UL Verification Services Inc. Cosmetic Pre-Audit Checklist

	Requirement	Regulation/Standard	Notes
	Quality System		
	Organization		
QS1	Verify Auditee's organization is appropriately structured (based upon company size and product portfolio), and includes an independent Quality Assurance/Quality Control unit. *ISO 22716:2007 - Clause 3.2.1.1 Personnel - Organization - Organizational Chart* *ISO 22716:2007 - Clause 3.2.1.3 Personnel - Organization - Organizational Chart* *ANSI 455-3 - 4.1.3; ANSI 455-3 - 4.1.4*	**22716 - 3.2.1.1 Personnel - Organization - Organizational Chart** The organizational structure should be defined such that the organization and functioning of the staff of the company be understood. It should be appropriate for the size of the company and the diversity of its products. **22716 - 3.2.1.3 Personnel - Organization - Organizational Chart** The organization chart should show the independence, from the other units of the plant, of each quality unit, such as quality assurance unit and quality control unit. The quality assurance and quality control responsibilities can be undertaken by a separate quality assurance unit and a quality control unit, or they can be undertaken by a single unit. **ANSI 455-3 - 4.1.3:** The organizational structure is defined so that the organization and functions of the staff are understandable and logical. **ANSI 455-3 - 4.1.4:** The organization chart shows the independence of the quality unit – including quality assurance (QA) and quality control (QC) activities – from other areas of the plant.	
QS2	Verify Auditee's organizational structure defines adequate roles with associated personnel count; these roles are filled and personnel count is maintained. *ISO 22716:2007 - Clause 3.2.1.2 Personnel - Organization - Organizational Chart* *ISO 22716:2007 - Clause 3.2.2 Personnel - Organization - Number of People* *ANSI 455-3 - 4.4.1; ANSI 455-3 - 4.4.26*	**22716 - 3.2.1.2 Personnel - Organization - Organizational Chart** Each company should ensure that there are adequate staffing levels in the different scope of activity, according to the diversity of its production. **22716 - 3.2.2 Personnel - Organization - Number of People** The company should have an adequate number of properly trained personnel with regards to the defined activities in these guidelines. **ANSI 455-3 - 4.4.1:** Staffing levels are adequate for the scope, diversity, and type of production. **ANSI 455-3 - 4.4.26:** An adequate number of trained personnel are provided to meet the activities of ISO 22716.	
QS3	Verify Auditee's top management has provided adequate resources and support both in terms of capital and qualified personnel, and has ultimate responsibility for implementation of GMPs. *ISO 22716:2007 - Clause 3.3.1.1 Personnel - Key Responsibilities - Management Responsibilities* *ISO 22716:2007 - Clause 3.3.1.2 Personnel - Key Responsibilities - Management Responsibilities* *ANSI 455-3 - 4.2.1*	**22716 - 3.3.1.1 Personnel - Key Responsibilities - Management Responsibilities** The organization should be supported by the top management of the company. **22716 - 3.3.1.2 Personnel - Key Responsibilities - Management Responsibilities** The implementation of Good Manufacturing Practices should be the responsibility of top management and should require the participation and commitment of personnel in all departments and at all levels within the company. **ANSI 455-3 - 4.2.1:** Management supports the organization through an established quality policy, provision of adequate resources (human, financial, materials, facilities, and equipment) and communicates achievements.	
QS4	Verify Auditee's management has defined and communicated areas which authorized personnel are allowed to access. *ISO 22716:2007 - Clause 3.3.1.3 Personnel - Key Responsibilities - Management Responsibilities* *2013 FDA Draft Cosmetic cGMP Guidance - 5(f)* *ANSI 455-3 - 4.2.2*	**22716 - 3.3.1.3 Personnel - Key Responsibilities - Management Responsibilities** Management should define and communicate the areas in which authorized personnel are allowed to access. **2013 FDA Draft Cosmetic cGMP Guidance - 5(f)** Only authorized personnel should be allowed access into production, storage, and product control areas **ANSI 455-3 - 4.2.2:** Access to areas by authorized personnel is defined, communicated, and controlled.	
QS5	Verify personnel: know their position in the organizational structure; know their defined responsibilities and activities; have access to and comply with documents relevant to their particular responsibility scope; comply with personal hygiene requirements; are encouraged to report irregularities or other non-conformities which may occur at the level of their responsibilities; and have adequate education training and skills to perform the assigned responsibilities and activities. *ISO 22716:2007 - Clause 3.3.2 Personnel - Key Responsibilities - Responsibilities of Personnel* *ANSI 455-3 - 4.4.27*	**22716 - 3.3.2 Personnel - Key Responsibilities - Responsibilities of Personnel** All personnel should: a) know their position in the organizational structure; b) know their defined responsibilities and activities; c) have access to and comply with documents relevant to their particular responsibility scope; d) comply with personal hygiene requirements; e) be encouraged to report irregularities or other non-conformities which may occur at the level of their responsibilities; f) have adequate education training and skills to perform the assigned responsibilities and activities. **ANSI 455-3 - 4.4.27:** Personnel understand their role in the organizational structure, know their defined responsibilities and activities, have access to and comply with documents relevant to their responsibilities, and comply with hygiene requirements.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

	Personnel		
QS6	Verify personnel are qualified based upon education, training, and experience for their assigned responsibilities and activities. *ISO 22716:2007 - Clause 3.4.1 Personnel - Training - Training and Skills* *2013 FDA Draft Cosmetic cGMP Guidance - 5(a)* *ANSI 455-3 - 4.4.28*	**22716 - 3.4.1 Personnel - Training - Training and Skills** Personnel involved in production, control, storage and shipment should have skills based on relevant training and experience acquired, or any combination thereof, that are appropriate to their responsibilities and activities. **2013 FDA Draft Cosmetic cGMP Guidance - 5(a)** You should determine whether personnel supervising or performing cosmetics manufacturing or control have the education, training, and/or experience to perform their assigned functions. **ANSI 455-3 - 4.4.28:** Personnel, both permanent and temporary, must be qualified and have adequate training, experience and/or education necessary to perform job functions.	
QS7	Verify Auditee has established and implemented documented training programs for ALL personnel. *ISO 22716:2007 - Clause 3.4.2.2 Personnel - Training - Training and Good Manufacturing Practices* *ISO 22716:2007 - Clause 3.4.2.3 Personnel - Training - Training and Good Manufacturing Practices*	**22716 - 3.4.2.2 Personnel - Training - Training and Good Manufacturing Practices** The training needs of all personnel, regardless of level or seniority in the company, should be identified and a corresponding training program should be developed and implemented. **22716 - 3.4.2.3 Personnel - Training - Training and Good Manufacturing Practices** Considering the expertise and experience of the respective personnel, training courses should be tailored to be appropriate to the jobs and responsibilities of individuals.	
QS8	If Auditee does not have adequate in house resources to design and execute personnel training, verify qualified external training resources are utilized. *ISO 22716:2007 - Clause 3.4.2.4 Personnel - Training - Training and Good Manufacturing Practices*	**22716 - 3.4.2.4 Personnel - Training - Training and Good Manufacturing Practices** According to the needs and in-house resources available, training courses may be designed and executed by the company itself or with the help of expert external organizations, if necessary.	
QS9	Verify Auditee provides training on 22716 GMPs to ALL personnel. *ISO 22716:2007 - Clause 3.4.2.1 Personnel - Training - Training and Good Manufacturing Practices* *ANSI 455-3 - 4.4.29*	**22716 - 3.4.2.1 Personnel - Training - Training and Good Manufacturing Practices** Appropriate Good Manufacturing Practices training relative to the defined activities of these guidelines should be provided for all personnel. **ANSI 455-3 - 4.4.29:** Personnel are trained in GMP defined in ISO 22716.	
QS10	Verify training programs are reviewed and updated on a regular basis. Verify appropriate "refresher" training is provided to personnel on a regular basis. *ISO 22716:2007 - Clause 3.4.2.5 Personnel - Training - Training and Good Manufacturing Practices*	**22716 - 3.4.2.5 Personnel - Training - Training and Good Manufacturing Practices** Training should be regarded as a constant and on-going process that is subject to regular updates.	
QS11	Verify newly hired personnel receive training appropriate to their assigned duties, prior to the performance of their assigned duties. *ISO 22716:2007 - Clause 3.4.3 Personnel - Training - Newly Recruited Personnel* *ANSI 455-3 - 4.4.30*	**22716 - 3.4.3 Personnel - Training - Newly Recruited Personnel** Besides basic training on the theory and practice of Good Manufacturing Practices, newly recruited personnel should receive training appropriate to the duties assigned to them. **ANSI 455-3 - 4.4.30:** Newly hired personnel are trained in the duties assigned to them and the theory and practice of GMP.	
QS12	Verify timely evaluations are performed to assess knowledge and competency of trainees. *ISO 22716:2007 - Clause 3.4.4 Personnel - Training - Newly Recruited Personnel* *ANSI 455-3 - 4.4.31*	**22716 - 3.4.4 Personnel - Training - Newly Recruited Personnel** Personnel training evaluations Knowledge accumulated by personnel should be evaluated during and/or after training. **ANSI 455-3 - 4.4.31:** Personnel are evaluated during and after training.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

QS13	Verify Auditee has established and implemented written procedures for Personnel Hygiene. Verify procedures are applicable to ALL personnel in GMP areas, and includes: hand hygiene; explicit instructions on hand washing; adequate gowning to prevent product contamination; eating, drinking, smoking, and storage of personal items are restricted to designated areas; prohibition of unhygienic practices; exclusion of personnel with illness or open lesions from GMP activities; and management notification of adverse personal health conditions. *ISO 22716:2007 - Clause 3.5.1.1; 3.5.1.2; 3.5.1.3; 3.5.1.4; 3.5.1.5 Personnel - Personnel Hygiene and Health - Personnel Hygiene* *Clause 3.5.2 - Personnel Health* *2013 FDA Draft Cosmetic cGMP Guidance - 5(b); 5(c); 5(d)* *ANSI 455-3 - 4.1.5; ANSI 455-3 - 4.1.6; ANSI 455-3 - 4.1.7; ANSI 455-3 - 4.1.8*	**22716 - 3.5.1.1:** Hygiene programs should be established and adapted to the needs of the plant. These requirements should be understood and followed by every person whose activities take them into production, control and storage areas. **22716 - 3.5.1.2:** Personnel should be instructed to use hand washing facilities. **22716 - 3.5.1.3:** Every person entering production, control and storage areas should wear appropriate clothing and protective garments to avoid contamination of cosmetic products. **22716 - 3.5.1.4:** Eating, drinking, chewing, smoking or the storage of food, drink or smoking materials or personal medication in the production, control and storage areas should be avoided. **22716 - 3.5.1.5:** Any unhygienic practice within the production, control and storage areas or in any other area where the product might be adversely affected should be forbidden. **22716 - 3.5.2:** Steps should be taken to ensure, as far as is practicable, that any person affected by an apparent illness or having open lesions on the exposed body surface should be excluded from direct contact with product until the condition is corrected or determined by medical personnel that the quality of cosmetic products will not be compromised. **2013 FDA Draft Cosmetic cGMP Guidance - 5(b):** Personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or contact surfaces should wear clean clothing appropriate for the duties they perform and necessary protective apparel (for example, uniforms, gloves, safety glasses, and hair restraints). **2013 FDA Draft Cosmetic cGMP Guidance - 5(c):** Personnel should also maintain adequate personnel cleanliness, and be free from abnormal sources of microbiological contamination (for example, sores and infected wounds) **2013 FDA Draft Cosmetic cGMP Guidance - 5(d):** Eating food, drinking beverages, or using tobacco should be restricted to appropriate designated areas away from storage and processing areas **ANSI 455-3 - 4.1.5:** Hygienic practices have been established to include appropriate garments, personal hygiene, hand washing and sanitization, etc. prior to starting work and at any time personnel can become soiled / contaminated. **ANSI 455-3 - 4.1.6:** Procedures have been established for use of impermeable gloves, hairnets, caps, beard covers, etc. in areas where product contamination could occur. Procedures have been established to prevent contamination from extraneous sources and unhygienic practices. **ANSI 455-3 - 4.1.7:** Procedures have been established to prevent eating, drinking, chewing, smoking or the storage of food, drink, or smoking materials or personal medication in the production, control, and storage areas. **ANSI 455-3 - 4.1.8:** Procedures have been established to prevent eating, drinking, chewing, smoking or the storage of food, drink, or smoking materials or personal medication in the production, control, and storage areas.	
QS14	Verify visitors or untrained personnel are provided training on personal hygiene, and are escorted by qualified personnel at all times. *ISO 22716:2007 - Clause 3.6 Personnel - Visitors and Untrained Personnel* *2013 FDA Draft Cosmetic cGMP Guidance - 5(e)* *ANSI 455-3 - 4.2.3*	**22716 - 3.6 Personnel - Visitors and Untrained Personnel** Visitors or untrained personnel should preferably not be taken into production, control and storage areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised. **2013 FDA Draft Cosmetic cGMP Guidance - 5(e)** All personnel and visitors should be properly supervised while in the manufacturing facility **ANSI 455-3 - 4.2.3:** A visitor policy is implemented to control access to secure areas, and visitors are provided information to assure safety and personal hygiene.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

	Documents		
QS15	Verify Auditee has established and implemented written procedures for QMS documentation. Verify procedures includes: composition of appropriate constituents; and document creation, approval, distribution, storage, revision, withdrawal, and archival. *ISO 22716:2007 - Clause 17.1.1 Documentation - Principle* *ISO 22716:2007 - Clause 17.2.1 Documentation - Type of Document* *ISO 22716:2007 - Clause 17.3.3 Documentation - Writing, Approval, and Distribution* *2013 FDA Draft Cosmetic cGMP Guidance - 1(b)* *2013 FDA Draft Cosmetic cGMP Guidance - 2(b)* *ANSI 455-3 - 4.4.32; ANSI 455-3 - 4.4.36; ANSI 455-3 - 4.4.33*	**22716 - 17.1.1 Documentation - Principle** Each company should establish, design, install and maintain its own system of documentation that is appropriate to its organizational structure and to the type of products. An electronic system can be used to prepare and manage documents. **22716 - 17.2.1 Documentation - Type of Document** Documents should be composed of constituents such as procedures, instructions, specifications, protocols, reports, methods, and records appropriate to the activities covered by these guidelines. **22716 - 17.3.3 Documentation - Writing, Approval, and Distribution** Documents should be: a) written in a legible and comprehensive way; b) approved, signed and dated by authorized persons before being used; c) prepared, updated, withdrawn, distributed, classified; d) referenced to ensure that obsolete documents are not used; e) accessible to appropriate personnel; f) removed from the job area and destroyed if they are outdated. **2013 FDA Draft Cosmetic cGMP Guidance - 1(b)** Documentation should define your organization's processes and capture every aspect of your manufacturing process. **2013 FDA Draft Cosmetic cGMP Guidance - 2(b)** Records should capture in detail the operations, procedures, deviations from procedures, justifications, instructions (including training), specifications, protocols, reports, methods, precautions, corrections and other measures, and other appropriate information related to GMPs. **ANSI 455-3 - 4.4.32:** A system has been established and maintained for creation, control, editing, and archiving documents such as procedures, instructions, specifications, protocols, reports, methods, and records appropriate to cosmetic GMP. **ANSI 455-3 - 4.4.36:** Procedures have been established that describe the requirements for record retention. Original documents are archived for a defined duration under secured storage. **ANSI 455-3 - 4.4.33:** Documents describe in appropriate detail operations that shall be carried out, precautions that shall be taken and measures that shall be applied. Documents are written in a legible and comprehensive way, approved, signed and dated by authorized persons, accessible to appropriate personnel, and removed and destroyed when out-of-date.	
QS16	Verify QMS documents adequately describe, with appropriate detail, Auditee's Quality Management System. Verify written procedures have been established and implemented for GMP activities. Verify procedures include: purpose statement; document title; revision numbers; and revision history. *ISO 22716:2007 - Clause 17.3.1 Documentation - Writing, Approval, and Distribution* *ISO 22716:2007 - Clause 17.3.2 Documentation - Writing, Approval, and Distribution* *ISO 22716:2007 - Clause 17.4 Documentation - Revision* *2013 FDA Draft Cosmetic cGMP Guidance - 1(b)* *2013 FDA Draft Cosmetic cGMP Guidance - 2(b)* *ANSI 455-3 - 4.4.33; ANSI 455-3 - 4.4.35*	**22716 - 17.3.1 Documentation - Writing, Approval, and Distribution** Documents should be defined and describe, with appropriate detail, the operations to be carried out, precautions to be taken and measures to be applied in all activities connected with these guidelines. **22716 - 17.3.2 Documentation - Writing, Approval, and Distribution** The title, nature and purpose of documents should be stated. **22716 - 17.4 Documentation - Revision** Documents should be updated, when necessary, and the revision number indicated. The reason for each revision should be retained. **2013 FDA Draft Cosmetic cGMP Guidance - 1(b)** Documentation should define your organization's processes and capture every aspect of your manufacturing process. **2013 FDA Draft Cosmetic cGMP Guidance - 2(b)** Records should capture in detail the operations, procedures, deviations from procedures, justifications, instructions (including training), specifications, protocols, reports, methods, precautions, corrections and other measures, and other appropriate information related to GMPs. **ANSI 455-3 - 4.4.33:** Documents describe in appropriate detail operations that shall be carried out, precautions that shall be taken and measures that shall be applied. Documents are written in a legible and comprehensive way, approved, signed and dated by authorized persons, accessible to appropriate personnel, and removed and destroyed when out-of-date. **ANSI 455-3 - 4.4.35:** Revision control is used for up-dated documents, with revision numbers and reason for the revision.	
QS17	Verify documents are maintained as either electronic or paper hard copies. *ISO 22716:2007 - Clause 17.2.2 Documentation - Type of Document* *2013 FDA Draft Cosmetic cGMP Guidance - 2(a)*	**22716 - 17.2.2 Documentation - Type of Document** Documents can be hard-copy papers or electronic data processing records. **2013 FDA Draft Cosmetic cGMP Guidance - 2(a)** Records should be retained in either paper or electronic format.	
QS18	Verify documents, forms, and records follow A.L.O.C.A. Good Documentation Practices. *ISO 22716:2007 - Clause 17.3.4 Documentation - Writing, Approval, and Distribution* *2013 FDA Draft Cosmetic cGMP Guidance - 2(i)* *ANSI 455-3 - 4.4.34*	**22716 - 17.3.4 Documentation - Writing, Approval, and Distribution** Records which require the entry of handwritten data should: a) indicate what is to be entered; b) be written legibly with permanent ink; c) be signed and dated; d) be corrected, if needed, leaving the original entry still readable; where appropriate, the reason for the correction should be recorded. **2013 FDA Draft Cosmetic cGMP Guidance - 2(i)** You should determine if records are developed in a timely manner after an event occurs. **ANSI 455-3 - 4.4.34:** Procedures describe GMP recordkeeping practices, e.g., permanent ink, identification of "who" and "when" for entries, and procedures for correcting entries (sign, date, explain, and not obliterate the original entry).	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

QS19	Verify archived documents are: retained per defined retention criteria, at least 12 months past product expiration date or 36 months, whichever is longer; secured and only accessible to authorized personnel; stored in a manner to ensure legibility throughout archival period. *ISO 22716:2007 - Clause 17.5.1 Documentation - Archiving* *ISO 22716:2007 - Clause 17.5.2 Documentation - Archiving* *ISO 22716:2007 - Clause 17.5.3 Documentation - Archiving* *ISO 22716:2007 - Clause 17.5.4 Documentation - Archiving*	**22716 - 17.5.1 Documentation - Archiving** Only original documents should be archived and only controlled copies should be used. **22716 - 17.5.2 Documentation - Archiving** The duration of archiving original documents should be defined according to applicable legislation and regulations. **22716 - 17.5.3 Documentation - Archiving** The storage of original documents should be properly secured. **22716 - 17.5.4 Documentation - Archiving** Documents may be archived as either electronic or hard-copies and their legibility should be ensured.	
QS20	Verify electronic data is backed up on regular intervals and stored in secure off-site location. *ISO 22716:2007 - Clause 17.5.5 Documentation - Archiving*	**22716 - 17.5.5 Documentation - Archiving** Backup data should be stored at a separate and secure location at regular intervals.	
QS21	Verify Auditee has established and implemented written procedures for Change Control. Verify procedures required QA approval and are supported with sufficient data. *ISO 22716:2007 - Clause 15 Change Control* *ANSI 455-3 - 4.3.2; ANSI 455-3 - 4.3.3*	**22716 - 15 Change Control** Changes that could affect the quality of product should be approved and performed by authorized personnel on the basis of sufficient data. **ANSI 455-3 - 4.3.2:** Changes that could affect the quality of product are approved and performed by authorized personnel and supported by data. **ANSI 455-3 - 4.3.3:** A procedure has been established to manage any change associated with the production of a cosmetic product, such as changes to specifications, formulations, raw material suppliers, equipment, process, physical plant, etc. The procedure shall describe how to document and effectively communicate changes to applicable parties in order to secure the necessary approvals prior to implementation of the change.	
	Subcontracting		
QS22	Verify Auditee has established and implemented written procedures for subcontracting or outsourcing of GMP activities (manufacturing; packaging; analysis; cleaning and sanitization of facility and site; pest control; equipment, facility, and site maintenance). Verify procedures include qualification, onboarding, and monitoring. *ISO 22716:2007 - Clause 12.3.1 Subcontracting - Contract Giver* *ISO 22716:2007 - Clause 12.2 Subcontracting - Types of Subcontracting* *ANSI 455-3 - 4.5.62*	**22716 - 12.3.1 Subcontracting - Contract Giver** The contract giver should assess the contract acceptor's ability and capacity to carry out the contracted operations. Further, the contract giver should ensure that the contract acceptor has all the means available to carry out the contract. The contract giver should assess the contract acceptor’s ability to comply with these guidelines, as appropriate, and to ensure the operations can be performed as agreed. **22716 - 12.2 Subcontracting - Types of Subcontracting** This clause concerns subcontracting of: a) manufacturing; b) packaging; c) analysis; d) cleaning, sanitization of premises; e) pest control; f) equipment and premises maintenance. **ANSI 455-3 - 4.5.62:** A documented system of communication, documentation, deviation reporting, decision making, data exchange, and change control with a subcontractor has been implemented.	
QS23	Verify Auditees assess and qualify a subcontractor based upon the subcontractor's resources, experience, competency, personnel, and ability to meet contract requirements. *ISO 22716:2007 - Clause 12.4.1 Subcontracting - Contract Acceptor* *ANSI 455-3 - 4.5.61*	**22716 - 12.4.1 Subcontracting - Contract Acceptor** The contract acceptor should ensure that they have the means, experience and competent personnel to meet the contract requirements. **ANSI 455-3 - 4.5.61:** The contract giver has assessed the contract acceptor's ability, capacity, and means to conduct the contracted operations. The contract giver has assessed the contract acceptor's ability to comply with cosmetic GMP.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

QS24	Verify agreements between Auditee and Subcontractors have been documented in written contracts that explicitly describes each parties' respective duties and responsibilities. Verify contracts include subcontractor's: restriction from outsourcing the work assigned to them, without first obtaining approval and consent from Auditee; requirement to accommodate any audits or assessments requested by the Auditee; requirement to obtain Auditee approval and consent before implementing any changes that may effect the quality of service or products provided; and role in complaint management. *ISO 22716:2007 - Clause 12.5.1 Subcontracting - Contact* *ISO 22716:2007 - Clause 12.4.2; 12.4.3; 12.4.4 Subcontracting - Contract Acceptor* *ISO 22716:2007 - Clause 14.1.3 Complaints and Recalls - Principle* *ANSI 455-3 - 4.5.62; ANSI 455-3 - 4.5.60*	**22716 - 12.5.1 Subcontracting - Contact** A contract or agreement should be drawn up between the contract giver and the contract acceptor which specifies their respective duties and responsibilities. **22716 - 12.4.2 Subcontracting - Contract Acceptor** The contract acceptor should not pass to a third party any of the work entrusted to them in the contract without the contractor giver's prior approval and consent. Arrangements should be made between the third party and the contract acceptor to ensure that all information about operations is made available to the contract giver in the same way as in the original contract. **22716 - 12.4.3 Subcontracting - Contract Acceptor** The contract acceptor should facilitate any checks and audits that the contract giver has defined in the contract. **22716 - 12.4.4 Subcontracting - Contract Acceptor** The contract acceptor should inform the contract giver of any changes that may affect the quality of the services or products provided prior to implementation unless otherwise specified in the contract. **22716 - 14.1.3 Complaints and Recalls - Principle** In the case of contracted operations, the contract giver and acceptor should agree on the process for managing complaints (see 12.1). **ANSI 455-3 - 4.5.62:** A documented system of communication, documentation, deviation reporting, decision making, data exchange, and change control with a subcontractor has been implemented. **ANSI 455-3 - 4.5.60:** A written contract or agreement is established and mutually confirmed between the contract giver and contract acceptor.	
QS25	Verify subcontractors have been provided all information required to perform their services correctly. *ISO 22716:2007 - Clause 12.3.2 Subcontracting - Contract Giver*	**22716 - 12.3.2 Subcontracting - Contract Giver** The contract giver should provide the contract acceptor with all the information required to carry out the operations correctly.	
QS26	Verify Subcontractor provides, or Auditee keeps all necessary information, data, and records related to subcontracted services. *ISO 22716:2007 - Clause 12.5.2 Subcontracting*	**22716 - 12.5.2 Subcontracting** All data should be kept or made available to the contract giver.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

	Complaint & Internal Audits		
QS27	Verify Auditee has established and implemented written procedures for Complaints. Verify procedures include: centralization of complaints with authorized personnel; adverse event reporting to FDA through MedWatch program; and periodic analysis to identify trends or recurrence of defects. *ISO 22716:2007 - Clause 14.2.1 Complaints and Recalls - Product Complaints* *ISO 22716:2007 - Clause 14.2.5 Complaints and Recalls - Product Complaints* *2013 FDA Draft Cosmetic cGMP Guidance - 10(a)(i)* *ANSI 455-3 - 4.6.11; ANSI 455-3 - 4.6.13; ANSI 455-3 - 4.6.14*	**22716 - 14.2.1 Complaints and Recalls - Product Complaints** Authorized personnel should centralize all complaints. **22716 - 14.2.5 Complaints and Recalls - Product Complaints** Complaints should be reviewed periodically to check for trends or recurrence of a defect. **2013 FDA Draft Cosmetic cGMP Guidance - 10(a)(i)** You should review product complaints, consumer adverse event reports, and product recall files and determine the following: For complaints: Whether there are SOPs for reporting , recording, filing, evaluating, and following up on both written and oral complaints. **ANSI 455-3 - 4.6.11:** Product complaints have been reviewed by a qualified person to determine if the complaint was the result of a failure of the cosmetic product to meet any of its specifications or quality requirements. **ANSI 455-3 - 4.6.13:** Complaints are periodically reviewed for trends or recurrence of a defect. **ANSI 455-3 - 4.6.14:** There is a system for investigating, reporting, and follow-up for complaints alleging adverse events involving bodily injury.	
QS28	Verify complaint investigations include: steps taken to prevent recurrence of the defect; checking of other batches to determine if they are affected; follow up, close out, and completion. *ISO 22716:2007 - Clause 14.2.4 Complaints and Recalls - Product Complaints* *ISO 22716:2007 - Clause 14.2.3 Complaints and Recalls - Product Complaints* *ANSI 455-3 - 4.6.12*	**22716 - 14.2.4 Complaints and Recalls - Product Complaints** Complaint investigations and follow-up should include: a) steps to prevent recurrence of the defect; b) checking other batches in order to determine whether they are also affected, where appropriate. **22716 - 14.2.3 Complaints and Recalls - Product Complaints** Appropriate follow-up on the concerned batch should be completed. **ANSI 455-3 - 4.6.12:** The investigation for a product complaint is appropriately extended to other batches, products, processes, etc.	
QS29	Verify complaint records are maintained, and include original complainant details and follow up information. *ISO 22716:2007 - Clause 14.2.2 Complaints and Recalls - Product Complaints*	**22716 - 14.2.2 Complaints and Recalls - Product Complaints** Any complaints concerning a product defect should be kept with the original details and follow-up information.	
QS30	Verify Auditee has established and implemented written procedures for Internal audits. Verify procedures include: frequency of performance; internal auditor qualification; and auditor independence from audit scope. *ISO 22716:2007 - Clause 16.2.1 Internal Audit - Approach* *2013 FDA Draft Cosmetic cGMP Guidance - 9(a)* *2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(i)* *2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(ii)* *ANSI 455-3 - 4.6.16*	**22716 - 16.2.1 Internal Audit - Approach** Specially designated competent personnel should conduct internal audits in an independent and detailed manner, regularly or on demand. **2013 FDA Draft Cosmetic cGMP Guidance - 9(a)** You should determine whether effective procedures for internal audits are followed. **2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(i)** At a minimum, internal audit procedures should provide that internal audits occur regularly or on demand; **2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(ii)** At a minimum, internal audit procedures should provide that internal audits are conducted by individuals who do not have direct responsibility for the matters being audited; **ANSI 455-3 - 4.6.16:** Designated competent personnel conduct internal audits in an independent manner to monitor the implementation and status of cosmetic GMP.	
QS31	Verify internal audit findings are evaluated and communicated to management and appropriate personnel. *ISO 22716:2007 - Clause 16.2.2 Internal Audit - Approach* *2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(iii)* *ANSI 455-3 - 4.6.17*	**22716 - 16.2.2 Internal Audit - Approach** All observations made during the internal audit should be evaluated and shared with appropriate management. **2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(iii)** At a minimum, internal audit procedures should provide that all observations made during the internal audit are evaluated and shared with appropriate management, production, quality control, and/or lab personnel; **ANSI 455-3 - 4.6.17:** Audit observations and results are evaluated and shared with appropriate management.	
QS32	Verify internal audit findings are formally addressed in Corrective Actions, that receive follow up to evaluate effectiveness. *ISO 22716:2007 - Clause 16.3 Internal Audit - Follow-up* *2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(iv)* *ANSI 455-3 - 4.6.18*	**22716 - 16.3 Internal Audit - Follow-up** Internal audit follow-up should confirm the satisfactory completion or implementation of corrective action. **2013 FDA Draft Cosmetic cGMP Guidance - 9(b)(iv)** At a minimum, internal audit procedures should provide that internal audit follow-up confirms the satisfactory completion or implementation of corrective actions **ANSI 455-3 - 4.6.18:** Corrective actions as a result of internal audits are implemented and evaluated for effectiveness.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

	Recalls & Returns		
QS33	Verify Auditee has established and implemented written procedures for the shipping and transportation of finished products. Verify procedures include consideration of specified finished product storage conditions and provide assurance these conditions are met during transport. *ISO 22716:2007 - Clause 8.4 Finished Products - Shipment* *ANSI 455-3 - 4.5.52*	**22716 - 8.4 Finished Products - Shipment** Measures should be taken to ensure the shipment of the defined finished product. Precautions should be taken to maintain the finished product quality, when appropriate. **ANSI 455-3 - 4.5.52:** Shipment records and conditions are defined, e.g., correct product, batch number, temperature control, as appropriate. Distribution of product occurs under conditions that protect against contamination and deterioration.	
QS34	Verify Auditee has established and implemented written procedures for Deviations. Verify procedures include: authorization by Quality; support with adequate data; and corrective actions to prevent recurrence of the deviation. *ISO 22716:2007 - Clause 13.1 Deviations* *ISO 22716:2007 - Clause 13.2 Deviations* *ANSI 455-3 - 4.7.3; ANSI 455-3 - 4.7.4*	**22716 - 13.1 Deviations** Deviations from the specified requirements should be authorized with sufficient data to support the decision. **22716 - 13.2 Deviations** Corrective action should be made to prevent recurrence of the deviation. **ANSI 455-3 - 4.7.3:** Deviations from specified requirements and/or written procedures are authorized with data to support the decision. **ANSI 455-3 - 4.7.4:** Corrective action is taken to prevent recurrence of the deviation (e.g., corrective action preventive action [CAPA]).	
QS35	Verify Auditee has established and implemented written procedures for the handling of Non-Conforming Materials (NCM). Verify procedures include investigation and disposition by Quality personnel. *ISO 22716:2007 - Clause 10.1.1; 10.1.2 Treatment of product that is out of specification - Rejected Finished Products, Bulk Products, Raw Materials, and Packaging Materials* *2013 FDA Draft Cosmetic cGMP Guidance - 2(d)* *ANSI 455-3 - 4.5.27; ANSI 455-3 - 4.7.1*	**22716 - 10.1.1 Treatment of product that is out of specification - Rejected Finished Products, Bulk Products, Raw Materials, and Packaging Materials** Investigations of rejected product or materials should be performed by personnel authorized to do so. **22716 - 10.1.2 Treatment of product that is out of specification - Rejected Finished Products, Bulk Products, Raw Materials, and Packaging Materials** Decisions to destroy or to reprocess should be approved by the personnel responsible for quality. **2013 FDA Draft Cosmetic cGMP Guidance - 2(d)** You should determine whether disposition of rejected materials or returned goods is documented. (For example, reworking operations, returns to suppliers, and disposals). **ANSI 455-3 - 4.5.27:** Rejected components, packaging, labeling, and in-process and finished products are appropriately quarantined and dispositioned. **ANSI 455-3 - 4.7.1:** Investigations of rejected product or materials are performed by authorized personnel according to a standard procedure such as an OOS procedure.	
QS36	Verify Auditee has established and implemented written procedures for the re-processing of products. Verify procedures include: identification, handling, storage, and release to ensure traceability and conformance with specifications; and QA approval. *ISO 22716:2007 - Clause 10.2.2; 10.2.1; 10.2.3 Treatment of product that is out of specification - Reprocessed Finished Products and Bulk Products* *ISO 22716:2007 - Clause 8.5.4 Finished Products - Returns* *ANSI 455-3 - 4.7.2*	**22716 - 10.2.2 Treatment of product that is out of specification - Reprocessed Finished Products and Bulk Products** The method of reprocessing should be defined and approved. **22716 - 10.2.1 Treatment of product that is out of specification - Reprocessed Finished Products and Bulk Products** If all or part of a batch of finished product or bulk product does not meet the defined acceptance criteria, a decision to reprocess in order to obtain the defined quality should be approved by personnel responsible for quality. **22716 - 10.2.3 Treatment of product that is out of specification - Reprocessed Finished Products and Bulk Products** Controls should be performed on the reprocessed finished products or bulk products. Results should be reviewed by authorized personnel in order to verify the conformity of the finished product or bulk product with the acceptance criteria. **22716 - 8.5.4 Finished Products - Returns** Measures should be established to distinguish any reprocessed return. Measures should be taken to avoid the inadvertent redistribution of unreleased finished product. **ANSI 455-3 - 4.7.2:** Methods for reprocessing are defined and approved. The Quality Unit approves decisions to destroy or reprocess rejected product or materials.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

QS37	Verify Auditee has established and implemented written procedures for returned products. Verify procedures include: receipt; storage; handling; QA investigation; QA review; QA disposition, and QA release. *ISO 22716:2007 - Clause 8.5.2 Finished Products - Returns* *ISO 22716:2007 - Clause 8.5.3 Finished Products - Returns* *ISO 22716:2007 - Clause 8.5.1 Finished Products - Returns* *2013 FDA Draft Cosmetic cGMP Guidance - 2(d)* *2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(vi)* *ANSI 455-3 - 4.5.53; ANSI 455-3 - 4.5.54*	**22716 - 8.5.2 Finished Products - Returns** Returns need to be evaluated against established criteria to determine their disposition. **22716 - 8.5.3 Finished Products - Returns** Release should be given before placing returns on the market again. **22716 - 8.5.1 Finished Products - Returns** Returns should be identified in an appropriate way and stored in defined areas. **2013 FDA Draft Cosmetic cGMP Guidance - 2(d)** You should determine whether disposition of rejected materials or returned goods is documented. (For example, reworking operations, returns to suppliers, and disposals). **2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(vi)** Laboratory controls should include provisions to ensure that returned cosmetics are examined for deterioration, contamination, and compliance with acceptance specifications **ANSI 455-3 - 4.5.53:** Procedures have been established for the handling of returned cosmetic product. **ANSI 455-3 - 4.5.54:** Returned cosmetic products have been appropriately quarantined, evaluated and dispositioned.	
QS38	Verify Auditee has established and implemented written procedures for product recalls and withdraws. Verify procedures include: explicit assignment of recall team roles and responsibilities to qualified personnel; regulatory and Certification Body notification in the event of recall; annual testing of procedures with "one-up/backward" and "one-down/forward" scenarios; ability to initiate recall operations within one business day of deciding to recall a product; and handling of recalled products. *ISO 22716:2007 - Clause 14.3.5; 14.3.1; 14.3.3; 14.3.2; 14.3.4 Complaints and Recalls - Product Recalls* *2013 FDA Draft Cosmetic cGMP Guidance - 2(g)* *ANSI 455-3 - 4.6.15*	**22716 - 14.3.5 Complaints and Recalls - Product Recalls** The product recall process should be periodically evaluated. **22716 - 14.3.1 Complaints and Recalls - Product Recalls** The authorized personnel should coordinate the recall process. **22716 - 14.3.3 Complaints and Recalls - Product Recalls** The appropriate authorities should be notified of recalls which could have an impact upon consumer safety. **22716 - 14.3.2 Complaints and Recalls - Product Recalls** Product recall operations should be capable of being initiated promptly and in a timely manner. **22716 - 14.3.4 Complaints and Recalls - Product Recalls** Recalled products should be identified and stored separately in a secure area while awaiting a decision. **2013 FDA Draft Cosmetic cGMP Guidance - 2(g)** You should determine if records are adequate to conduct an effective recall. **ANSI 455-3 - 4.6.15:** Procedures have been established to define the recall process of a product. The recall process is evaluated through a recall or mock recall exercise at least once a year.	
QS39	Verify Auditee has established and implemented written procedures for notification of UL-VS SQAC in writing without undue delay upon issuing a recall notification or receiving a Warning Letter from the FDA. *UL-VS SQAC Procedures for Certification 11.0 Complaints and Recalls*	**UL-VS SQAC Procedures for Certification:** 11.0 Complaints and Recalls In the event of a warning letter, recall or market withdrawal of product that is covered and described on the certificate's scope of certification, UL Verification Services Supplier Quality Audits & Certifications shall be notified via email to ULWarningsRecalls@ul.com without undue delay. Upon receipt of such notice, UL Verification Services Supplier Quality Audits & Certifications performs a review of the recall or warning letter, including additional information from the firm, if necessary.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

	Facilities and Equipment		
	Facility and Site		
FE1	Verify Auditee has clearly defined separate areas within their facility, with adequate physical space for each distinct GMP activity. *ISO 22716:2007 - Clause 4.2 Premises - Types of Area* *ISO 22716:2007 - Clause 4.3 Premises - Space* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(i)* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(v)* *ANSI 455-3 - 4.4.3; ANSI 455-3 - 4.4.4; ANSI 455-3 - 4.4.5*	**22716 - 4.2 Premises - Types of Area** Separate or defined areas should be provided for storage, production, quality control, ancillary, washing and toilets. **22716 - 4.3 Premises - Space** Sufficient space should be provided to facilitate operations such as receipt, storage and production. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(i)** Buildings should provide space of sufficient size and adequate organization to prevent selection errors (i.e., mix-ups) or cross contamination between consumables, raw materials, intermediate formulations (i.e., in-process materials), and finished products (This applies to containers, closures, labels and labeling materials as well.); **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(v)** Buildings should provide adequate washing, cleaning, plumbing, toilet, and locker facilities to allow for sanitary operation; cleaning of facilities, equipment, and utensils; and personal cleanliness; **ANSI 455-3 - 4.4.3:** The following areas have been clearly defined or separated: receiving, storage, QC, hand washing stations, and restrooms. **ANSI 455-3 - 4.4.4:** Facilities are of adequate size, construction, and design for their intended use such as receipt, storage, and production. **ANSI 455-3 - 4.4.5:** There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding. Flow of materials, products, and personnel is defined to prevent mix-ups.	
FE2	Verify Auditee has a defined "flow" for products, processes, and personnel to prevent mix-ups and contamination. *ISO 22716:2007 - Clause 4.4 Premises - Flow* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(i)* *ANSI 455-3 - 4.4.5; ANSI 455-3 - 4.4.2*	**22716 - 4.4 Premises - Flow** Flow of materials, products and personnel through the building or buildings should be defined in order to prevent mix-ups. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(i)** Buildings should provide space of sufficient size and adequate organization to prevent selection errors (i.e., mix-ups) or cross contamination between consumables, raw materials, intermediate formulations (i.e., in-process materials), and finished products (This applies to containers, closures, labels and labeling materials as well.); **ANSI 455-3 - 4.4.5:** There is adequate space for performing all operations and to prevent mix-ups, contaminations, and cross-contaminations during manufacturing, packaging, labeling, or holding. Flow of materials, products, and personnel is defined to prevent mix-ups. **ANSI 455-3 - 4.4.2:** Premises are located, designed, constructed and utilized to ensure protection of the product, permit efficient cleaning, sanitizing and maintenance, and to minimize the risk of mix-up of products, raw materials, and packaging materials.	
FE3	Verify personnel are provided an adequate number of washing, hand washing, toilet facilities. If appropriate, verify personnel changing rooms and showering facilities are also provided. *ISO 22716:2007 - Clause 4.6 Premises - Washing and Toilet Facilities* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(v)* *ANSI 455-3 - 4.4.7; ANSI 455-3 - 4.4.8*	**22716 - 4.6 Premises - Washing and Toilet Facilities** Adequate, clean, washing and toilet facilities should be provided for personnel. The washing and toilet facilities should be differentiated from, but accessible to, production areas. Adequate facilities for showering and changing clothes should be provided when appropriate. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(v)** Buildings should provide adequate washing, cleaning, plumbing, toilet, and locker facilities to allow for sanitary operation; cleaning of facilities, equipment, and utensils; and personal cleanliness; **ANSI 455-3 - 4.4.7:** Hand washing facilities are constructed and located in appropriate areas to ensure proper hand washing of personnel. **ANSI 455-3 - 4.4.8:** Bathrooms and wash facilities are kept clean and are not a potential source of contamination to components, products, contact surfaces, etc.	
FE4	Verify facility is adequately illuminated; lighting is installed and maintained to prevent product or material contamination. *ISO 22716:2007 - Clause 4.7.1 Premises - Lighting* *ISO 22716:2007 - Clause 4.7.2 Premises - Lighting* *ANSI 455-3 - 4.4.9; ANSI 455-3 - 4.4.10*	**22716 - 4.7.1 Premises - Lighting** Adequate lighting, that is sufficient for operations, should be installed in all areas. **22716 - 4.7.2 Premises - Lighting** Lighting should be installed in a manner to ensure containment of any debris from potential breakage. Alternatively, measures should be taken to protect the product. **ANSI 455-3 - 4.4.9:** Adequate lighting is provided in all production areas, examination areas, where equipment is cleaned and examined, etc. **ANSI 455-3 - 4.4.10:** Lighting that is suspended or located above areas where materials or equipment are exposed is of adequate construction or lighting type to prevent contamination and enable ease of cleaning.	
FE5	Verify facility has adequate ventilation or other mitigating factors to prevent product/material contamination. *ISO 22716:2007 - Clause 4.8 Premises - Ventilation* *ANSI 455-3 - 4.4.11*	**22716 - 4.8 Premises - Ventilation** Ventilation should be sufficient for the intended production operations. Alternatively, specific measures should be taken to protect the product. **ANSI 455-3 - 4.4.11:** Adequate ventilation and airflow, including appropriate filtration and bacteriological controls, are provided in all areas of the facility.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

FE6	Verify floors, walls, ceilings, and windows have been designed and constructed to facilitate cleaning and sanitation activities. *ISO 22716:2007 - Clause 4.5.1 Premises - Floors, Walls, Ceilings, Windows* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(iii)* *ANSI 455-3 - 4.4.2; ANSI 455-3 - 4.4.6*	**22716 - 4.5.1 Premises - Floors, Walls, Ceilings, Windows** Floors, walls, ceilings and windows in production areas should be designed or constructed for ease of cleaning and, if necessary, sanitization and be kept clean and in good repair. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(iii)** Buildings should provide floors, walls, and ceilings constructed of smooth, easily cleanable surfaces; **ANSI 455-3 - 4.4.2:** Premises are located, designed, constructed and utilized to ensure protection of the product, permit efficient cleaning, sanitizing and maintenance, and to minimize the risk of mix-up of products, raw materials, and packaging materials. **ANSI 455-3 - 4.4.6:** Walls, floors, ceilings, and windows can be adequately cleaned and are kept in good repair.	
FE7	Verify windows, vents, and openings are adequately screened or otherwise protected. *ISO 22716:2007 - Clause 4.5.2 Premises - Floors, Walls, Ceilings, Windows*	**22716 - 4.5.2 Premises - Floors, Walls, Ceilings, Windows** Windows should be of non-opening design where ventilation is adequate. If windows are opened to the outside environment, they should be properly screened.	
FE8	Verify plumbing system and HVAC system is installed and maintained in such a manner so that drip or condensation does not contaminate materials, products, surfaces, and equipment. *ISO 22716:2007 - Clause 4.9.1 Premises - Pipework, Drains, and Ducts* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(vi)* *ANSI 455-3 - 4.4.12*	**22716 - 4.9.1 Premises - Pipework, Drains, and Ducts** Pipework, drains and ducts should be installed in such a manner so that drip or condensation does not contaminate materials, products, surfaces and equipment. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(vi)** Buildings should provide fixtures, ducts, pipes, and drainages installed to prevent condensate or drip contamination **ANSI 455-3 - 4.4.12:** Plumbing is of adequate size and design for intended usage. Pipework, drains, and ducts shall be installed so that drip or condensation does not contaminate products.	
FE9	Verify plumbing system: has appropriate backflow prevention; is free from cross-connections; and drains are kept in clean and sanitary condition. *ISO 22716:2007 - Clause 4.9.2 Premises - Pipework, Drains, and Ducts* *ANSI 455-3 - 4.4.12; ANSI 455-3 - 4.4.13; ANSI 455-3 - 4.4.14*	**22716 - 4.9.2 Premises - Pipework, Drains, and Ducts** Drains should be kept clean and should not allow back flow. **ANSI 455-3 - 4.4.12:** Plumbing is of adequate size and design for intended usage. Pipework, drains, and ducts shall be installed so that drip or condensation does not contaminate products. **ANSI 455-3 - 4.4.13:** Floor drainage is adequate (immediate and continuous drainage, no pooling, proper drain covers, etc.). **ANSI 455-3 - 4.4.14:** Backflow and cross-connection prevention is in place.	
FE10	Verify Auditee has established and implemented written procedures to ensure sanitary design principles guide the repair, maintenance, and upgrade to Auditee's facility. *ISO 22716:2007 - Clause 4.5.3 Premises - Floors, Walls, Ceilings, Windows* *ISO 22716:2007 - Clause 4.9.3 Premises - Pipework, Drains, and Ducts*	**22716 - 4.5.3 Premises - Floors, Walls, Ceilings, Windows** New construction of production areas should incorporate considerations for proper cleaning and maintenance. Design of new construction should include smooth surfaces if appropriate and these surfaces should allow for resistance to corrosive cleaning and sanitizing agents. **22716 - 4.9.3 Premises - Pipework, Drains, and Ducts** Design considerations should be given to the following: a) exposed overhead roof beams, pipes and ducts should be avoided; b) exposed pipes should not touch walls, but be suspended from or supported by brackets, sufficiently separated to allow thorough cleaning; c) alternatively, specific measures should be taken to protect the product.	
	Equipment		
FE11	Verify equipment is of suitable design, size, and accuracy for its intended purpose and use. *ISO 22716:2007 - Clause 5.1 Equipment - Principle* *2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(ii)* *2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(iii)*	**22716 - 5.1 Equipment - Principle** Equipment should be suitable for the intended purpose and capable of being cleaned and, if necessary, sanitized and maintained. This clause applies to all equipment within the scope of these guidelines. If automated systems are introduced into activities described in these guidelines, they should take into account the application of the given relevant principles. **2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(ii)** The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be constructed to facilitate adjustment, cleaning, and maintenance; **2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(iii)** The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be of suitable size and accuracy for measuring, mixing, and weighing operations ;	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

FE12	Verify equipment is of adequate design and construction to prevent product contamination; constructed from appropriate materials; compatible with cleaning and sanitizing agents. *ISO 22716:2007 - Clause 5.2.1 Equipment - Equipment Design* *ISO 22716:2007 - Clause 5.2.4 Equipment - Equipment Design* *2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(ii)* *ANSI 455-3 - 4.5.1; ANSI 455-3 - 4.5.4*	**22716 - 5.2.1 Equipment - Equipment Design** Production equipment should be designed to prevent contamination of the product. **22716 - 5.2.4 Equipment - Equipment Design** The material used in the construction of equipment should be compatible with products and the cleaning and sanitizing agents. **2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(ii)** The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be constructed to facilitate adjustment, cleaning, and maintenance; **ANSI 455-3 - 4.5.1:** Equipment and utensils are of appropriate design so as to not contaminate components, products, or contact surfaces with lubricants, fuel, coolants, metal or glass fragments, filth or any extraneous materials, contaminated water, or other contaminants. **ANSI 455-3 - 4.5.4:** Equipment and utensils are corrosion resistant, made of nontoxic materials, and are compatible with products and the cleaning and sanitizing agents.	
FE13	Verify Work In Progress containers (hoppers, bulk tanks, totes, drums) are adequately protected from airborne contaminates. *ISO 22716:2007 - Clause 5.2.2 Equipment - Equipment Design* *ANSI 455-3 - 4.4.15; ANSI 455-3 - 4.5.2*	**22716 - 5.2.2 Equipment - Equipment Design** Bulk product containers should be protected from air contaminants, such as dust and moisture. **ANSI 455-3 - 4.4.15:** In areas where open vessels are used, there is adequate protection against contamination, e.g., use of protective coverings, physical location, use of skimming equipment, use of screening, etc. **ANSI 455-3 - 4.5.2:** Bulk product containers are protected from air contaminants such as dust and moisture.	
FE14	Verify equipment is installed with consideration of product, process, and personnel flow to prevent contamination and quality issues. *ISO 22716:2007 - Clause 5.3.2 Equipment - Installation*	**22716 - 5.3.2 Equipment - Installation** Equipment should be placed so that movement of materials, mobile equipment and personnel do not pose a risk to quality.	
FE15	Verify equipment is designed and installed to facilitate effective cleaning, sanitizing, and drainage, including installation to provide adequate access for cleaning, sanitizing, and maintenance activities. *ISO 22716:2007 - Clause 5.3.1 Equipment - Installation* *ISO 22716:2007 - Clause 5.3.3 Equipment - Installation* *ANSI 455-3 - 4.5.5*	**22716 - 5.3.1 Equipment - Installation** The design and the installation of equipment should ease its drainage in order to facilitate cleaning and sanitization. **22716 - 5.3.3 Equipment - Installation** Reasonable access under, inside and around equipment should be provided for maintenance and cleaning. **ANSI 455-3 - 4.5.5:** Equipment is designed and installed to ease drainage in order to facilitate cleaning and sanitization, and provide access under, inside and around equipment for maintenance and cleaning.	
FE16	Verify production and laboratory equipment is uniquely identified with operational status indicated; defective or inoperable equipment are identified as such and removed from service. *ISO 22716:2007 - Clause 5.3.4 Equipment - Installation* *ISO 22716:2007 - Clause 5.6.3 Equipment - Maintenance* *2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(v)* *ANSI 455-3 - 4.5.6; ANSI 455-3 - 4.5.9*	**22716 - 5.3.4 Equipment - Installation** Major equipment should be readily identifiable. **22716 - 5.6.3 Equipment - Maintenance** Defective equipment should be identified accordingly, excluded from use and isolated if possible. **2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(v)** The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be removed from use if it is defective, does not meet recommended tolerances, or cannot be repaired and calibrated immediately . **ANSI 455-3 - 4.5.6:** Major equipment has been identified and tagged or labeled. **ANSI 455-3 - 4.5.9:** Defective equipment is identified and excluded from use or isolated.	
FE17	Verify controls are in place to ensure only authorized personnel have access and the ability to use production equipment or automated systems. *ISO 22716:2007 - Clause 5.8 Equipment - Authorizations* *ANSI 455-3 - 4.5.11*	**22716 - 5.8 Equipment - Authorizations** Equipment or automated systems used in production and control should be accessed and used by authorized personnel. **ANSI 455-3 - 4.5.11:** Equipment or automated systems used in production and control are accessed and used only by authorized personnel.	

FE18	Verify Auditee has established and implemented adequate written procedures that address alternative actions to be taken in the event of equipment failure or breakdown. *ISO 22716:2007 - Clause 5.9 Equipment - Back-up Systems* *ANSI 455-3 - 4.5.12*	**22716 - 5.9 Equipment - Back-up Systems** Adequate alternative arrangements should be available for systems which need to be operated in the event of a failure or breakdown. **ANSI 455-3 - 4.5.12:** Back-up systems are available for systems which need to be operated in the event of a failure or breakdown.	
	Sanitation and Maintenance		
FE19	Verify Auditee has established and implemented written procedures for the cleaning and sanitation of their equipment, facility, and site. *ISO 22716:2007 - Clause 4.10.4 Premises - Cleaning and Sanitation* *ISO 22716:2007 - Clause 5.5.1 Equipment - Cleaning and Sanitation* *2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(i)* *ANSI 455-3 - 4.4.17; ANSI 455-3 - 4.5.7*	**22716 - 4.10.4 Premises - Cleaning and Sanitation** There should be cleaning and, if necessary, sanitization programs corresponding to specific needs of each area. **22716 - 5.5.1 Equipment - Cleaning and Sanitation** All equipment should be subject to an appropriate cleaning and, if necessary, sanitization program. **2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(i)** The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants; **ANSI 455-3 - 4.4.17:** Cleaning procedures are established and implemented for cleaning of the plant. **ANSI 455-3 - 4.5.7:** Equipment, instruments, utensils, contact surfaces etc. are cleaned and sanitized as necessary.	
FE20	If CIP equipment or continuous production is utilized, verify cleaning and sanitation procedures document effective methods and appropriate frequencies. *ISO 22716:2007 - Clause 5.5.3 Equipment - Cleaning and Sanitation*	**22716 - 5.5.3 Equipment - Cleaning and Sanitation** Where equipment is assigned to continuous production or production of successive batches of the same product, equipment should be cleaned and, if necessary, sanitized at appropriate intervals.	
FE21	Verify transfer hoses and other production accessories are cleaned and sanitized prior to storage; and are adequately stored to maintain clean and sanitary status. *ISO 22716:2007 - Clause 5.2.3 Equipment - Equipment Design* *2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(i)* *ANSI 455-3 - 4.5.3*	**22716 - 5.2.3 Equipment - Equipment Design** Transfer hoses and accessories that are not in use should be cleaned and, if necessary sanitized, kept dry and protected from dust, splash or other contamination. **2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(i)** The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be maintained in a clean and orderly condition, sanitized at appropriate times, and stored in a manner that protects against splash, dust, and other contaminants; **ANSI 455-3 - 4.5.3:** Transfer hoses and accessories that are not in use are cleaned, sanitized, kept dry, and protected from dust, splash, or other contamination.	
FE22	Verify cleaning, sanitation, and maintenance activities for Auditee's facility and equipment are performed in a manner that protects products and materials from contamination. *ISO 22716:2007 - Clause 4.10.2 Premises - Cleaning and Sanitation* *ISO 22716:2007 - Clause 5.6.2 Equipment - Maintenance*	**22716 - 4.10.2 Premises - Cleaning and Sanitation** Cleaning and, if necessary, sanitization should be carried out to achieve the objective of protecting each product. **22716 - 5.6.2 Equipment - Maintenance** Maintenance operations should not affect the quality of the product.	
FE23	Verify cleaning and sanitizing agents for Auditee's facility and equipment are: specified in procedures; free from undesirable microorganisms; and are safe and effective under the conditions of use. *ISO 22716:2007 - Clause 4.10.3 Premises - Cleaning and Sanitation* *ISO 22716:2007 - Clause 5.5.2 Equipment - Cleaning and Sanitation* *ANSI 455-3 - 4.4.18; ANSI 455-3 - 4.5.10*	**22716 - 4.10.3 Premises - Cleaning and Sanitation** Cleaning and, if necessary, sanitizing agents to be used should be specified and effective. **22716 - 5.5.2 Equipment - Cleaning and Sanitation** Cleaning and sanitizing agents should be specified and effective. **ANSI 455-3 - 4.4.18:** Cleaning and sanitizing compounds have been established for cleaning the facility. These agents are safe and effective under the conditions of use. **ANSI 455-3 - 4.5.10:** Consumables and process gases that are used and which contact cosmetic products, components, and contact surfaces are to be controlled so as not to cause contamination (e.g., filters).	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

FE24	Verify consumables (such as process gasses, cleaning agents or lubricants, used in cleaning, sanitation, or maintenance activities) for Auditee's facility and equipment are: approved for use; are handled and stored to prevent product and material contamination. *ISO 22716:2007 - Clause 5.7 Equipment - Consumables* *ISO 22716:2007 - Clause 4.12 Premises - Consumables* *ANSI 455-3 - 4.4.19; ANSI 455-3 - 4.5.10*	**22716 - 5.7 Equipment - Consumables** Consumables used for equipment should not affect the quality of the product. **22716 - 4.12 Premises - Consumables** Consumables used for premises should not affect the quality of the product. **ANSI 455-3 - 4.4.19:** Cleaning and sanitizing agents, pesticide chemicals, and fungicides have been identified, used, held and stored in a manner that protects against adulteration of raw materials and in-process or finished products, and against contamination of processing equipment, utensils, and packaging materials. **ANSI 455-3 - 4.5.10:** Consumables and process gases that are used and which contact cosmetic products, components, and contact surfaces are to be controlled so as not to cause contamination (e.g., filters).	
FE25	Verify Auditee's entire facility (interior/exterior) and site (adjacent/proximal grounds) are maintained in a clean condition. *ISO 22716:2007 - Clause 4.10.1 Premises - Cleaning and Sanitation* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)* *ANSI 455-3 - 4.4.16*	**22716 - 4.10.1 Premises - Cleaning and Sanitation** Premises used for activities described in these guidelines should be maintained in a clean condition. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)** Buildings should provide adequate filth and pest controls (Examples of filth may include any objectionable matter, contributed by animal contamination such as rodent, insect, or bird matter; or any other objectionable matter contributed by insanitary conditions.); **ANSI 455-3 - 4.4.16:** Premises are maintained in a clean and sanitary condition.	
FE26	Verify Auditee's equipment, facility (interior/exterior), and site (adjacent grounds) are maintained in good repair. *ISO 22716:2007 - Clause 4.11 Premises - Maintenance* *ISO 22716:2007 - Clause 5.6.1 Equipment - Maintenance* *ANSI 455-3 - 4.4.6; ANSI 455-3 - 4.4.20; ANSI 455-3 - 4.5.8*	**22716 - 4.11 Premises - Maintenance** Premises used in activities described in these guidelines should be maintained in a good state of repair. **22716 - 5.6.1 Equipment - Maintenance** Equipment should be regularly maintained. **ANSI 455-3 - 4.4.6:** Walls, floors, ceilings, and windows can be adequately cleaned and are kept in good repair. **ANSI 455-3 - 4.4.20:** Premises are maintained in a good state of repair. **ANSI 455-3 - 4.5.8:** Equipment, instruments, utensils, contact surfaces, etc., are maintained and inspected at routine intervals for signs of wear, damage, etc.	
FE27	Verify appropriate measures are taken to handle, store, and dispose of waste. Verify measures include: disposal in a timely and sanitary manner; adequate identification of waste containers; "flow" as to not impact production or laboratory operations; and under adequate control. *ISO 22716:2007 - Clause 11.3.2 Wastes - Flow* *ISO 22716:2007 - Clause 11.1 Wastes - Principle* *ISO 22716:2007 - Clause 11.2 Wastes - Types of Waste* *ISO 22716:2007 - Clause 11.4 Wastes - Containers* *ISO 22716:2007 - Clause 11.3.1 Wastes - Flow* *ISO 22716:2007 - Clause 11.5 Wastes - Disposal* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)* *ANSI 455-3 - 4.5.56; ANSI 455-3 - 4.5.57; ANSI 455-3 - 4.5.58; ANSI 455-3 - 4.5.59*	**22716 - 11.3.2 Wastes - Flow** Appropriate measures should be taken concerning collection, transportation, storage and disposal of wastes. **22716 - 11.1 Wastes - Principle** Wastes should be disposed of in a timely and sanitary manner. **22716 - 11.2 Wastes - Types of Waste** The company should define the different types of waste (from production and from the quality control laboratory) that could affect the quality of the product. **22716 - 11.4 Wastes - Containers** Containers of waste should be properly identified as to contents and other information, as appropriate. **22716 - 11.3.1 Wastes - Flow** The flow of waste should not impact on the production and laboratory operations. **22716 - 11.5 Wastes - Disposal** The disposal of waste should be performed in an appropriate way with an adequate level of control. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)** Buildings should provide adequate filth and pest controls (Examples of filth may include any objectionable matter, contributed by animal contamination such as rodent, insect, or bird matter; or any other objectionable matter contributed by insanitary conditions.); **ANSI 455-3 - 4.5.56:** Solid waste and trash are disposed of appropriately and not allowed to accumulate. **ANSI 455-3 - 4.5.57:** Solid waste and trash does not provide a potential source of contamination to components, products, contact surfaces, etc. **ANSI 455-3 - 4.5.58:** Hazardous waste is properly controlled so as not to provide a potential source of contamination to components, products, contact surfaces, etc. **ANSI 455-3 - 4.5.59:** Containers of waste are properly identified as to contents and other appropriate safety / hazard information.	
	Pest Control		
FE28	Verify Auditee has established and implemented an appropriate and effective Integrated Pest Management program; meeting regulatory requirements. *ISO 22716:2007 - Clause 4.13.2 Premises - Pest Control* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)* *ANSI 455-3 - 4.4.22*	**22716 - 4.13.2 Premises - Pest Control** There should be a pest control program appropriate for the premises. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)** Buildings should provide adequate filth and pest controls (Examples of filth may include any objectionable matter, contributed by animal contamination such as rodent, insect, or bird matter; or any other objectionable matter contributed by insanitary conditions.); **ANSI 455-3 - 4.4.22:** Pest control procedures are established. Controls scheduled and planned for the appropriate use of any insecticides, fungicides, fumigants, rodenticides, etc.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

FE29	Verify Auditee's facility and site is designed, constructed, and maintained to prevent attracting pests, pest ingress, and pest harborage. *ISO 22716:2007 - Clause 4.13.1; 4.13.3 Premises - Pest Control* *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)* *ANSI 455-3 - 4.4.21; ANSI 455-3 - 4.4.23*	**22716 - 4.13.1 Premises - Pest Control** Premises should be designed, constructed and maintained so as to restrict access to insects, birds, rodents, pests and other vermin. **22716 - 4.13.3 Premises - Pest Control** Measures should be taken to control the exterior of the premises to prevent attracting or harboring pests. **2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(ii)** Buildings should provide adequate filth and pest controls (Examples of filth may include any objectionable matter, contributed by animal contamination such as rodent, insect, or bird matter; or any other objectionable matter contributed by insanitary conditions.); **ANSI 455-3 - 4.4.21:** Controls have been established to prevent entrance to the facility by pests and animals, including screens and barriers, rodent traps, insect traps or lights, etc. **ANSI 455-3 - 4.4.23:** Grounds have been properly maintained to prevent attracting or harboring pests (e.g., through removal of litter and waste, cutting of grass and weeds adjacent to the plant, providing adequate drainage, etc.)	
	Material and Supplier Management		
	Receiving		
MS1	Verify Auditee has established and implemented adequate written procedures for raw materials and packaging materials. Verify procedures include receiving, identification, storage, and release. *ISO 22716:2007 - Clause 6.1 Raw materials and packaging materials - Principle* *2013 FDA Draft Cosmetic cGMP Guidance - 2(c)* *ANSI 455-3 - 4.5.15*	**22716 - 6.1 Raw materials and packaging materials - Principle** Raw materials and packaging materials that are purchased should meet defined acceptance criteria relevant to the quality of finished products. **2013 FDA Draft Cosmetic cGMP Guidance - 2(c)** You should review raw material records to determine if raw material is adequately controlled. These records may include origin, receipt, examination, testing, disposition, and use records. **ANSI 455-3 - 4.5.15:** Receiving, sampling, testing, release procedures have been established.	
MS2	Verify Auditee has established and implemented written procedures for Supplier Approval. Verify procedures include: purchasing of raw materials and packaging materials; supplier qualification, evaluation, monitoring, and disqualification. *ISO 22716:2007 - Clause 6.2 Raw materials and packaging materials - Purchasing* *ANSI 455-3 - 4.5.14*	**22716 - 6.2 Raw materials and packaging materials - Purchasing** Purchasing of raw materials and packaging materials should be based on: a) evaluation and selection of the supplier; b) establishment of technical clauses such as type of selection to be conducted, acceptance criteria, actions in the case of defect or modifications, transport conditions; c) setting of relations and exchanges between the company and supplier such as questionnaire, assistance and audits. **ANSI 455-3 - 4.5.14:** Suppliers of raw materials and packaging materials are evaluated, selected, and formal relationships are established for technical clauses, acceptance criteria, defect actions, and audit.	
MS3	Verify personnel perform incoming goods/receipt inspections. Verify inspections include: reconciliation of delivered materials against purchase orders; inspection of transportation conditions; and assessment of the integrity of the packaging that raw materials and product packaging materials were shipped in. *ISO 22716:2007 - Clause 6.3.1 Raw materials and packaging materials - Receipt* *ISO 22716:2007 - Clause 6.3.2 Raw materials and packaging materials - Receipt* *ANSI 455-3 - 4.5.16*	**22716 - 6.3.1 Raw materials and packaging materials - Receipt** The purchase order, the delivery note and the delivered materials should match. **22716 - 6.3.2 Raw materials and packaging materials - Receipt** The integrity of the raw materials and packaging materials shipping containers should be checked visually. If necessary, additional checks of transport data should be performed. **ANSI 455-3 - 4.5.16:** Procedures are established and implemented for checking the integrity of shipping containers is checked, and verifying the purchase orders, delivery notes, and delivered materials match.	
MS4	Verify raw materials and packaging materials with defects are: quarantined or rejected upon receipt; segregated; and under controls to prevent their use. *ISO 22716:2007 - Clause 6.4.2 Raw materials and packaging materials - Identification and Status* *ISO 22716:2007 - Clause 6.6.6 Raw materials and packaging materials - Storage* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(v)*	**22716 - 6.4.2 Raw materials and packaging materials - Identification and Status** Raw materials and packaging materials showing defects that might affect product quality should be held pending a decision. **22716 - 6.6.6 Raw materials and packaging materials - Storage** When raw materials and packaging materials are quarantined or rejected, they should be stored in their respective physical locations or by using any other system providing the same level of assurance. **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(v)** Raw materials should be properly identified and controlled to prevent the use of materials that fail to meet acceptance specifications	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

MS5	Verify Auditee has established systems that only allow for the use of released raw materials and packaging materials; only designated qualified Quality personnel have responsibility, authority, and ability to release materials. *ISO 22716:2007 - Clause 6.5.1 Raw materials and packaging materials - Release* *ISO 22716:2007 - Clause 6.5.2 Raw materials and packaging materials - Release* *2013 FDA Draft Cosmetic cGMP Guidance - 2(c)* *ANSI 455-3 - 4.5.18*	**6.5.1 Raw materials and packaging materials - Release** Physical or alternative systems should be set up to ensure that only released raw materials and packaging materials are used. **6.5.2 Raw materials and packaging materials - Release** The release of materials should be carried out by the authorized personnel responsible for quality. **2013 FDA Draft Cosmetic cGMP Guidance - 2(c)** You should review raw material records to determine if raw material is adequately controlled. These records may include origin, receipt, examination, testing, disposition, and use records. **ANSI 455-3 - 4.5.18:** Materials are released prior to use in production by authorized personnel responsible for quality. Raw materials and packaging components meet defined specifications.	
MS6	If raw materials and packaging materials are accepted based upon supplier COA, verify supplier is fully qualified and has appropriate performance history. *ISO 22716:2007 - Clause 6.5.3 Raw materials and packaging materials - Release* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iv)* *ANSI 455-3 - 4.5.19*	**22716 - 6.5.3 Raw materials and packaging materials - Release** Raw materials and packaging materials can be accepted on the basis of the supplier certificate of analysis only if there are established technical requirements, experience and knowledge of the supplier, supplier audit and agreed supplier's test methods. **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iv)** Raw materials should be sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage (Animal and vegetable origin materials and those produced by cold processing methods should be reviewed for filth and/or microorganism contamination.); **ANSI 455-3 - 4.5.19:** If a certificate of analysis (COA) is used to confirm the component, the supplier shall be qualified and documentation shall be maintained for this qualification.	
MS7	Verify raw materials and packaging materials are uniquely identified upon receipt, and clearly identified as to: supplier; product name; receiving records; date of receipt; supplier lot code. *ISO 22716:2007 - Clause 6.4.1 Raw materials and packaging materials - Identification and Status* *ISO 22716:2007 - Clause 6.4.4 Raw materials and packaging materials - Identification and Status* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iii)* *ANSI 455-3 - 4.5.17*	**22716 - 6.4.1 Raw materials and packaging materials - Identification and Status** Containers of raw materials and packaging materials should be labelled in order to identify the material and the batch information. **22716 - 6.4.4 Raw materials and packaging materials - Identification and Status** Identification of raw materials and packaging materials should contain the following information: a) name of the product marked on the delivery note; b) name of the product as given by the company, if different from the name given by the supplier and/or its code number; c) date or number of receipt, if appropriate; d) supplier's name; e) batch reference given by the supplier and the one given at receipt, if different. **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iii)** Raw materials should be maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine); **ANSI 455-3 - 4.5.17:** Containers of raw materials and packaging materials are labeled with the name of the material, date of receipt, supplier name, batch reference, or control number, or both, and material status.	
MS8	If raw materials and packaging materials are re-packaged, verify label and identification information is appropriately transferred. *ISO 22716:2007 - Clause 6.6.5 Raw materials and packaging materials - Storage*	**22716 - 6.6.5 Raw materials and packaging materials - Storage** When raw materials and packaging materials are repacked, they should carry the same labelling as at origin.	
MS9	Verify finished product containers indicate: product name; batch number; required storage condition and duration; quantity. *ISO 22716:2007 - Clause 8.3.4 Finished Products - Storage*	**22716 - 8.3.4 Finished Products - Storage** Identification of finished product containers should indicate: a) name or identifying code; b) batch number; c) storage conditions when such information is critical to assure the quality of the product; d) quantity.	
MS10	Verify the status of raw materials, packaging materials, bulk, WIP, and finished product is appropriately identified. *ISO 22716:2007 - Clause 6.4.3 Raw materials and packaging materials - Identification and Status* *ISO 22716:2007 - Clause 8.3.3 Finished Products - Storage* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iii)*	**22716 - 6.4.3 Raw materials and packaging materials - Identification and Status** Raw materials and packaging materials should be identified in an appropriate way according to their status such as accepted, rejected or quarantined. Other systems can replace this physical system of identification, if they ensure the same level of assurance. **22716 - 8.3.3 Finished Products - Storage** When finished products are released, quarantined or rejected, they should be stored in their respective physical locations or by using any other system providing the same level of assurance. **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iii)** Raw materials should be maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine);	

MS11	Verify any raw, packaging, or labeling materials returned to storage after weighing, packaging, or labeling operations were determined acceptable for return; adequately stored and identified. *ISO 22716:2007 - Clause 7.2.7 Production - Manufacturing Operations - Re-stocking Raw Materials* *ISO 22716:2007 - Clause 7.3.7 Production - Packaging Operations - Re-stocking of Packaging Materials* *ANSI 455-3 - 4.5.36; ANSI 455-3 - 4.5.45*	**22716 - 7.2.7 Production - Manufacturing Operations - Re-stocking Raw Materials** If raw materials remain unused after weighing and are intended and deemed acceptable to return to stock, their containers should be closed and properly identified. **22716 - 7.3.7 Production - Packaging Operations - Re-stocking of Packaging Materials** If packaging materials remain unused after packaging operations and are intended and deemed acceptable to return to stock, their containers should be closed and properly identified. **ANSI 455-3 - 4.5.36:** Unused raw materials returned to stock are properly closed, identified, and stored. **ANSI 455-3 - 4.5.45:** Unused packaging materials returned to stock are properly closed, identified, and stored.	
	Storage		
MS12	Verify Auditee is capable of providing and maintaining adequate environmental conditions (temperature, humidity, and light) within their facility, as required per material and product specifications. *ISO 22716:2007 - Clause 6.6.1 Raw materials and packaging materials - Storage* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(i)*	**22716 - 6.6.1 Raw materials and packaging materials - Storage** Storage conditions should be appropriate for each raw material and packaging material. **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(i)** Raw materials should be stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.);	
MS13	Verify raw materials, packaging materials, bulk product, WIP, and finished product are appropriately stored and handled; in defined areas; under suitable conditions; and for a defined duration in accordance with specifications. *ISO 22716:2007 - Clause 6.6.4 Raw materials and packaging materials - Storage* *ISO 22716:2007 - Clause 6.6.2 Raw materials and packaging materials - Storage* *ISO 22716:2007 - Clause 7.2.6.1 Production - Manufacturing Operations - Bulk Product Storage* *ISO 22716:2007 - Clause 8.3.1 Finished Products - Storage* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(i)* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(ii)* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(vii)* *ANSI 455-3 - 4.5.20; ANSI 455-3 - 4.5.35; ANSI 455-3 - 4.5.49*	**22716 - 6.6.4 Raw materials and packaging materials - Storage** Containers of raw materials and packaging materials should be closed and should be stored off the floor. **22716 - 6.6.2 Raw materials and packaging materials - Storage** Raw materials and packaging materials should be stored and handled in a manner appropriate to their characteristics. **22716 - 7.2.6.1 Production - Manufacturing Operations - Bulk Product Storage** Bulk product should be stored in suitable containers, in defined areas, and under appropriate conditions. **22716 - 8.3.1 Finished Products - Storage** Finished products should be stored in defined areas under appropriate conditions for an appropriate length of time. If necessary, finished products should be monitored while stored. **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(i)** Raw materials should be stored and handled to prevent mistakes (i.e., mix-ups or selection errors), contamination with microorganisms or other chemicals, and degradation from exposure to excessive environmental conditions (e.g., heat, cold, sunlight, moisture, etc.); **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(ii)** Raw materials should be held in closed containers and stored off the floor; **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(vii)** Procedures should include provisions to ensure that the storage and handling of packaging materials that are intended to come into direct contact with the product prevent selection errors and microbiological or chemical contamination; **ANSI 455-3 - 4.5.20:** Raw materials and packaging materials are stored and handled to maintain their quality, e.g., containers are closed and stored off the floor. **ANSI 455-3 - 4.5.35:** Bulk product is stored in suitable containers under appropriate conditions, and with defined maximum storage duration. In-process materials requiring specific holding conditions (temperature, humidity etc.) are stored appropriately. **ANSI 455-3 - 4.5.49:** Finished product is stored in a designated area under appropriate conditions, and under a defined maximum storage time.	
MS14	Verify environmental conditions are actively monitored; monitoring is valid; and environmental conditions meet material specifications. *ISO 22716:2007 - Clause 6.6.3 Raw materials and packaging materials - Storage* *ANSI 455-3 - 4.5.21*	**22716 - 6.6.3 Raw materials and packaging materials - Storage** Specific storage conditions should be respected and monitored, where appropriate. **ANSI 455-3 - 4.5.21:** Specific storage condition requirements are controlled and monitored.	
MS15	Verify product storage areas are organized. *ISO 22716:2007 - Clause 8.3.2 Finished Products - Storage*	**22716 - 8.3.2 Finished Products - Storage** Storage areas should permit organized storage.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

MS16	Verify Auditee has established and implemented written procedures for "re-qualification" of raw materials, bulk, WIP, and finished products. Verify procedures include re-qualification for expired materials, and after an appropriate defined period. *ISO 22716:2007 - Clause 6.7 Raw materials and packaging materials - Re-evaluation* *ISO 22716:2007 - Clause 7.2.6.3 Production - Manufacturing Operations - Bulk Product Storage* *ANSI 455-3 - 4.5.24*	**22716 - 6.7 Raw materials and packaging materials - Re-evaluation** A system should be set up to re-evaluate materials as appropriate to determining their suitability for use, after a defined period of storage. The system should be set up so as to prevent the use of materials which require re-evaluation. **22716 - 7.2.6.3 Production - Manufacturing Operations - Bulk Product Storage** When this duration is reached, the bulk product should be re-evaluated before use. **ANSI 455-3 - 4.5.24:** A system of re-evaluation is implemented to determine suitability of use after a defined period of storage.	
MS17	Verify the maximum storage duration for bulk products and WIP has been defined, and expiration dates are indicated on bulk products and WIP. *ISO 22716:2007 - Clause 7.2.6.2 Production - Manufacturing Operations - Bulk Product Storage*	**22716 - 7.2.6.2 Production - Manufacturing Operations - Bulk Product Storage** The maximum bulk product storage duration should be defined.	
MS18	Verify raw material and finished product rotation follows First In First Out/First Expired First Out, as applicable. *ISO 22716:2007 - Clause 6.6.7 Raw materials and packaging materials - Storage* *ISO 22716:2007 - Clause 8.3.5 Finished Products - Storage* *ANSI 455-3 - 4.5.22; ANSI 455-3 - 4.5.50*	**22716 - 6.6.7 Raw materials and packaging materials - Storage** Measures should be set up to ensure stock turnover. Except in special circumstances, stock rotation should ensure that the oldest released stock is used first. **22716 - 8.3.5 Finished Products - Storage** Measures should be set up to ensure stock turnover. Except in special circumstances, stock rotation should ensure that the oldest released stock is used first. **ANSI 455-3 - 4.5.22:** Stock turnover and rotation procedures are implemented, e.g., first in, first out (FIFO). **ANSI 455-3 - 4.5.50:** Finished goods stock turnover and rotation procedures are implemented, e.g., FIFO.	
MS19	Verify Auditee has established and implemented written procedures for the periodic inventory of raw materials and finished products. Verify procedures include: appropriate frequency; acceptable variance; and required investigations of discrepancies with corrective actions. *ISO 22716:2007 - Clause 6.6.8 Raw materials and packaging materials - Storage* *ISO 22716:2007 - Clause 8.3.6 Finished Products - Storage* *ANSI 455-3 - 4.5.23; ANSI 455-3 - 4.5.51*	**22716 - 6.6.8 Raw materials and packaging materials - Storage** Periodic inventory should be performed to ensure stock reliability. Any significant discrepancy should be investigated and corrective action taken. **22716 - 8.3.6 Finished Products - Storage** Periodic inventory checks should be performed to: a) ensure inventory accuracy; b) ensure that acceptance criteria are met. Any significant discrepancy should be investigated. **ANSI 455-3 - 4.5.23**: Periodic inventory is performed to ensure stock reliability. **ANSI 455-3 - 4.5.51:** Periodic inventory is performed to ensure inventory accuracy, acceptance criteria are met, and overage stock is addressed.	
	Water System		
MS20	Verify Auditee has established and implemented written procedures for the operation and maintenance of water system used in production. Verify procedures include: defined quality specifications; parameters for water system output; monitoring and testing frequency. *ISO 22716:2007 - Clause 6.8.1 Raw materials and packaging materials - Quality of Water Used in Production* *ISO 22716:2007 - Clause 6.8.2 Raw materials and packaging materials - Quality of Water Used in Production* *2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(a)* *2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(b)* *2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(c)* *ANSI 455-3 - 4.5.25*	**22716 - 6.8.1 Raw materials and packaging materials - Quality of Water Used in Production** The water treatment system should supply a defined quality of water. **22716 - 6.8.2 Raw materials and packaging materials - Quality of Water Used in Production** Water quality should be verified by either testing or monitoring of process parameters. **2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(a)** There are established procedures for ensuring that the water used as a cosmetic ingredient is of a defined quality; **2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(b)** There are established procedures for ensuring that the water used as a cosmetic ingredient is not affected by materials used in the water treatment equipment; **2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(c)** There are established procedures for ensuring that the water used as a cosmetic ingredient is being tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality; **ANSI 455-3 - 4.5.25:** The quality of water used in production is specified, and the quality is verified by testing or monitoring of process parameters.	

MS21	Verify water system is designed and constructed: of adequate components and materials as to have no adverse impact on water quality; to facilitate needed sanitization; and to avoid stagnation and risks of contamination. *ISO 22716:2007 - Clause 6.8.3 Raw materials and packaging materials - Quality of Water Used in Production* *ISO 22716:2007 - Clause 6.8.4 Raw materials and packaging materials - Quality of Water Used in Production* *ISO 22716:2007 - Clause 6.8.5 Raw materials and packaging materials - Quality of Water Used in Production* *2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(d)* *ANSI 455-3 - 4.5.26*	**22716 - 6.8.3 Raw materials and packaging materials - Quality of Water Used in Production** The water treatment system should permit sanitization. **22716 - 6.8.4 Raw materials and packaging materials - Quality of Water Used in Production** Water treatment equipment should be set up so as to avoid stagnation and risks of contamination. **22716 - 6.8.5 Raw materials and packaging materials - Quality of Water Used in Production** Materials used in water treatment equipment should be selected to ensure that water quality is not affected. **2013 FDA Draft Cosmetic cGMP Guidance - 6(c)(i)(2)(d)** There are established procedures for ensuring that the water used as a cosmetic ingredient the entire system for supplying water used as a cosmetic ingredient is set up to avoid stagnation and risks of contamination (This system should be routinely cleaned and sanitized according to an appropriate SOP that ensures no biofilm build-up.) **ANSI 455-3 - 4.5.26:** Water sources do not act as a potential source of contamination of the cosmetic products, either due to water purity or due to the configuration and construction of the water delivery system.	
	Production System		
PS1	Verify Auditee has established and implemented Master Manufacturing Records for each bulk product. Verify MMRs contain adequate detail with regards to: product formulation; raw materials; production equipment; and manufacturing steps. *ISO 22716:2007 - Clause 7.2.1.2 Production - Manufacturing Operations - Availability of Relevant Documents* *2013 FDA Draft Cosmetic cGMP Guidance - 2(e)* *2013 FDA Draft Cosmetic cGMP Guidance - 7(a)* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iv)*	**22716 - 7.2.1.2 Production - Manufacturing Operations - Availability of Relevant Documents** Manufacturing operations should be carried out according to manufacturing documentation, including: a) suitable equipment; b) formula for the product; c) list of all raw materials identified according to relevant documents indicating batch numbers and quantities; d) detailed manufacturing operations for each stage, such as addition of raw materials, temperatures, speeds, mixing times, sampling, cleaning and, if necessary, sanitizing of equipment, and bulk product transfer. **2013 FDA Draft Cosmetic cGMP Guidance - 2(e)** You should evaluate batch production control records, which should include: i)Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch; ii)Documentation of all production steps (for example, processing, handling, transferring, holding, and filling); iii)In-process sampling, controlling, and adjusting steps; iv)Batch and finished product lot or control numbers; v)The finished products control status – accepted or rejected **2013 FDA Draft Cosmetic cGMP Guidance - 7(a)** You should determine whether written manufacturing and control SOPs have been established (for example, formulations, processing instructions, in-process control methods, packaging instructions, instructions for operating equipment). **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iv)** Procedures should include provisions to ensure that there are in-process controls to ensure product uniformity, integrity (for example, in process batch weights), accurate fill of mixing containers, and adequacy of mixing;	
PS2	Verify Batch Production Records, as well as applicable policies, procedures, and work instructions are available at each stage of manufacturing operations. *ISO 22716:2007 - Clause 7.2.1.1 Production - Manufacturing Operations - Availability of Relevant Documents* *ANSI 455-3 - 4.5.28*	**22716 - 7.2.1.1 Production - Manufacturing Operations - Availability of Relevant Documents** Relevant documentation should be available at each stage of manufacturing operations. **ANSI 455-3 - 4.5.28:** Relevant documentation is available at each stage of manufacturing operations; documentation includes suitable equipment, formula for the product, raw material list, and detailed manufacturing operations such as addition of raw materials, temperatures, mixing speeds and times, sampling, cleaning, sanitizing, and bulk product transfer.	
PS3	Verify necessary monitoring, in process control activities, and associated acceptance criteria are documented in MMR/BPRs. *ISO 22716:2007 - Clause 7.2.5.1 Production - Manufacturing Operations - In-process Control* *2013 FDA Draft Cosmetic cGMP Guidance - 2(e)*	**22716 - 7.2.5.1 Production - Manufacturing Operations - In-process Control** In-process controls and their acceptance criteria should be defined. **2013 FDA Draft Cosmetic cGMP Guidance - 2(e)** You should evaluate batch production control records, which should include: i)Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch; ii)Documentation of all production steps (for example, processing, handling, transferring, holding, and filling); iii)In-process sampling, controlling, and adjusting steps; iv)Batch and finished product lot or control numbers; v)The finished products control status – accepted or rejected	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

PS4	Verify Auditee has established and implemented written procedures for start-up checks and line clearance for manufacturing operations. *ISO 22716:2007 - Clause 7.2.2 Production - Manufacturing Operations - Start-up Checks* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iii)* *ANSI 455-3 - 4.5.29*	**22716 - 7.2.2 Production - Manufacturing Operations - Start-up Checks** Before starting any manufacturing operations, it should be ensured that: a) all documentation relevant to the manufacturing operations is available; b) all raw materials are available and released; c) suitable equipment is available for use, in working order, cleaned and, if necessary, sanitized; d) clearance of the area has been performed to avoid mixing with materials from previous operations. **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iii)** Procedures should include provisions to ensure that there are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material; **ANSI 455-3 - 4.5.29:** Start-up checks are made prior to production to ensure that all relevant documentation is available, raw materials are available and released, equipment is available for use, in working order, clean and sanitized, and material from other products is cleared from the area.	
PS5	Verify Auditee has established and implemented written procedures for the creation and assignment of batch/lot numbers. Verify procedures include: assignment of a unique batch number to each bulk product, which is traceable to finished products. *ISO 22716:2007 - Clause 7.2.3 Production - Manufacturing Operations - Assignment of Batch Number* *2013 FDA Draft Cosmetic cGMP Guidance - 2(e)* *ANSI 455-3 - 4.5.30*	**22716 - 7.2.3 Production - Manufacturing Operations - Assignment of Batch Number** A batch number should be assigned to each batch of manufactured bulk product. This number does not need to be identical with the batch number that appears on the label of the finished product, but, if not, it should be easy to relate to that number. **2013 FDA Draft Cosmetic cGMP Guidance - 2(e)** You should evaluate batch production control records, which should include: i)Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch; ii)Documentation of all production steps (for example, processing, handling, transferring, holding, and filling); iii)In-process sampling, controlling, and adjusting steps; iv)Batch and finished product lot or control numbers; v)The finished products control status – accepted or rejected **ANSI 455-3 - 4.5.30:** Batch numbers or unique identification schema are used.	
PS6	Verify equipment, raw materials, bulk materials, and WIP in production are all adequately identified, including to the batch code being processed. *ISO 22716:2007 - Clause 7.2.4.2 Production - Manufacturing Operations - Identification of In-process Operations* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(ii)* *ANSI 455-3 - 4.5.31*	**22716 - 7.2.4.2 Production - Manufacturing Operations - Identification of In-process Operations** At all times, it should be possible to identify major equipment, containers of raw materials and containers of bulk products. **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(ii)** Procedures should include provisions to ensure that major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification/designation, stage of processing and control status; **ANSI 455-3 - 4.5.31:** Containers of materials used in production, equipment, and bulk product are identified with name, batch number, status, and date.	
PS7	Verify raw materials used in manufacturing are: appropriately measured or weighed; stored in suitable containers; and appropriately identified. *ISO 22716:2007 - Clause 7.2.4.1 Production - Manufacturing Operations - Identification of In-process Operations*	**22716 - 7.2.4.1 Production - Manufacturing Operations - Identification of In-process Operations** In accordance with the formula, all raw materials should be measured or weighed, into clean and suitable containers labelled with appropriate identification or directly into the equipment used for manufacturing.	
PS8	Verify bulk product containers indicate: product name; batch number; and storage requirements to assure product quality. *ISO 22716:2007 - Clause 7.2.4.3 Production - Manufacturing Operations - Identification of In-process Operations*	**22716 - 7.2.4.3 Production - Manufacturing Operations - Identification of In-process Operations** Identification of containers of bulk products should indicate: a) name or identifying code; b) batch number; c) storage conditions when such information is critical to assure the quality of the product.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

PS9	Verify Auditee has established and implemented written procedures for the monitoring, performance, and recording of in process controls. Verify procedures require out of specification events to be investigated. *ISO 22716:2007 - Clause 7.2.5.2 Production - Manufacturing Operations - In-process Control* *ISO 22716:2007 - Clause 7.2.5.3 Production - Manufacturing Operations - In-process Control* *ISO 22716:2007 - Clause 7.3.6.2 Production - Packaging Operations - In-process Control* *ISO 22716:2007 - Clause 7.3.6.3 Production - Packaging Operations - In-process Control* *ANSI 455-3 - 4.5.32; ANSI 455-3 - 4.5.42; ANSI 455-3 - 4.5.46; ANSI 455-3 - 4.5.33; ANSI 455-3 - 4.5.34; ANSI 455-3 - 4.5.43; ANSI 455-3 - 4.5.44*	**22716 - 7.2.5.2 Production - Manufacturing Operations - In-process Control** In-process controls should be performed according to a defined program. **22716 - 7.2.5.3 Production - Manufacturing Operations - In-process Control** Any result outside the acceptance criteria should be reported and appropriately investigated. **22716 - 7.3.6.2 Production - Packaging Operations - In-process Control** In-process controls should be performed according to a defined program. **22716 - 7.3.6.3 Production - Packaging Operations - In-process Control** Any result that is outside the acceptance criteria should be reported and appropriately investigated. **ANSI 455-3 - 4.5.32:** In-process controls and specifications have been established for in-process material and batches during production, and such tests and controls are performed. **ANSI 455-3 - 4.5.42**: In-process controls and specifications have been established for in-process materials and products during packaging, and such tests and controls are performed. **ANSI 455-3 - 4.5.46**: Specifications have been established for finished products, and finished product meets the defined acceptance criteria. **ANSI 455-3 - 4.5.33:** A system has been established to determine if all specifications have been met for in-process materials and batches during production. **ANSI 455-3 - 4.5.34:** Procedures and controls have been established for investigation and handling of in-process materials that do not meet specification requirements. **ANSI 455-3 - 4.5.43:** A system has been established to determine if all specifications during packaging operations have been met. **ANSI 455-3 - 4.5.44:** Procedures and controls have been established for investigation and handling of packaging operations and products that do not meet specification requirements.	
	Packaging System		
PA1	Verify Auditee has established and implemented Master Manufacturing Records for each finished product. Verify MMRs contain adequate detail with regards to: packaging/labeling materials; packaging/labeling equipment; and packaging/labeling steps. *ISO 22716:2007 - Clause 7.3.1.2 Production - Packaging Operations - Availability of Relevant Documents* *2013 FDA Draft Cosmetic cGMP Guidance - 2(e)* *2013 FDA Draft Cosmetic cGMP Guidance - 7(a)* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iv)*	**22716 - 7.3.1.2 Production - Packaging Operations - Availability of Relevant Documents** Packaging operations should be carried out according to packaging documentation including: a) suitable equipment; b) list of packaging materials defined for the intended finished product; c) detailed packaging operations such as filling, closing, labelling, and coding. **2013 FDA Draft Cosmetic cGMP Guidance - 2(e)** You should evaluate batch production control records, which should include: i)Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch; ii)Documentation of all production steps (for example, processing, handling, transferring, holding, and filling); iii)In-process sampling, controlling, and adjusting steps; iv)Batch and finished product lot or control numbers; v)The finished products control status – accepted or rejected **2013 FDA Draft Cosmetic cGMP Guidance - 7(a)** You should determine whether written manufacturing and control SOPs have been established (for example, formulations, processing instructions, in-process control methods, packaging instructions, instructions for operating equipment). **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iv)** Procedures should include provisions to ensure that there are in-process controls to ensure product uniformity, integrity (for example, in process batch weights), accurate fill of mixing containers, and adequacy of mixing;	
PA2	Verify Batch Production Records, as well as applicable policies, procedures, and work instructions are available at each stage of packaging and labeling operations. *ISO 22716:2007 - Clause 7.3.1.1 Production - Packaging Operations - Availability of Relevant Documents* *ANSI 455-3 - 4.5.37*	**22716 - 7.3.1.1 Production - Packaging Operations - Availability of Relevant Documents** Relevant documentation should be available at each stage of packaging operations. **ANSI 455-3 - 4.5.37:** Relevant documentation is available at each stage of packaging operations; documentation includes suitable equipment, packaging material list, and detailed packaging operations such as filling, closing, labelling, and coding.	
PA3	Verify necessary monitoring, in process control activities, and associated acceptance criteria are documented in MMR/BPRs. *ISO 22716:2007 - Clause 7.3.6.1 Production - Packaging Operations - In-process Control* *2013 FDA Draft Cosmetic cGMP Guidance - 2(e)*	**22716 - 7.3.6.1 Production - Packaging Operations - In-process Control** In-process controls and their acceptance criteria should be defined. **2013 FDA Draft Cosmetic cGMP Guidance - 2(e)** You should evaluate batch production control records, which should include: i)Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch; ii)Documentation of all production steps (for example, processing, handling, transferring, holding, and filling); iii)In-process sampling, controlling, and adjusting steps; iv)Batch and finished product lot or control numbers; v)The finished products control status – accepted or rejected	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

PA4	Verify Auditee has established and implemented written procedures for start-up checks and line clearance for packaging and labeling operations, including checking or verification of on-line control equipment at an adequate frequency. *ISO 22716:2007 - Clause 7.3.2 Production - Packaging Operations - Start-up Checks* *ISO 22716:2007 - Clause 7.3.5 Production - Packaging Operations - Checks of On-line Control Equipment* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iii)* *ANSI 455-3 - 4.5.38; ANSI 455-3 - 4.5.41*	**22716 - 7.3.2 Production - Packaging Operations - Start-up Checks** Before starting any packaging operation, it should be ensured that: a) the area has been cleared of materials to avoid mixing with materials from previous operations; b) all documentation relevant to the packaging operations, is available; c) all packaging materials are available; d) suitable equipment is available for use, in working order, cleaned and, if necessary, sanitized; e) any coding to permit identification of the product is defined. **22716 - 7.3.5 Production - Packaging Operations - Checks of On-line Control Equipment** If used, on-line control equipment should be regularly checked according to a defined program. **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(iii)** Procedures should include provisions to ensure that there are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material; **ANSI 455-3 - 4.5.38:** Start-up checks are made prior to packaging to ensure that all relevant documentation is available, packaging materials are available and released, equipment is available for use, in working order, clean and sanitized, coding for the product is defined, and material from other products is cleared from the area. **ANSI 455-3 - 4.5.41:** On-line control equipment is checked, verified, or calibrated, or both, according to a defined program.	
PA5	Verify each unit, of each batch of finished products, is assigned a unique batch number that is traceable to bulk products. *ISO 22716:2007 - Clause 7.3.3.2 Production - Packaging Operations - Assignment of Batch Number* *ISO 22716:2007 - Clause 7.3.3.1 Production - Packaging Operations - Assignment of Batch Number* *2013 FDA Draft Cosmetic cGMP Guidance - 2(e)* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(viii)* *ANSI 455-3 - 4.5.39*	**22716 - 7.3.3.2 Production - Packaging Operations - Assignment of Batch Number** This number does not need to be identical with the batch number that appears on the label of the bulk product, but, if not, it should be easy to relate to that number. **22716 - 7.3.3.1 Production - Packaging Operations - Assignment of Batch Number** A batch number should be assigned to each unit of finished product. **2013 FDA Draft Cosmetic cGMP Guidance - 2(e)** You should evaluate batch production control records, which should include: i)Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch; ii)Documentation of all production steps (for example, processing, handling, transferring, holding, and filling); iii)In-process sampling, controlling, and adjusting steps; iv)Batch and finished product lot or control numbers; v)The finished products control status – accepted or rejected **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(viii)** Procedures should include provisions to ensure that finished product packages bear permanent meaningful, unique lot or control numbers and you have a coding system that corresponds to these numbers **ANSI 455-3 - 4.5.39:** Batch/lot numbers or unique identification schema are used on each unit of packaged product.	
PA6	Verify packaging and labeling equipment is adequately identified as to the batch code being processed. *ISO 22716:2007 - Clause 7.3.4 Production - Packaging Operations - Packaging Line Identification* *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(ii)* *ANSI 455-3 - 4.5.40*	**22716 - 7.3.4 Production - Packaging Operations - Packaging Line Identification** At all times, it should be possible to identify the packaging line with its name or identifying code, the name or identifying code of the finished product and the batch number. **2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(ii)** Procedures should include provisions to ensure that major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification/designation, stage of processing and control status; **ANSI 455-3 - 4.5.40:** Packaging line, the name or identifying code of the finished product, and batch number are identified.	
PA7	If packaging and labeling are separate activities (e.g. brite stock), verify Auditee has established and implemented written procedures to prevent mix-ups or mislabeling. *ISO 22716:2007 - Clause 7.3.8 Production - Packaging Operations - Identification and Handling of Work-in progress*	**22716 - 7.3.8 Production - Packaging Operations - Identification and Handling of Work-in progress** Filling and labelling is usually a continuous process. Where this is not the case, special measures including segregation and identification should be applied so that no mix-ups or mislabeling can occur.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

	Laboratory System		
LS1	Verify Auditee has established and implemented written procedures for QA/QC/Laboratory. Verify procedures include: roles, responsibilities, and authorities; Quality's responsibility for sampling, testing, and release of materials and products. *ISO 22716:2007 - Clause 9.1.2 Quality control laboratory - Principle* *2013 FDA Draft Cosmetic cGMP Guidance - 2(f)* *ANSI 455-3 - 4.5.15; ANSI 455-3 - 4.6.1; ANSI 455-3 - 4.6.2; ANSI 455-3 - 4.6.6*	**22716 - 9.1.2 Quality control laboratory - Principle** The quality control laboratory is responsible for ensuring that the necessary and relevant controls, within its activity, are carried out for sampling and testing so that materials are released for use and products are released for shipment, only if their quality fulfils the required acceptance criteria. **2013 FDA Draft Cosmetic cGMP Guidance - 2(f)** You should evaluate laboratory control records for raw materials, in-process materials, and finished products. These records should include documentation of sampling procedures, test results, and interpretation of the test results (accepts or reject). **ANSI 455-3 - 4.5.15:** Receiving, sampling, testing, release procedures have been established. **ANSI 455-3 - 4.6.1:** Procedures have been established for laboratory operations. **ANSI 455-3 - 4.6.2:** QC responsibilities for laboratory test methods and examinations used to test specification requirements have been defined and are being followed. Proper testing procedures or programs have been established to determine if in-process and finished product specifications have been met. **ANSI 455-3 - 4.6.6:** Laboratory controls have been established and have been approved by QC (including any outside contracted laboratories). Controls include reagents and standards; calibration of instruments and equipment; sample receipt, handling and traceability; test methods; calculations and data reduction; raw data handling and storage.	
LS2	Verify acceptance criteria or specifications have been established for raw materials, packaging materials, components, labels, WIP/in process, bulk products, and finished products. Verify criteria or specifications include: appropriate quantitative, qualitative, organoleptic, analytical, and microbiological criteria. *ISO 22716:2007 - Clause 9.3 Quality control laboratory - Acceptance Criteria* *2013 FDA Draft Cosmetic cGMP Guidance - 8(a)* *ANSI 455-3 - 4.5.32; ANSI 455-3 - 4.5.42; ANSI 455-3 - 4.5.46; ANSI 455-3 - 4.5.13*	**22716 - 9.3 Quality control laboratory - Acceptance Criteria** Acceptance criteria should be established to specify the requirements to be met for raw materials, packaging materials, bulk products and finished products. **2013 FDA Draft Cosmetic cGMP Guidance - 8(a)** You should evaluate laboratory controls including sample collection techniques, specifications, test methods, laboratory equipment, and technician qualifications. **ANSI 455-3 - 4.5.32:** In-process controls and specifications have been established for in-process material and batches during production, and such tests and controls are performed. **ANSI 455-3 - 4.5.42:** In-process controls and specifications have been established for in-process materials and products during packaging, and such tests and controls are performed. **ANSI 455-3 - 4.5.46:** Specifications have been established for finished products, and finished product meets the defined acceptance criteria. **ANSI 455-3 - 4.5.13:** Specifications have been established for raw materials, labels, and packaging materials.	
LS3	Verify Quality lab has qualified personnel, equipment, and methods to perform necessary assessments to determine if raw materials, bulk product, WIP, in process, and finished products meet defined acceptance criteria. *ISO 22716:2007 - Clause 9.2.1 Quality control laboratory - Test Methods* *ISO 22716:2007 - Clause 9.2.2 Quality control laboratory - Test Methods* *2013 FDA Draft Cosmetic cGMP Guidance - 8(a)* *ANSI 455-3 - 4.5.55; ANSI 455-3 - 4.6.3*	**22716 - 9.2.1 Quality control laboratory - Test Methods** The quality control laboratory should use all test methods necessary to confirm that the product complies with acceptance criteria. **22716 - 9.2.2 Quality control laboratory - Test Methods** Controls should be performed on the basis of defined, appropriate and available test methods. **2013 FDA Draft Cosmetic cGMP Guidance - 8(a)** You should evaluate laboratory controls including sample collection techniques, specifications, test methods, laboratory equipment, and technician qualifications. **ANSI 455-3 - 4.5.55:** Laboratory facilities used are adequate for testing of components, in-process materials, and cosmetic products. This includes any outside contracted laboratories. **ANSI 455-3 - 4.6.3:** Scientifically valid test methods are used for testing of components, packaging materials, in-process materials, and final products.	
LS4	Verify Auditee has established and implemented written procedures for the calibration of production and laboratory measuring instruments. Verify procedures include: frequency of calibration; handling and investigation of out of calibration events; and handling of out of calibration instruments. *ISO 22716:2007 - Clause 5.4.1 Equipment - Calibration* *ISO 22716:2007 - Clause 5.4.3 Equipment - Calibration* *ISO 22716:2007 - Clause 5.4.2 Equipment - Calibration* *2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(iv)* *ANSI 455-3 - 4.4.24; ANSI 455-3 - 4.4.25; ANSI 455-3 - 4.6.4*	**22716 - 5.4.1 Equipment - Calibration** Laboratory and production measuring instruments that are important for the quality of the product, should be calibrated regularly. **22716 - 5.4.3 Equipment - Calibration** An out-of-calibration condition should be investigated to determine if there is any impact to the quality of the product and appropriate steps taken based on this investigation. **22716 - 5.4.2 Equipment - Calibration** If results of calibration are out-of-acceptance criteria, measuring instruments should be appropriately identified and removed from service. **2013 FDA Draft Cosmetic cGMP Guidance - 4(b)(iv)** The equipment (for example, utensils, pipework, cosmetic contact surfaces, and balances) should be calibrated regularly or checked according to an SOP with results documented, where appropriate; **ANSI 455-3 - 4.4.24:** Laboratory and production measuring instruments must be accurate and precise, calibrated where necessary, and maintained. There is a calibration and preventive maintenance (PM) program. **ANSI 455-3 - 4.4.25:** Measuring instruments with out-of-calibration results are removed from service; the condition is investigated to determine if there is any impact to product quality with appropriate corrective action. **ANSI 455-3 - 4.6.4:** All results are reviewed and used to make a decision of approval, rejection, or pending.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

LS5	Verify all laboratory consumables (reagents; solutions; reference standards; culture media; etc.) are clearly identified, including: name; strength or concentration; expiration date; preparation or open date; storage conditions; and name of preparer. *ISO 22716:2007 - Clause 9.6 Quality control laboratory - Reagents, Solutions, Reference Standards, Culture Media*	**22716 - 9.6 Quality control laboratory - Reagents, Solutions, Reference Standards, Culture Media** Reagents, solutions, reference standards, culture media, etc. should be identified by the following information: a) the name; b) its strength or concentration, when appropriate; c) expiration date, when appropriate; d) the name and/or signature of the person who prepared it, when appropriate; e) opening date; f) storage conditions, when appropriate.	
LS6	Verify Auditee has established and implemented written procedures for sampling. Verify procedures include: valid sampling method; equipment to be used; amounts to be taken; any precautions to be observed to avoid contamination or deterioration; identification of sample; frequency; and use of authorized qualified personnel. *ISO 22716:2007 - Clause 9.7.2 Quality control laboratory - Sampling* *ISO 22716:2007 - Clause 9.7.1 Quality control laboratory - Sampling* *ISO 22716:2007 - Clause 9.7.3 Quality control laboratory - Sampling* *2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iv)* *2013 FDA Draft Cosmetic cGMP Guidance - 8(a)* *2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(ii)* *ANSI 455-3 - 4.6.7*	**22716 - 9.7.2 Quality control laboratory - Sampling** Sampling should be defined in terms of: a) sampling method; b) equipment to be used; c) amounts to be taken; d) any precautions to be observed to avoid contamination or deterioration; e) identification of sample; f) frequency. **22716 - 9.7.1 Quality control laboratory - Sampling** Sampling should be performed by authorized personnel. **22716 - 9.7.3 Quality control laboratory - Sampling** Samples should be identified by: a) the name or identifying code; b) the batch number; c) the date of sampling; d) the container from which the sample was taken; e) the sampling point, if applicable. **2013 FDA Draft Cosmetic cGMP Guidance - 6(b)(iv)** Raw materials should be sampled and tested for conformance with specifications and to ensure the absence of filth, microorganisms, and other adulterants prior to processing or usage (Animal and vegetable origin materials and those produced by cold processing methods should be reviewed for filth and/or microorganism contamination.); **2013 FDA Draft Cosmetic cGMP Guidance - 8(a)** You should evaluate laboratory controls including sample collection techniques, specifications, test methods, laboratory equipment, and technician qualifications. **2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(ii)** Laboratory controls should include provisions to ensure that samples are representative of the lot; **ANSI 455-3 - 4.6.7:** Procedures have been established for the collection of representative samples for analysis including sampling method, equipment, amounts, precautions, identification, and frequency.	
LS7	Verify Auditee has established and implemented written procedures for out of specification events. Verify procedures include: required investigation, disposition, and close out by authorized personnel; and adequate justification to support re-testing. *ISO 22716:2007 - Clause 9.5.1 Quality control laboratory - Out-of-specification Results* *ISO 22716:2007 - Clause 9.5.2 Quality control laboratory - Out-of-specification Results* *ISO 22716:2007 - Clause 9.5.3 Quality control laboratory - Out-of-specification Results* *ANSI 455-3 - 4.6.5*	**22716 - 9.5.1 Quality control laboratory - Out-of-specification Results** Out-of-specification results should be reviewed by authorized personnel and properly investigated. **22716 - 9.5.2 Quality control laboratory - Out-of-specification Results** There should be sufficient justification for any re-testing to be performed. **22716 - 9.5.3 Quality control laboratory - Out-of-specification Results** After the investigation, a decision by authorized personnel should be made, notably in terms of deviation, rejection or pending. **ANSI 455-3 - 4.6.5:** Out of specification (OOS) results are reviewed by authorized personnel according to a standard procedure, and decision made in terms of deviation, rejection, or pending.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

LS8	Verify Auditee has established and implemented written procedures for the testing, approval, and release of finished products. Verify procedures include: authorized QA personnel having responsibility, authority, and ability to release finished products; review of laboratory test results by authorized personnel prior to disposition; and verification finished products meet defined specifications before release. *ISO 22716:2007 - Clause 8.2.1 Finished Products - Release* *ISO 22716:2007 - Clause 8.2.2 Finished Products - Release* *ISO 22716:2007 - Clause 9.4 Quality control laboratory - Results* *2013 FDA Draft Cosmetic cGMP Guidance - 2(e)* *ANSI 455-3 - 4.5.48*	**22716 - 8.2.1 Finished Products - Release** Prior to being placed on the market, all finished products should be controlled in accordance with established test methods and should comply with acceptance criteria. **22716 - 8.2.2 Finished Products - Release** Product release should be carried out by the authorized personnel responsible for quality. **22716 - 9.4 Quality control laboratory - Results** All results should be reviewed. After this review, a decision should be made, notably in terms of approval, rejection or pending. **2013 FDA Draft Cosmetic cGMP Guidance - 2(e)** You should evaluate batch production control records, which should include: i)Documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch; ii)Documentation of all production steps (for example, processing, handling, transferring, holding, and filling); iii)In-process sampling, controlling, and adjusting steps; iv)Batch and finished product lot or control numbers; v)The finished products control status – accepted or rejected **ANSI 455-3 - 4.5.48:** Product release is conducted by authorized personnel for quality.	
LS9	Verify Auditee has established and implemented written procedures for Raw Material and Finished Product Retain Samples. Verify procedures include: minimum sample size; storage area; storage conditions; retention period; and stability testing. *ISO 22716:2007 - Clause 9.8.1 Quality control laboratory - Retain Sample* *ISO 22716:2007 - Clause 9.8.4 Quality control laboratory - Retain Sample* *ISO 22716:2007 - Clause 9.8.2 Quality control laboratory - Retain Sample* *ISO 22716:2007 - Clause 9.8.3 Quality control laboratory - Retain Sample* *2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(iv)* *2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(v)* *ANSI 455-3 - 4.6.8; ANSI 455-3 - 4.6.9*	**22716 - 9.8.1 Quality control laboratory - Retain Sample** Samples of finished product should be retained in an appropriate manner and in designated areas. **22716 - 9.8.4 Quality control laboratory - Retain Sample** Samples of raw materials may be retained according to company practice or in accordance with local regulations. **22716 - 9.8.2 Quality control laboratory - Retain Sample** Sample size of finished products should allow analyses to be carried out in accordance with local regulations. **22716 - 9.8.3 Quality control laboratory - Retain Sample** Retain samples of finished product should be kept in their primary package for an appropriate time under the recommended storage conditions. **2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(iv)** Laboratory controls should include provisions to ensure that samples of approved lots of raw materials and finished products are retained for an adequate time period; **2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(v)** Laboratory controls should include provisions to ensure that retained samples are stored under conditions which protect their integrity (for example, to avoid contamination and deterioration), and are retested at appropriate intervals to assure continued compliance with established specifications; **ANSI 455-3 - 4.6.8:** Samples of finished products in their primary package are retained under controlled conditions for a defined time. The sample size allows analysis to be carried out for acceptance criteria. **ANSI 455-3 - 4.6.9:** Samples of raw materials are retained according to a defined program.	
	2013 FDA Draft Cosmetic cGMP Guidance & 21 CFR 700 + (Optional)		
CG1	Verify product distribution records identify the consignee, the product, and the lot or control number. *2013 FDA Draft Cosmetic cGMP Guidance - 2(h)*	**2013 FDA Draft Cosmetic cGMP Guidance - 2(h)** Initial distribution records identifying the consignee, the product, and the lot or control number should be retained.	
CG2	Verify complaint procedures address adverse events, including bodily injury. Verify complaint records include: the kind and severity of each reported injury; the body part involved; product and code numbers; whether medical treatment was sought, and, if so, the nature of the medical treatment and the name of the attending physician or other healthcare professional; whether resolution of the event occurred, with or without long-term or persistent effects (If long-term or persistent effects occurred, the nature of those effects); the name(s) and location(s) of any poison control center, government agency, physicians group, etc., to whom formula information and/or toxicity data has been provided; and reporting to FDA via MedWatch. *2013 FDA Draft Cosmetic cGMP Guidance - 10(a)(ii)* *ANSI 455-3 - 4.6.14*	**2013 FDA Draft Cosmetic cGMP Guidance - 10(a)(ii)** You should review product complaints, consumer adverse event reports, and product recall files and determine the following: For complaints alleging adverse events involving bodily injury: (1)The kind and severity of each reported injury; (2)The body part involved; (3)Product and code numbers; (4)Whether medical treatment was sought, and, if so, the nature of the medical treatment and the name of the attending physician or other healthcare professional; (5)Whether resolution of the event occurred, with or without long-term or persistent effects (If long-term or persistent effects occurred, the nature of those effects); (6)The name(s) and location(s) of any poison control center, government agency, physicians group, etc., to whom formula information and/or toxicity data has been provided; (7)Whether you are voluntarily reporting adverse events to FDA through the MedWatch program. **ANSI 455-3 - 4.6.14:** There is a system for investigating, reporting, and follow-up for complaints alleging adverse events involving bodily injury.	

UL Verification Services Inc. Cosmetic Pre-Audit Checklist

CG3	Verify adequate screening, filtering, dust, humidity, temperature, and bacteriological controls are provided to prevent product contamination. *2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(iv)* *ANSI 455-3 - 4.4.11*	**2013 FDA Draft Cosmetic cGMP Guidance - 3(b)(iv)** Buildings should provide adequate lighting and ventilation, and, if necessary for control purposes, screening, filtering, dust, humidity, temperature, and bacteriological controls; **ANSI 455-3 - 4.4.11:** Adequate ventilation and airflow, including appropriate filtration and bacteriological controls, are provided in all areas of the facility.	
CG4	Verify raw material selection, weighing, measuring, and charging are reviewed and documented by a second individual. *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(i)*	**2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(i)** Procedures should include provisions to ensure that the selection, weighing, and measuring of raw materials and the determination of finished yield are reviewed by a second individual;	
CG5	Verify Quality reviews completed BPRs. Verify review includes a comparison of actual and theoretical yields. *2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(v)* *ANSI 455-3 - 4.5.47*	**2013 FDA Draft Cosmetic cGMP Guidance - 7(b)(v)** Procedures should include provisions to ensure that the theoretical yield for a production batch is compared with the actual yield; **ANSI 455-3 - 4.5.47:** The theoretical yield for a production batch is compared with the actual yield.	
CG6	Verify identity specifications have been established for raw materials. Verify raw materials are tested for identity. *2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(i)*	**2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(i)** Laboratory controls should include provisions to ensure that raw materials (including water), in-process and finished product samples are tested or examined for identity and compliance with applicable specifications (for example, physical and chemical properties), microbial contamination, and hazards or other chemical contamination;	
CG7	Verify finished products and retain samples are tested for efficacy of preservation agents/mechanisms against microbial contaminations. Verify tests are performed under reasonable conditions of storage and use. *2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(iii)* *ANSI 455-3 - 4.3.1*	**2013 FDA Draft Cosmetic cGMP Guidance - 8(b)(iii)** Laboratory controls should include provisions to ensure that current finished product samples as well as retained product samples are tested for adequacy of preservation against microbial contamination under reasonable conditions of storage and use; **ANSI 455-3 - 4.3.1:** Current finished product samples as well as retained product samples are tested for adequacy of preservation against microbial contamination under reasonable conditions of storage and use.	
CG8	Verify Auditee has registered their establishment with FDA, in accordance with 21 CFR 710 Voluntary Registration of Cosmetic Product Establishments. *§ 710.1 Who should register.* *ANSI 455-3 - 4.1.1*	**§ 710.1 Who should register.** The owner or operator of a cosmetic product establishment which is not exempt under § 710.9 and engages in the manufacture or packaging of a cosmetic product is requested to register for each such establishment, whether or not the product enters interstate commerce. This request extends to any foreign cosmetic product establishment whose products are exported for sale in any State as defined in section 201(a)(1) of the act. No registration fee is required. **ANSI 455-3 - 4.1.1:** The Voluntary Cosmetic Registration Program (VCRP) is a US FDA reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. The VCRP applies only to cosmetic products being sold to consumers in the United States. It does not apply to cosmetic products for professional use only, such as products used in beauty salons, spas, or skin care clinics. It also does not apply to products that are not for sale. The VCRP applies to products that are cosmetics as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), section 201(i).	