech (PS5-101755)  
Chinese (Simplified) (PS5-101754)  
French (Canadian) (PS5-102719)  
German (PS5-101757)  
Japanese (PS5-101758)  
Polish (PS5-101759)  
Portuguese (Brazil) (PS5-101760)  
Spanish (Latin America) (PS5-102383)  
Thai (PS5-101761)  
English

### Course Objectives:

Identify the four key inspection points;Describe how to perform pre-use inspections;Recall safety procedures to take when refueling, changing and charging batteries

**Runtime:** 20





## Powered Industrial Trucks Module 3 - Stability and Handling Loads

PS5-00772

Powered industrial trucks like forklifts, motorized pallet jacks, tuggers, tow motors and other powered equipment are used every day to lift and move equipment or materials. Every year, powered industrial trucks are involved in tens of thousands of accidents and injuries, some of which are fatal. If you are going to operate a powered industrial truck, you need to be trained and tested to make sure you know how to do it safely. Module 3 covers stability and handling loads.

**Format:** eLearning - Claro

<b>Libraries:</b>	<b>Topic/Industry:</b>	<b>Languages Available:</b> Dutch (PS5-101672) Czech (PS5-101671) Chinese (Simplified) (PS5-101670) French (Canadian) (PS5-102704) German (PS5-101673) Japanese (PS5-101674) Polish (PS5-101675) Portuguese (Brazil) (PS5-101676) Spanish (Latin America) (PS5-01165) Thai (PS5-101677) English
<ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul>	<ul style="list-style-type: none"> <li>• General Safety and Manufacturing</li> </ul>	
	<b>Content Suite:</b>	
	<ul style="list-style-type: none"> <li>• Powered Industrial Trucks (PIT), Modules 1-3</li> </ul>	

### Course Objectives:

Describe how powered industrial trucks' engineering affects their stability; Recall how to pick up, handle and place loads

**Runtime:** 17

## Preventing Sexual Harassment

ETHICS18

You have a responsibility to yourself and your co-workers to take action when faced with sexual harassment in the workplace. This course describes workplace policies that ensure a harassment-free workplace. Topics in this course include: Definitions, Gray Areas, Taking Action, and Consequences. After completing this course, learners will be able to identify appropriate and inappropriate behavior as defined by the law and company policy.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

<b>Libraries:</b>	<b>Topic/Industry:</b>
<ul style="list-style-type: none"> <li>• Ethics &amp; Corporate Responsibility Library</li> <li>• HealthCare Catalog</li> <li>• Pharmaceutical Catalog</li> <li>• Medical Device Catalog</li> </ul>	<ul style="list-style-type: none"> <li>• Corporate Compliance</li> </ul>

### Course Objectives:

Identify appropriate and inappropriate behavior as defined by the law and company policy. ;Recognize how to respond effectively when faced with sexual harassment. ;Recognize what to do if you feel you have been harassed.;Recognize how to respond in situations where you are not the primary target of sexual harassment.

**Runtime:** 30

## Principles of Auditing

PHDV69

This course focuses on the purpose and conduct of internal and external quality audits. Topics in this course include: Scope, Types of Audits, Benefits, Preparation, Performing Audits, and Audit Closeout. After completing this course, learners will be able to recognize the importance of an effective audit program, the benefits that can result, actual conduct of an audit, and how proper corrective action and follow-up yield the ultimate benefits of the program.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

- |   |   |
|---|---|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>  |
| <ul style="list-style-type: none"><li>• Medical Device GMPs Library</li><li>• Pharmaceutical GMPs Library</li><li>• Medical Device Catalog</li><li>• Pharmaceutical Catalog</li></ul> | <ul style="list-style-type: none"><li>• Medical Device</li><li>• Pharmaceutical</li></ul> |

### Course Objectives:

Identify the definition of an audit and the benefits audits provide. Recognize how to develop an audit team and what the team should address during an audit. Identify how to properly respond to observations listed in an audit.

**Runtime:** 45

## Principles of Restricted Access Barrier Systems and Isolators

Aseptic03

This course introduces the basic principles of two specific types of improved Aseptic Processing Library: Restricted Access Barrier Systems (RABSs) and isolators. Topics in this course include: RABS, Isolators, and Key Elements. After completing this course, learners will be able to recognize the basic attributes and functions of RABS and isolators, identify regulatory requirements for these systems, and recognize key elements of each type of system.

**Languages Available:**  
French (European)  
German  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning (Editable) - CREATE, eLearning - SCORM

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li><li>• Aseptic Processing Library</li></ul> | <ul style="list-style-type: none"><li>• CoursePartners</li></ul> |

### Course Objectives:

Recognize the basic attributes and functions of RABS and isolators.; Identify regulatory requirements for these systems.; Recognize key elements of each type of system.

**Runtime:** 30

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## Principles of Sterilization

PHDV81

The success of sterilization can directly impact the quality and safety of products used by consumers. This course discusses the purpose of sterilization and basic principles of several commonly used sterilization techniques. Topics in this course include: Sterilization, Moist Heat, Dry Heat, Gas, Radiation, Chemical, Filtration, and Sterility Assurance. After completing this course the learner will be able to identify six types of sterilization, recognize methods for validating sterilization, and identify the key aspects of sterility assurance.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Course Objectives:**

Recognize the definition of sterilization and identify the most common sterilization methods. Recognize the general approaches for validating and monitoring sterilization processes. Identify the key aspects of sterility assurance.

**Runtime:** 60

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## Process: Device Marketing Authorization & Facil Reg

MDSAP02

This course covers Chapter 5 of the Medical Device Single Audit Program (MDSAP) - Process: Design and Development.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 45

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## Process: Medical Device Adverse Events & Advisory Notices

MDSAP04

This course covers Tasks 16-29 of Chapter 6 of the Medical Device Single Audit Program (MDSAP) - Production and Service Controls.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 45

## Protection of Human Subjects in Clinical Trials

PHA46

Protection of human subjects is the foremost and most important duty of investigators conducting clinical trials. This course will provide you with a working knowledge of informed consent regulations, Institutional Review Board/Independent Ethics Committee responsibilities, and the obligations of the individuals responsible for protecting patient rights and welfare. Topics in this course include: Consent Form, Consent Process, Consent Exceptions, IRB/IEC, and IRB/IEC Responsibilities. After completing this course, learners will be able to identify the measures that are in place to protect the rights and welfare of subjects in clinical studies. Learners will also be able to recognize informed consent requirements and regulations, the responsibilities of an IRB/IEC, and the obligations of individuals responsible for working according to GCP.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the measures that are in place to protect the rights and welfare of subjects in clinical studies.;Recognize informed consent requirements and regulations, the responsibilities of an IRB/IEC, and the obligations of individuals responsible for working according to GCP.

**Runtime:** 60

## QS Regulation 1: Overview and General Provisions

QSR01

This course introduces the Quality System (QS) Regulation (21 CFR Part 820) — a framework of basic requirements for manufacturers of finished medical devices. The course covers the history of the regulation, as well as its requirements, scope, and key terms. The course also discusses the manufacturer's responsibility for a quality system under this regulation. Topics in this course include: Origin, QS Regulation, Terms, Scope, and Responsibility. After completing this course, learners will be able to recognize the origin and scope of the QS Regulation. You will also be able to identify the purpose of the Preamble and general requirements of a quality system. Finally, you will be able to recognize key definitions.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize the origin and scope of the QS Regulation. Identify the purpose of the Preamble and general requirements of a quality system. Recognize key definitions.

**Runtime:** 45

## QS Regulation 10: Servicing; Statistical Techniques

QSR10

The Quality System (QS) regulation sets forth certain responsibilities for manufacturers relative to the servicing and statistical techniques requirements of the QS Regulation. This course is the tenth in a series of Quality System (QS) Regulation courses and focuses on Servicing (21 CFR Part 820 Subpart N) and Statistical Techniques (21 CFR Part 820 Subpart O). Topics in this course include: Key Terms, Analysis, Statistical Techniques, Preamble, and FDA Resources. After completing this course, learners will be able to recognize requirements for identifying valid statistical techniques.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize a manufacturer's responsibilities relative to the servicing and statistical techniques requirements of the QS Regulation.

**Runtime:** 30

## QS Regulation 11: Application and Inspection of QS Regulation Requirements

QSR11

The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. This course is the eleventh and final course in a series of Quality System (QS) Regulation courses. Topics in this course include: Key Terms, Seven Subsystems, Subsystems and QSIT, and Learn More. After completing this course, learners will be able to recognize the application and inspection of Quality System Regulation requirements within a medical device manufacturer's quality system.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize the application and interrelationship of QS Regulation requirements within a medical device manufacturer's quality system. Identify the basic concepts of the Quality System Inspection Technique (QSIT), which is the inspection process currently used by the FDA to conduct Level 2 Baseline (Comprehensive) quality system inspections.

**Runtime:** 30

## QS Regulation 2: Quality System Requirements

QSR02

The second in a series of Quality System (QS) Regulation courses, this course focuses on the management responsibility, quality auditing, and personnel requirements of 21 CFR Part 820, Subpart B. The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Terms, Requirements, Structure, Management Representative, Management Reviews, Plan and Procedures, Audits, Personnel, and Preamble. After completing this course, learners will be able to recognize the QS Regulation requirements associated with a firm's management responsibility, quality auditing, and personnel. Learners should complete QS Regulation 1: Overview and General Provisions before taking this course.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize the QS Regulation requirements associated with a firm's management responsibility, quality auditing, and personnel.

**Runtime:** 60

## QS Regulation 3: Design Controls

QSR03

Based on regulatory authority and findings that a significant portion of device recalls were attributed to faulty design, FDA included design control requirements in the Quality System (QS) Regulation. This course, the third in a series of Quality System Regulation courses, addresses design controls requirements of the Quality System Regulation. Topics include the design plan, the design review, verification, and validation. After completing this course, you will be able to recognize: the design control requirements of the QS Regulation; terms associated with design controls; and requirements for design control procedures. Learners should complete QS Regulation 1: Overview and General Provisions and QS Regulation 2: Quality System Requirements before taking this course.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize the design control requirements of the QS Regulation. Recognize the terms associated with design controls. Recognize requirements for design control procedures (including planning, input and output, review, verification, validation, transfer, changes, and the design history file).

**Runtime:** 60

## QS Regulation 4: Document and Purchasing Controls

QSR04

The fourth in a series of Quality System Regulation (QS Regulation) courses, this course focuses on the document controls requirements of 21 CFR Part 820, Subpart D and the purchasing controls requirements of 21 CFR Part 820, Subpart E. The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Key Terms, Document Control, Evaluation & Selection, Records & Data, and Preamble. After completing this course, learners will be able to recognize the document and purchasing controls requirements of the QS Regulation. Learners should complete QS Regulation 1: Overview and General Provisions, QS Regulation 2: Quality System Requirements, and QS Regulation 3: Design Controls before taking this course.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
  - Medical Device GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize the document and purchasing controls requirements of the QS Regulation. Recognize document and purchasing control procedures that manufacturers must establish and maintain. Identify key definitions relating to these requirements. Recognize some of the comments and responses that relate to document and purchasing controls in the Preamble to the regulation.

**Runtime:** 45

## QS Regulation 5: Identification and Traceability; Production and Process Controls

QSR05

The fifth in a series of Quality System (QS) Regulation courses, this course focuses on Identification and Traceability (21 CFR Part 820, Subpart F) and Production and Process Controls (21 CFR Part 820 Subpart G). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Identify and Trace, Production Processes, Controlling Changes, Other Controls, Software Validation, Equipment Calibration, and Process Validation. After completing this course, learners will be able to recognize a manufacturer's responsibilities relative to the Identification and Traceability requirements and Production and Process Controls requirements of the QS Regulation.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
  - Medical Device GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize a manufacturer's responsibilities relative to the Identification and Traceability requirements and Production and Process Controls requirements of the QS Regulation.

**Runtime:** 60

## QS Regulation 6: Acceptance Activities; Nonconforming Product

QSR06

The sixth in a series of Quality System (QS) Regulation courses, this course focuses on Acceptance Activities (21 CFR Part 820 Subpart H) and Nonconforming Product (21 CFR Part 820 Subpart I). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize a manufacturer's responsibilities relative to the Receiving, In-Process, and Finished Device Acceptance. Identify the Acceptance Status and Nonconforming Product requirements of the Quality System Regulation.

**Runtime:** 30

## QS Regulation 7: Corrective and Preventive Action

QSR07

The seventh in a series of Quality System (QS) Regulation courses, this course focuses on Corrective and Preventive Action (21 CFR Part 820 Subpart J). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics include: Key Terms, Investigate and Identify, Changes, Information, and Analyzing Data. After completing this course, you will be familiar with a manufacturer's responsibilities relative to the corrective and preventive action requirements of the QS Regulation. Learners should complete the previous courses in the series before taking this course.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Identify a manufacturer's responsibilities relative to the corrective and preventive action requirements of the QS Regulation.

**Runtime:** 60



## QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution, and Installation

QSR08

The eighth in a series of Quality System (QS) Regulation courses, this course focuses on Labeling and Package Control (21 CFR Part 820 Subpart K) and Handling, Storage, Distribution, and Installation (21 CFR Part 820 Subpart L). The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. Topics in this course include: Key Terms, Label Integrity, Labeling Operations, Handling/Storage Areas, Control & Distribution, and Device Installation. After completing this course, you will be able to recognize a manufacturer's responsibilities relative to the labeling, packaging control, handling, storage, distribution, and installation requirements of the QS Regulation.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Recognize a manufacturer's responsibilities relative to the labeling, packaging control, handling, storage, distribution, and installation requirements of the QS Regulation.

**Runtime:** 45

## QS Regulation 9: Records

QSR09

The QS Regulation provides a framework of basic requirements for manufacturers of finished medical devices. This course, the ninth in a series of Quality System (QS) Regulation courses, focuses on Records (21 CFR Part 820 Subpart M). Topics include key terms, general requirements, Device Master Records, and investigations. After completing this course, you will be able to identify a manufacturer's responsibilities relative to the records requirements of the QS Regulation.

**Languages Available:**  
Chinese (Simplified)  
Korean  
Japanese

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Medical Device GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Identify a manufacturer's responsibilities relative to the records requirements of the QS Regulation.

**Runtime:** 60

## Quality Systems Inspection Technique (QSIT)

DEV42

Manufacturing companies within the biomedical industry are subject to routine inspections of their quality systems by FDA. This course describes an FDA Quality System inspection by explaining the key objectives that an investigator will address when reviewing each subsystem. Topics in this course include: Procedure, Management Controls, Design Controls, Corrective and Preventive Actions (CAPA), Production and Process Controls (P&PC), and Preparation. After completing this course, learners will be able to identify the key elements for meeting the Quality System Regulation requirements.

**Languages Available:**

Chinese (Simplified)  
French (European)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize how to properly prepare for a Quality Systems inspection.

**Runtime:** 60

## RABS for Aseptic Processing Library

Aseptic05

Restricted Access Barrier System (RABS) technology was developed to remove operators from the critical processing zones during sterile product manufacturing. This course describes key features and critical operating principles of a RABS used for Aseptic Processing Library. Topics in this course include: Prepare, Leak Test, Disinfection, Setup, Operate, Monitor, Clean, and Maintain. After completing this course, learners will be able to identify the key benefits of RABS for Aseptic Processing Library, and identify methods for material transfer with a RABS unit.

**Languages Available:**

French (European)  
German  
Spanish (Spain)

**Format:** eLearning (Editable) - CREATE, eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Pharmaceutical Catalog
- Medical Device Catalog
- Aseptic Processing Library

**Course Objectives:**

Identify the key benefits of RABS for Aseptic Processing Library.;Recognize the major process steps for Aseptic Processing Library using RABS technology.;Recognize the importance of proper glove use and aseptic technique in a RABS environment.;Identify methods for material transfer with a RABS unit.;Recognize the environmental monitoring techniques applicable to RABS.

**Runtime:** 20

## Recalls of FDA Regulated Products

FDA24

The monitoring of recalls of potentially hazardous consumer products is one of the most important activities performed by FDA personnel. This course explores the basics of product recalls and personnel responsibilities during recall situations. Topics in this course include: Purpose and Types, Causes, Classifying Recalls, Responsibilities, and Audit Check. After completing this course, learners will be able to recognize FDA's definition of a product recall; recognize the contents of a recall letter; identify the types, depth, and classification of a recall; and recognize the responsibilities of FDA personnel during a product recall.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize FDA's definition of a product recall.;Recognize the contents of a recall letter.;Identify the types, depth, and classification of a recall.;Recognize the responsibilities of FDA personnel during a product recall.

**Runtime:** 45

## Recognizing and Avoiding Insider Trading

ETHICS23

This course will identify common situations that violate insider trading laws. Topics in this course include: Recognizing Inside Information and Insider Trading Situations. After completing this course, learners will be able to recognize what constitutes inside information, and how to recognize common insider trading violations.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Corporate Compliance

**Course Objectives:**

Recognize what constitutes as inside information.;Recognize common insider trading violations.

**Runtime:** 30

## Recognizing Electrical Hazards Awareness

PS5-00204

This course explains how and why electricity is dangerous so that employees may recognize when hazards are present. It is intended for workers in all industries.

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- Awareness
- General Safety and Manufacturing

**Content Suite:**

- Working from Home Suite
- Advanced Safety Orientation for General Industry (IACET CEU=0.9)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0) (Actively Proctored)

**Languages Available:**

- Dutch (PS5-101232)
- Czech (PS5-101231)
- Chinese (Simplified) (PS5-101237)
- French (Canadian) (PS5-102327)
- French (European) (PS5-101233)
- German (PS5-101234)
- Italian (PS5-102465)
- Japanese (PS5-102464)
- Korean (PS5-102463)
- Polish (PS5-101235)
- Portuguese (Brazil) (PS5-101236)
- Russian (PS5-102462)
- Spanish (Latin America) (PS5-102246)
- Thai (PS5-101238)
- English

**Course Objectives:**

Recall how electricity works; Define key electrical terms; Recognize why electrical incidents occur; Recall the dangers associated with electrical hazards

**Runtime:** 13

## Recruitment and Retention of Study Patients

GCP29

This course will discuss recruitment and retention of volunteers within a clinical trial. Topics in this course include: Pre-recruitment, Recruitment, Recruiting Methods, Special Populations, and Enrollment & Retention. After completing this course, learners will be able to identify acceptable ethical and regulatory recruitment and retention methods that can be used for clinical research trials and recognize key factors in recruiting and retaining subjects.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog

**Topic/Industry:**

- Clinical Quality Manager

**Course Objectives:**

Identify acceptable ethical and regulatory recruitment and retention methods that can be used for clinical research trials.; Recognize key factors in recruiting and retaining subjects.

**Runtime:** 60

## Regulatory Requirements for Medical Devices in the Republic of Korea

DEV58

This course covers the regulatory framework for medical devices in the Republic of Korea, recent and upcoming regulatory changes, and the medical device market in the Republic of Korea.

**Languages Available:**  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the regulations that apply to the marketing of medical devices in Korea. ;Recognize upcoming changes to those regulations as well as aspects of the Korean medical device market.

**Runtime:** 60

## Reporting Adverse Events for Medical Devices

MDSM02

This course introduces the process for filing medical device reports (MDRs) for adverse events and identifies the different types of reports used.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device - Sales & Marketing Library
- Medical Device Catalog
- Medical Device

**Course Objectives:**

Identify what a medical device report is and the types of reports that exist. Recognize a company's requirements for reporting adverse events for medical devices.

**Runtime:** 30

## Requirements for Computerized Systems Validation and Compliance

PHDV102

This course, the first in a four-part series, describes regulatory requirements and expectations regarding the validation and compliance of computerized systems used in the manufacture of pharmaceuticals, biologicals, and medical devices. It does not cover the detailed requirements of 21 CFR Part 11, except for the requirement that systems be validated. Even though it draws upon medical device guidance, it is not intended to cover all the requirements of producing software that subsequently becomes part of a medical device.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical
- Medical Device

**Course Objectives:**

Recognize the regulatory requirements for the validation and compliance of computerized systems used in the manufacture of pharmaceuticals, biologicals, and medical devices.

**Runtime:** 45

## Resolving Out Of Specification Test Results

PHA50

Obtaining an out of specification test result can be unsettling, and it is important that you know what to do with it. This course will provide you with the information to respond accordingly when an OOS result is encountered. Topics in this course include: Phase One, Phase Two, Averages, Outliers, and Failure Investigations. After completing this course, learners will be able to recognize what to look for and what to investigate when an OOS result occurs.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize the possible causes of OOS results. ;Identify the requirements for handling an investigation of OOS results. ;Identify how to work with your laboratory supervisor or manager to conduct proper investigations (laboratory, full-scale, and failure) and document OOS results.

**Runtime:** 45

## Resource Conservation and Recovery Act (RCRA) Part 1 (US)

PS5-00727

The Resource Conservation and Recovery Act (RCRA) places controls on the management of hazardous waste from its generation to its ultimate disposal. This course provides you with important information on RCRA, hazardous waste and your role in staying safe if your facility or organization produces, disposes of or accumulates hazardous waste.

**Languages Available:**  
French (Canadian) (PS5-102777)  
Spanish (Latin America) (PS5-102752)  
English

**Format:** eLearning - Claro

**Libraries:**                      **Topic/Industry:**

- Safety Catalog
  - EHS for Life Science - Basics Library
  - Medical Device Catalog
  - Pharmaceutical Catalog
  - Environmental
  - Environmental
- Content Suite:**
- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
  - Resource Conservation and Recovery Act (RCRA) Parts 1-2 (US)
  - Resource Conservation and Recovery Act (RCRA) Parts 1-2 (US) (IACET CEU=0.1)
  - Environmental Responsibility Suite (IACET CEU=0.3)

**Course Objectives:**

Define the purpose of RCRA;Determine if a waste is a hazardous waste;Identify categories of hazardous waste generators;Determine your generator status;Follow hazardous waste management and accumulation requirements;Prepare your hazardous waste for shipment off-site

**Runtime:** 33

## Resource Conservation and Recovery Act (RCRA) Part 2 (US)

PS5-00729

Whenever you generate hazardous waste and accumulate it on-site, you must take the necessary precautions and steps to prevent any sudden or accidental release into the environment. This course explores the actions you must take to carefully operate and maintain your facility and therefore reduce the possibility of fire, explosion and release of hazardous waste.

**Languages Available:**  
 French (Canadian) (PS5-102778)  
 Spanish (Latin America) (PS5-102753)  
 English

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Environmental

### Content Suite:

- DOT/EPA Hazardous Materials Suite (IACET CEU=0.5)
- Resource Conservation and Recovery Act (RCRA) Parts 1-2 (US)
- Resource Conservation and Recovery Act (RCRA) Parts 1-2 (US) (IACET CEU=0.1)
- Environmental Responsibility Suite (IACET CEU=0.3)

### Course Objectives:

Prepare for and prevent accidents involving hazardous waste;Recognize why training is necessary to comply with RCRA;Recall waste minimization techniques;Conduct a self-inspection;Prepare for a facility inspection;Identify where to find answers to your questions about hazardous waste management

**Runtime:** 15

## Respiratory Protection

PS5-00276

A single exposure to an airborne chemical can cause health effects that may last for the rest of your life. If your workplace contains dangerous chemicals or hazardous atmospheres, you need to know when and how to wear a respirator. This training will present the basic requirements of respiratory protection and will focus on the types and limitations of respirators. Ideal learners include all employees.

**Languages Available:**  
 Dutch (PS5-101265)  
 Czech (PS5-101264)  
 Chinese (Simplified) (PS5-102484)  
 French (Canadian) (PS5-102689)  
 French (European) (PS5-101266)  
 German (PS5-101268)  
 Italian (PS5-102487)  
 Japanese (PS5-101267)  
 Polish (PS5-101269)  
 Portuguese (Brazil) (PS5-101270)  
 Russian (PS5-102485)  
 Spanish (Latin America) (PS5-100562)  
 Thai (PS5-101271)  
 English  
 Korean

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- General Safety and Manufacturing
- Construction

### Course Objectives:

Identify employer and employee respirator responsibilities;Describe what happens during medical evaluations and fit testing;Recognize characteristics of different types of respirators;Recall how to inspect respirators before each use;Recognize the signs of respirator failure;Recall how to maintain respirators

**Runtime:** 24

## Review of Basic Statistical Techniques

DEV44

The use of statistics in medical device manufacturing is now expected and regulated by the Food and Drug Administration in the Quality System Regulation, Subpart O, "Statistical Techniques." This course describes the proper use of statistical techniques as they apply to medical device manufacturing. Topics in this course include: Data Analysis, Histograms, and Variability. After completing this course, learners will be able to recognize how to interpret data using basic statistical techniques.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize how to interpret data using basic statistical techniques; Recognize how to solve technical problems in a straightforward manner and comply with FDA's Quality System Regulation

**Runtime:** 45

## Risk Management 1: Key Concepts and Definitions

FDA29

FDA manages risk in an attempt to prevent loss or injury by ensuring their medical devices, human and veterinary drugs, food additives, biologics, or other products are safe. This course focuses on Risk Management as it applies to FDA and its regulated industries. This course is also designed to provide an understanding of Risk Management as defined by the International Organization for Standardization (ISO). Topics in this course include: Risk, Calculating Risk, Safety, and Managing Risk. After completing this course, learners will be able to recognize the key concepts and definitions associated with risk management.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the definitions of risk and related terms.;Identify the ways risk can be expressed.;Differentiate between safety and risk.;Identify the criteria FDA uses to judges safety for different types of products.;Recognize the steps of the risk management process.

**Runtime:** 30



## Risk Management in Pharmaceutical Manufacturing

PHA72

The role of the Qualified Person (QP) is defined in European Union legislation. This course explains the release of medicinal products to the market, the release of clinical trial materials, and pharmacovigilance. Topics in this course include: Regulation, Qualifications/Codes of Practice, Batch Certification, Different Supply Situations, Clinical Trials, and Pharmacovigilance. After completing this course, learners will be able to identify the role and responsibilities of both types of QP defined in EU legislation.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library

**Course Objectives:**

Identify the role and responsibilities of both types of QP.;Recognize how these fit within EU legislation.

**Runtime:** 60

## Role of the Qualified Person

PHA76

The role of the Qualified Person (QP) is defined in European Union legislation. This course explains the release of medicinal products to the market, the release of clinical trial materials, and pharmacovigilance. Topics in this course include: Regulation, Qualifications/Codes of Practice, Batch Certification, Different Supply Situations, Clinical Trials, and Pharmacovigilance. After completing this course, learners will be able to identify the role and responsibilities of both types of QP defined in EU legislation.

**Languages Available:**

French (European)  
German  
Spanish (Spain)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library

**Course Objectives:**

Identify management's specific responsibilities in developing and maintaining a Quality System.

**Runtime:** 60

## Safeguarding Intellectual Property

ETHICS12

This course discusses how to identify and protect the Intellectual Property (IP) assets of a company. It also covers the four primary types of intellectual property with which a company deals. This course explores the business, ethical, and legal consequences of violating IP laws and protections, and an individual's responsibility for safeguarding the IP of a company and that of others.

**Format:** eLearning - EduFlex, eLearning - SCORM

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Ethics &amp; Corporate Responsibility Library</li> <li>• HealthCare Catalog</li> <li>• Pharmaceutical Catalog</li> <li>• Medical Device Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• Corporate Compliance</li> </ul> |

### Course Objectives:

Identify the definition of intellectual property.;Identify the four basic types of IP that our company is involved with. ;Recognize the legal and business consequences of failing to protect our IP and that of others. ;Identify the basics of IP management, or how to protect our IP and that of others.

**Runtime:** 60

## Safety Orientation

PS5-01352

This employee safety program is much more than an examination of set rules. It is a common sense approach to training employees in order to prevent injuries and illness. Ideal learners are new employees.

**Format:** eLearning - Claro

- |   |  |
|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• General Safety and Manufacturing</li> </ul> |

**Languages Available:**  
 Dutch (PS5-101595)  
 Czech (PS5-101594)  
 Chinese (Simplified) (PS5-101593)  
 French (European) (PS5-101596)  
 German (PS5-101597)  
 Polish (PS5-101598)  
 Portuguese (Brazil) (PS5-101599)  
 Spanish (Latin America) (PS5-102255)  
 Thai (PS5-101600)  
 English

### Course Objectives:

Realize the importance of safety in your daily responsibilities;Recall the rules to follow when handling hazardous materials or operating equipment;Report safety incidents

**Runtime:** 10

## Sample Collection

FDA23

This course explores sample collection as a critical responsibility of field personnel. It explains the purpose of sampling and covers how to properly perform sampling. Topics in this course include: Purpose, Types, Preparation, Size, Techniques, Conduct, Submission, and Sample Validity. After completing this course, learners will be able to recognize the reasons for collecting and maintaining samples, identify the major samples types, and identify the differences between domestic and import samples. Learners will also be able to recognize how to prepare and conduct proper sampling and identify the appropriate steps for submitting a sample.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the reasons for collecting and maintaining samples. Identify the major samples types. Identify the differences between domestic and import samples. Recognize how to prepare and conduct proper sampling. Identify the appropriate steps for submitting a sample.

**Runtime:** 60

## Sarbanes-Oxley Act: An Overview

ETHICS07

The Sarbanes-Oxley Act of 2002 initiated the biggest change in corporate governance since the Great Depression. This course describes each section of the Sarbanes-Oxley Act along with insights about how it impacts companies and their employees. Topics in this course include: Purpose, Effects, Audit Committees, Executives, Government Agencies, and Crimes and Penalties. After completing this course, learners will be able to identify the purpose and main provisions of the Sarbanes-Oxley Act.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- Corporate Compliance

**Course Objectives:**

Identify the purpose and main provisions of the Sarbanes-Oxley Act. Identify corporate responsibilities that Sarbanes-Oxley mandates.

**Runtime:** 45

## Selecting and Managing Clinical Contract Research Organizations (CROs)

GCP12

This course provides information on the processes commonly used to select and manage a clinical contract research organization (CRO) and other supportive contract service providers for the clinical stages of the investigation product development process. Topics in this course include: Outsourcing, Pre-Selection Criteria, Selection Techniques, Managing CROs, and Communications. After completing this course, learners will be able to identify the requirements for selecting and effectively managing CROs and other service providers.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the requirements for selecting CROs and other service providers.;Identify the requirements for effectively managing CROs and other service providers.

**Runtime:** 75

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## Self-Motivation

EHS94

This course covers the five characteristics of self-motivated people and the five skills that are necessary to develop these characteristics. Topics in this course include: Self-Motivation, Skills, Mission Statement, Goals, Creative Thinking, Self-Discipline, and Self-Talk. After completing this course, learners will be able to recognize how to apply the skills and characteristics of self-motivation at work, at home, and in the community.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
  - HR Compliance & Risk Management Library
  - HealthCare Catalog
  - Pharmaceutical Catalog
  - Medical Device Catalog
- HR Compliance & Risk Management

**Course Objectives:**

Recognize how to apply the skills and characteristics of self-motivation at work, at home, and in the community.

**Runtime:** 30

## Sexual Harassment Awareness for California Employees

LAV24

Sexual harassment is a serious issue facing employers. This course is designed to educate you about the State of California's and the Equal Employment Opportunity Commission's (EEOC) definition of sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Definition, Guidelines, Confrontation, and Reporting Incidents. After completing this course, learners will be able to recognize that harassment is a personal issue and that your definition of offensive behavior may differ from that of your coworkers. Learners will also be able to identify behaviors that are considered inappropriate and know how to avoid engaging in inappropriate behaviors.

**Format:** eLearning - EduFlex, eLearning - SCORM

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• HR Compliance &amp; Risk Management Library</li><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Recognize that harassment is a personal issue and that your definition of offensive behavior may differ from that of your coworkers. ;Identify behaviors that are considered inappropriate and know how to avoid engaging in inappropriate behaviors.;Identify ways to report harassment.

**Runtime:** 60

## Sexual Harassment Awareness for Managers

LAV09

This course presents an overview of sexual harassment and emphasizes the specific responsibilities of managers and supervisors in preventing and responding to sexual harassment. Responding appropriately to sexual harassment may reduce the potential liability of employers in this area. It is highly recommended that individuals take Investigating Employee Claims in conjunction with this course. Reviewing Sexual Harassment Awareness for Employees will also be helpful. Topics in this course include: Definitions, Employer Liabilities, Prevention and Response, and Legal Issues. After completing this course, learners will be able to recognize, prevent, and respond to sexual harassment in a responsible manner.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HR Compliance &amp; Risk Management Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li></ul> |

### Course Objectives:

Recognize, prevent, and respond to sexual harassment in a responsible manner.

**Runtime:** 30

## Sexual Harassment Awareness for New York Employees and Supervisors

LAV23

Sexual harassment is a serious issue facing employers. This course is designed to educate you about New York and federal laws regarding sexual harassment as well as to present information on identifying harassing behavior, avoiding harassment, and what steps to take should harassment issues arise involving the workplace. Topics in this course include: Guidelines, Confrontation, Reporting Incidents, Supervisor Responsibilities, and Rights and Remedies. After completing this course, learners will be able to recognize that harassment is a personal issue and that definitions of offensive behavior may differ amongst coworkers. Learners also will be able to identify behaviors that are considered inappropriate and recognize how to avoid engaging in inappropriate behaviors.

**Format:** eLearning - EduFlex, eLearning - SCORM

- |  |  |
|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• HR Compliance &amp; Risk Management Library</li><li>• Ethics &amp; Corporate Responsibility Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Corporate Compliance</li><li>• HR Compliance &amp; Risk Management</li></ul> |

### Course Objectives:

Recognize that harassment is a personal issue and that definitions of offensive behavior may differ amongst coworkers. ;Identify behaviors that are considered inappropriate.;Recognize how to avoid engaging in inappropriate behaviors.

**Runtime:** 30

## SMART Goal Setting

EHS99

Goals that adhere to Specific, Measurable, Attainable,;Results-Oriented, and Time-Bounded (SMART) criteria are more likely to lead to;completion of tasks and higher satisfaction. This course will help participants;understand the impact of goal setting on their lives, and give them a road map;they can use to achieve higher personal and professional productivity. Topics;in this course include: Goals, Specific, Measurable, Attainable,;Results-Oriented, Time-Bound, and Putting It Together. After completing this;course, learners will be able to recognize the essential elements of effective;goal setting. Learners will also be able to differentiate between well-written;and poorly written goals.

**Format:** eLearning - EduFlex, eLearning - SCORM

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|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"><li>• HR Compliance &amp; Risk Management Library</li><li>• HealthCare Catalog</li><li>• Pharmaceutical Catalog</li><li>• Medical Device Catalog</li></ul> | <ul style="list-style-type: none"><li>• Professional Development</li></ul> |

### Course Objectives:

Recognize the essential elements of effective goal setting. ;Differentiate between well-written and poorly written goals.

**Runtime:** 30

## Special Investigations

FDA25

This course will provide an overview of the broad spectrum of investigations performed by the Food and Drug Administration (FDA). Topics in this course include: Complaint Investigation, Surveillance Investigation, Disaster Investigation, Health Fraud Investigation, Product Tampering Investigation, and Criminal Investigation. After completing this course, learners will be able to identify the purpose of special investigations. Learners will also be able to recognize the properties of special investigations, as well as things to look for during each of these investigations.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

### Course Objectives:

Identify the purpose of special investigations.;Identify the properties of complaint investigations, surveillance investigations, disaster investigations, health fraud investigations, product tampering investigations, and criminal investigations.;Recognize things to look for during each of these special investigations.

**Runtime:** 60

## Spill Prevention Control and Countermeasure (SPCC) (US)

PS5-00191

You have seen media reports about the catastrophic effects an oil spill has on wildlife, the environment, and the livelihood of affected communities. The SPCC regulation was developed to prevent oil releases at facilities from polluting navigable waters of the United States. This course gives employees a general overview of SPCC requirements. Ideal learners are any employee involved in oil handling, transfer, storage, spill response or maintenance of oil equipment.

**Languages Available:**  
Dutch (PS5-101505)  
Chinese (Simplified) (PS5-101509)  
French (Canadian) (PS5-102759)  
German (PS5-101506)  
Polish (PS5-101507)  
Portuguese (Brazil) (PS5-101508)  
Spanish (Latin America) (PS5-101510)  
English

**Format:** eLearning - Claro

**Libraries:**                      **Topic/Industry:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Environmental

### Course Objectives:

List the general requirements and goals of an SPCC plan;Identify the potential types and sources of oils and oil products covered by the regulations;State the steps to take in the event of a spill;Give examples of what you can do to prevent spills

**Runtime:** 22

## Sterile Dosage Forms Introduction

Because of the risk of infection from non-oral medications, manufacturers must ensure the sterility of sterile dosage forms. This course describes the reasons that some drugs need to be sterile and the practices required for sterile dosage form manufacturing. Topics in this course include: Sterility, Requirements and Preparations, and Cleanrooms. After completing this course, learners will be able to identify the role of cleanroom facilities and personnel in the sterile dosage forms manufacturing process.

**Format:** eLearning - EduFlex, eLearning - SCORM

### Libraries:

- Pharmaceutical Catalog
- Medical Device Catalog
- Aseptic Processing Library

### Course Objectives:

Identify the requirements of sterile products.;Identify the methods of aseptic production.;Identify the cleanroom requirements.

**Runtime:** 20

## Aseptic02

### Languages Available:

- Chinese (Simplified)
- French (European)
- German
- Japanese
- Spanish (Spain)

## Stormwater Pollution Prevention (US)

Laws require us to regulate stormwater in order to reduce the pollution of rivers and lakes. Identifying sources of storm water pollution and keeping them from coming in contact with runoff is one of the best and most economical ways of protecting the quality of our waters. This course presents best management practices to prevent stormwater pollution.

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- Environmental

### Content Suite:

- Environmental Responsibility Suite (IACET CEU=0.3)

### Course Objectives:

Define stormwater;Discuss how the regulation of stormwater has developed;List common sources of stormwater pollution;Discuss the effects of stormwater pollution on the environment;Give examples of best management practices for preventing stormwater pollution;Describe how to respond to a spill;State the fines and penalties for polluting stormwater;Describe the purpose and requirements of a Stormwater Pollution Prevention Plan

**Runtime:** 25

## PS5-00256

### Languages Available:

- Dutch (PS5-101222)
- Czech (PS5-101221)
- Chinese (Simplified) (PS5-101228)
- French (Canadian) (PS5-102758)
- French (European) (PS5-101223)
- German (PS5-101224)
- Japanese (PS5-101225)
- Polish (PS5-101226)
- Portuguese (Brazil) (PS5-101227)
- Spanish (Latin America) (PS5-101229)
- Thai (PS5-101230)
- English

## Summary of the California Consumer Privacy Act (CCPA) of 2018

## DP03

This course describes the general requirements of the California Consumer Privacy Act (CCPA) of 2018 in comparison to the requirements of the General Data Protection Regulation (GDPR) in place in the EU.

**Format:** eLearning - EduFlex, eLearning - SCORM\*, eLearning (Editable) - CREATE

### Libraries:

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Medical Device Catalog
- Pharmaceutical Catalog

**Runtime:** 60



## Systems Based Drug Inspections

FDA55

FDA has a series of compliance programs that provide guidance and instructions to help meet FDA regulations for pharmaceutical manufacturers. This course describes FDA's Drug Manufacturing Inspections program. Topics in this course include: Guidance, Systems, Inspections, Quality, Facilities and Equipment, Materials, Production, and Laboratory Control. After completing this course, learners will be able to recognize what can happen if a firm is not following FDA regulations.

**Languages Available:**  
Chinese (Simplified)  
Japanese

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- FDA Inspections and Enforcement Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the guidance provided by FDA for investigators inspecting drug firms for GMP compliance. ;Recognize the guidance provided in CP 7356.002 for conducting inspections, sampling, analyzing samples, and evaluating compliance.

**Runtime:** 60

## Testing for Bacterial Endotoxins

PHDV86

This course;will provide a general overview of bacterial endotoxins and the methods used to;test for their presence in products. Topics in this course include: Endotoxin;Reduction, Gel-Clot LAL Testing, Chromogenic LAL Testing, and Choosing a Test.;After completing this course, learners will be able to recognize the principles;of bacterial endotoxins and ways they are detected in products.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
  - Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize principles of bacterial endotoxins.;Recognize ways bacterial endotoxins are detected in products.

**Runtime:** 30

## The Approval Process for New Medical Devices

DEV47

This course provides an overall view of the development regulatory process for legally marketing a new medical device in the US. Topics in this course include: Classification, Approval Process, IDE, Clinical Studies, and PMA. After completing this course, learners will be able to identify the major steps in new device development and the required regulatory process for the US market. Learners will also recognize the purpose and requirements of clinical studies. Learners will be able to identify the elements of a 510(k), an IDE, and a PMA. Finally, learners will recognize key information about the classification of medical devices and the role of FDA in the approval of medical devices for the US marketplace.

**Languages Available:**  
Chinese (Simplified)  
Japanese  
Korean

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the major steps in new device development.;Identify the required regulatory process for the US market. ;Identify the purpose and requirements of clinical studies. ;Identify the elements of a 510(k), an IDE, and a PMA. ;Recognize key information about the classification of medical devices. ;Recognize the role of FDA in the approval of medical devices for the US marketplace.

**Runtime:** 45

## The Clinical Development Process: Investigational Product, Plan, and Data Management

GCP28

This course will discuss the clinical development process, including the regulatory obligations of the sponsor of a new drug or product. Topics in this course include: Clinical Research Plan, Protocol Plan, Subject Selection Process, Data Collection, and NDA Submission. After completing this course, learners will be able to identify the steps leading to the final FDA review and approval for marketing of a new product.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Clinical Quality Manager

**Course Objectives:**

Identify the steps leading to the final FDA review and approval for marketing of a new product.

**Runtime:** 45

## The Design and Development of Software Used in Automated Process Controls

PHDV80

Regulators require that manufacturers apply the principles and practices of software quality assurance to automated systems that may ultimately affect product safety and effectiveness. This course examines the process of developing software for automated process control. Topics in this course include: Automated Process Controls, Specifications and Design, Verification and Validation, and Maintenance and Retirement. After completing this course you will be able to identify the Software Development Life Cycle (SDLC) and recognize several aspects of software quality assurance and documentation.

**Languages Available:**  
Chinese (Simplified)

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Identify the SDLC under regulatory requirements for the design, development, and control of software used in automated process controls. ;Recognize all of the steps in the SDLC process.

**Runtime:** 45

## The Role of the Clinical Research Associate

GCP17

This course explores the role of the clinical research;associate (CRA) in monitoring a clinical trial and acting as a liaison between;the investigative site and the sponsor company. The course will introduce key;CRA responsibilities widely recognized throughout the industry and globally;applicable. Topics in this course include: Definition, Visits, Recruitment and;Retention, Informed Consent, Source Documentation, and Essential Documents. After;completing this course, learners will be able to recognize the current role of;the CRA during each stage of a clinical trial and identify specific;responsibilities for documents and processes in those stages.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
- Clinical: Pharmaceutical Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Recognize the current role of the CRA during each stage of a clinical trial.;Identify specific responsibilities for documents and processes in those stages.

**Runtime:** 45

## The Role of the Clinical Research Coordinator

GCP18

The clinical research coordinator (CRC) has a key role in executing a clinical trial and acting as a liaison to the investigator, sponsor, and monitor. This course will introduce key CRC responsibilities at the site, including subject recruitment, informed consent, source document and case report form (CRF) completion, and test article accountability. Topics in this course include: CRC, Visits Before Study, Visits During & After Study, Recruitment & Retention, Informed Consent, Source Documentation, Case Report Forms, and Essential Documents. After completing this course, learners will be able to identify the CRC's key roles in research and patient protection from pre-study visits through study completion.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Clinical: Medical Device Library
  - Clinical: Pharmaceutical Library
  - Pharmaceutical Catalog
  - Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the CRC's key roles in research and patient protection from pre-study visits through study completion.

**Runtime:** 60

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## Trade Secrets

ETHICS28

This course discusses trade secrets and keeping a competitive edge in the marketplace. Topics in this course include: Definition, Risks, and Protecting Trade Secrets. After completing this course, learners will be able to identify trade secrets, and recognize the necessary steps to safeguard trade secrets in the workplace.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Course Objectives:**

Identify trade secrets. Recognize the necessary steps to safeguard trade secrets in the workplace.

**Runtime:** 20

## Understanding GMPs for Facilities and Equipment

PHDV63

Facilities and equipment GMP requirements impact many aspects of plant operation — from setup to maintenance and cleaning. This course introduces the general layout and equipment used within a pharmaceutical or medical device manufacturing plant. Topics in this course include: Facilities, Cleanliness, Process Flow, Equipment, Maintenance, Calibration, and Cleaning. After completing this course, you will recognize the importance of Good Manufacturing Practices and you will be able to identify the requirements that specifically apply to facilities and equipment.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Medical Device
- Pharmaceutical

**Course Objectives:**

Recognize the importance of Good Manufacturing Practices. Identify the requirements that specifically apply to facilities and equipment.

**Runtime:** 60

## Understanding Post-Approval Changes

PHA49

FDA has made a number of recent changes to its regulations concerning post-approval manufacturing changes for drug products. This course covers categories of post-approval changes (PAC), the requirements for each, and PAC guidance. Topics in this course include: SUPAC, Components and Composition, Site of Manufacture, Scale of Manufacture, and Manufacturing. After completing this course, learners will be able to recognize the requirements related to PAC and FDA guidance for those requirements.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Pharmaceutical GMPs Library
- Pharmaceutical Catalog
- Medical Device Catalog
- Medical Device GMPs Library
- QA/GMP Trainer

**Course Objectives:**

Recognize PAC guidance and how these documents are used to provide notification to FDA for post-approval changes to an approved drug application. Identify the categories of PAC and the recommended chemistry, manufacturing, and control (CMC) requirements for each change. Identify the tests and documents needed for each category of change.

**Runtime:** 45

## Understanding the Principles and Practices of Process Controls

PHA47

Recently FDA has become increasingly concerned with the number of Warning Letters being issued due to problems with the control of manufacturing processes. Items listed in these various Warning Letters include lack of validation of manufacturing processes, lack of written procedures, improper sampling and testing of materials, and failure to follow written procedures. This course provides an understanding of what process control is. You will also learn about the written procedures involved in validation, how equipment affects process controls, batch production records, correct sampling and testing methods, proper reprocessing techniques, contamination control, change control, and process analytical technology.

**Languages Available:**  
Chinese (Simplified)  
Japanese

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical

**Course Objectives:**

Recognize what process control is. Identify the written procedures involved in validation. Identify the ways that equipment affects process controls, batch production records, correct sampling and testing methods, proper reprocessing techniques, contamination control, change control, and the role of PAT.

**Runtime:** 60

## United States Food and Drug Administration (FDA) ? MDSAP Country-Specific Tasks

MDSAP\_US

Chapter 2 in the Medical Device Single Audit Program (MDSAP) is to verify that the organization has performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP. This course covers tasks in Chapter 2 of the MDSAP.

**Format:** eLearning - EduFlex, eLearning - SCORM\*

**Libraries:**

- Pharmaceutical Catalog
- MDSAP Library
- Medical Device Catalog

**Runtime:** 15

## US Trade Controls

ETHICS27

US trade control regulations are designed to control access to US products and information that could be misused in ways that are contrary to US interests. This course covers the scope and contents of those regulations. Topics in this course include: Trade Control, Regulatory Environment, Item and Classification, Destination, Receiving Party, High-Risk Factors, Boycotts, End Use, Export License, and Documentation and Disclosure. After completing this course, learners will be able to recognize potential US trade control violations and identify ways to find help.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**

- Ethics & Corporate Responsibility Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog

**Course Objectives:**

Recognize potential US trade control violations; Identify ways to find help.

**Runtime:** 45

## Using Electrical Safety Programs (US)

PS5-00207

Electricity can kill. That is why NFPA 70E® was created. It requires employers to develop and implement an electrical safety program. This course explains basic electrical safety practices that apply to electrical work. These practices include wearing personal protective equipment and completing arc-flash hazard analyses. Ideal learners include people in all industries, particularly supervisors, electrical maintenance and installation workers, and safety managers.

**Format:** eLearning - Claro

**Libraries:**

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

**Topic/Industry:**

- General Safety and Manufacturing

**Course Objectives:**

Explain the purpose of electrical safety programs; Recognize the elements of an electrical safety program; Recall how to complete an arc-flash hazard analysis; Distinguish between arc-flash, limited and restricted approach boundaries; Identify appropriate personal protective equipment for electrical hazards

**Runtime:** 25

**Languages Available:**  
French (Canadian) (PS5-102326)  
Portuguese (Brazil) (PS5-101772)  
Spanish (Latin America) (PS5-102254)  
English

## Validation of Analytical Laboratory Procedures

ICHreg04

This course describes a model for an effective quality management system for the pharmaceutical industry. The course is based on guidance developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is supported by the Food and Drug Administration (FDA) and is representative of their current thinking on this topic. Topics in this course include: Enablers, Management, Product Lifecycle, Process Performance, CAPA and Change, and Management Review and Improvement. After completing this course, learners will be able to recognize the approach to take in ensuring the pharmaceutical Quality System has the important principles needed to meet regulatory guidance. References: FDA Guidance for Industry ?Q10 Pharmaceutical Quality System,? ICH, April, 2009. 21 CFR Parts 210, 211, 600, and 606. Guidance for Industry, ?Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations,? FDA, September 2006. Compliance Program Guidance Manual for FDA Staff: Drug Manufacturing Inspections, Program 7356.002, FDA, September 11, 2015. ?Quality Systems for Drugs and Biologics,? Pharmaceutical Technology, February 2, 2008.

**Format:** eLearning - EduFlex, eLearning - SCORM

**Libraries:**                      **Topic/Industry:**

- Global Regulatory Library
- Pharmaceutical Catalog
- Medical Device Catalog
- QA/GMP Trainer

**Course Objectives:**

Identify the approach to take in ensuring the pharmaceutical Quality System has the important principles needed to meet regulatory guidance.

**Runtime:** 60

## Violence in the Workplace

LAV11

Disputes between employees, or between employees and their supervisors, are not unusual in a stressful workplace environment. Occasionally, conflicts may escalate into heated exchanges or even a physical confrontation. Every year, a handful of cases involve extreme violence, including the use of firearms, and result in severe injuries or the tragic loss of life. After completing this course, participants will know how to identify individuals prone to violent behavior and apply proven techniques to diffuse dangerous situations.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Ethics & Corporate Responsibility Library
- HR Compliance & Risk Management Library
- HealthCare Catalog
- Pharmaceutical Catalog
- Medical Device Catalog
- HR Compliance & Risk Management

**Course Objectives:**

Recognize individuals prone to violent behavior. ;Identify proven techniques to diffuse dangerous situations.

**Runtime:** 60



## Walking/Working Surfaces

Slips, trips and falls remain one of the most common causes of employee injury in the workplace. Understanding the actions you can take to prevent these incidents will help keep you and your co-workers safe and productive. This course provides a clear understanding of general guidelines for staying safe on walking and working surfaces. Ideal learners are all employees.

**Format:** eLearning - Claro

### Libraries:

- Safety Catalog
- EHS for Life Science - Basics Library
- Medical Device Catalog
- Pharmaceutical Catalog

### Topic/Industry:

- General Safety and Manufacturing

### Content Suite:

- Advanced Safety Orientation for General Industry (IACET CEU=0.9)
- Advanced Safety Orientation for Managers and Supervisors in Construction (IACET CEU=2.7)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0)
- OSHA 10: General Industry Outreach Training Course (IACET CEU=1.0) (Actively Proctored)
- OSHA 10: General Industry Outreach Training Course (High-Tech/Semiconductor) (IACET CEU=1.0)
- OSHA 30: Construction Outreach Training Course (IACET CEU=3.0)
- OSHA 30: Construction Outreach Training Course (IACET CEU=3.0) (Actively Proctored)

### Course Objectives:

Know how housekeeping helps keep walking and working surfaces safe; Recall general safety recommendations for floors, passageways, ladders, step bolts, stairways and steps, scaffolds, dockboards and ramps

**Runtime:** 13

**PS5-01378**

### Languages Available:

- Dutch (PS5-101725)
- Czech (PS5-101724)
- Chinese (Simplified) (PS5-101730)
- French (Canadian) (PS5-102736)
- German (PS5-101726)
- Japanese (PS5-101727)
- Polish (PS5-101728)
- Portuguese (Brazil) (PS5-101729)
- Spanish (Latin America) (PS5-102240)
- Thai (PS5-101731)
- English



## Welding, Cutting and Brazing

PS5-01400

Welding, cutting, brazing and other hot work are common, and inherently dangerous, activities on many jobsites. Care must be taken to ensure that work is performed safely. This course introduces common hazards associated with welding, cutting and brazing and ways to prevent injury and damage. Ideal learners are workers who perform welding, cutting and brazing.

**Languages Available:**  
Portuguese (Brazil) (PS5-102010)  
Spanish (Latin America) (PS5-01027)  
English

**Format:** eLearning - Claro

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|---|--|
| <b>Libraries:</b>   | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Safety Catalog</li> <li>• EHS for Life Science - Basics Library</li> <li>• Medical Device Catalog</li> <li>• Pharmaceutical Catalog</li> </ul> | <ul style="list-style-type: none"> <li>• General Safety and Manufacturing</li> </ul> |

### Course Objectives:

Describe the roles of personnel involved in welding, cutting, brazing and other hot work operations;Recognize how the hot work permit system ensures that all hazards are identified, communicated and controlled;Identify fire prevention techniques used during welding, cutting and brazing;Understand hazards associated with oxyacetylene and arc welding and methods to mitigate risks;Recall the proper storage, handling, transportation and use of compressed gas cylinders;Be aware of the chemical and physical agents produced in welding operations;Identify personal protective equipment (PPE) to be worn

**Runtime:** 38

## Writing and Reviewing SOPs

PHA48

Manufacturing facilities rely on Standard Operating Procedures (SOPs) to establish controlled manufacturing processes for quality products. This course identifies the principles and practices applicable to written SOPs. Topics in this course include GMP Requirements, Elements of SOPs, Review & Approval, and Document Control. After completing this course, learners will be able to recognize the different types of SOPs and methods for developing them. Learners will also be able to identify the appropriate measures for document control.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

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|--|--|
| <b>Libraries:</b>  | <b>Topic/Industry:</b>   |
| <ul style="list-style-type: none"> <li>• Pharmaceutical GMPs Library</li> <li>• Pharmaceutical Catalog</li> <li>• Medical Device Catalog</li> <li>• Medical Device GMPs Library</li> </ul> | <ul style="list-style-type: none"> <li>• QA/GMP Trainer</li> </ul> |

### Course Objectives:

Identify the rationale and GMP requirements for written SOPs.;Recognize which areas require procedures and how those procedures are developed.;Identify the appropriate measures for document control.

**Runtime:** 45

## Writing Validation Protocols

PHA51

This course is an introduction to the importance and content of the documentation that comprises validation. Topics in this course include: Validation, Documentation, and Elements. After completing this course, you will be able to identify validation protocols and the three types of qualifications. You will also be able to recognize the key elements involved in writing a validation protocol.

**Format:** eLearning - EduFlex, eLearning - SCORM, eLearning (Editable) - CREATE

**Libraries:**                      **Topic/Industry:**

- Medical Device GMPs Library
- Pharmaceutical GMPs Library
- Medical Device Catalog
- Pharmaceutical Catalog
- Pharmaceutical
- Medical Device

**Course Objectives:**

Identify what validation protocols are. Identify the three types of qualifications and their properties. Recognize the key elements involved in writing a validation protocol.

**Runtime:** 30



### About UL Learning

Since 1980, UL Learning has been providing computer-based instruction, compliance management solutions, and advisory services to corporate and government customers with a strong focus on the needs of Life Sciences, Health Care, Energy, and Industrial sectors.

Our unique partnership with the FDA provides online training tools to train and certify more than 36,000 federal, state, local and global investigators in the areas of quality and compliance. UL and the FDA jointly develop content and deliver it via ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. More than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.