ESTĒE LAUDER COMPANIES

Packaging

Supplier Quality Manual

Version 1

Estée Lauder Companies, Inc.

ESTĒE LAUDER COMPANIES

Welcome Letter

Dear Valuable Supplier,

The safety and quality of our products are the foundation on which the success of our company as well as the trust of our customers and consumers is built. As a valuable supplier to ELC, your company plays a critical role in our supply chain to assure safety and quality of our products. We value each of our suppliers as part of our team. We appreciate your dedicated support in providing safe and high-quality products to our customers and consumers.

Here enclosed you will find a copy of ELC's Packaging Supplier Quality Manual which contains requirements, guidelines, and good practices to assist your company in establishing a successful partnership with ELC. This manual should be used in conjunction with the Quality Agreement and specifications. You are expected to organize your internal teams to learn these requirements, guidelines, and good practices, incorporate them in your Quality Management System and ensure to meet them in your daily operations.

The expectations outlined in this manual have been developed by ELC after a review of product defects, quality audits of manufacturing sites and a study of product retrievals throughout the industry. This review led us to identify programs, if executed properly, that help prevent product retrievals, consumer complaints, rework and plant downtime and produce high quality, safe products. The expectations outlined in this manual are not intended to alter or eliminate any requirements that may be set in any contract, specification, or government regulation.

As ELC policies and procedures change, it is important that you visit the Supplier Portal on a regular basis to ensure the most up-to-date information.

The contents of this manual are confidential and remain the property of ELC.

Best Regards,

Steve Gong	Daniel Dowd
Global Lead of Packaging Supplier Quality	Vice President, Supplier Quality
Nirav Mehta	Allan Hafkin
Vice President, Direct Procurement	Senior Vice President, Global Packaging Development

ESTĒE LAUDER COMPANIES

Table of Contents

ESTĒE LAUDER COMPANIES

ESTĒE LAUDER COMPANIES

1. Purpose

This document aims to provide Packaging Suppliers with guidelines for development, production, packing, storage, and shipment of packaging components that are intended for use in either ELC facilities or third-party manufacturer facilities.

2. Scope

This manual applies to all packaging suppliers who manufacture packaging components and accessories for ELC.

3. Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Acceptance Criteria - numerical limits, ranges, or other suitable measures for acceptance of test results.

3.2 Accessories - products that are used to enhance or complement the application and use of cosmetic products. These accessories may include tools, applicators, containers, and other items that are used in conjunction with cosmetic products to achieve a desired image, look or effect.

3.3 Audit - systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

3.4 Batch or Lot - defined quantity of products manufactured from one process or series of processes that have homogeneous quality.

3.5 Batch or Lot number - distinctive combination of numbers, letters and/or symbols, which specifically identifies a batch or lot.

3.6 Calibration - set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.

3.7 CAPA - Corrective Action / Preventive Action - Corrective Action - A solution meant to reduce or eliminate the root cause of an identified problem. Preventive Action - Actions taken to eliminate the potential for a non-conformance to occur.

3.8 Change control - process relative to any planned or unplanned change of one or several activities, process, procedure, facility, specification covered by the Good Manufacturing Practices to ensure that all the manufactured, packaged, controlled, and stored products correspond to the defined acceptance criteria.

3.9 Cleaning - The process of removing product residue and contaminants such as dirt, dust, and grease from surfaces by mechanical and/or manual means in conjunction with appropriate cleaning chemicals. Cleaning is an essential step that needs to be performed before the sanitization procedure.

3.10 Contamination - occurrence of any undesirable matter such as chemical, physical and/or microbiological matter in the product.

3.11 Consumables - materials such as cleaning agents and lubricants that are used up during cleaning, sanitization, or maintenance operations.

3.12 CPP (Critical Process Parameter) - A process parameter whose variability might have an impact on a critical quality attribute and so must be monitored or controlled within predefined limits to ensure the process produces the desired quality.

3.13 CQA (Critical Quality Attribute) - A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

3.14 Deviation - relative to the authorization to internal organization and responsibilities deviate from specified requirements due to a planned or unplanned and, in any case, temporary

ESTĒE LAUDER COMPANIES

situation concerning one or several activities covered by the Good Manufacturing Practices, process or specification.

3.15 Deviation control - a process of managing and controlling any deviations from established standards or procedures in a systematic and controlled manner. Any deviations are identified, investigated, evaluated, and addressed in a timely and effective manner to prevent them from recurring in the future.

3.16 Finished goods (FG) - product that has undergone all stages of production, including packaging in its final container, ready for shipment.

3.17 GXP - Good 'X' Practice where 'X' is used as a collective term for various topics such as Manufacturing, Documentation, Distribution.

3.18 In-process quality control (IPQC) - controls performed during production to monitor process and quality for conformance or non-conformance and adjust the process to ensure that the product meets the defined acceptance criteria or statistical process control requirements.

3.19 Internal audit - systematic and independent examination made by qualified personnel inside the company, the aim of which is to determine whether activities covered by site policies and procedures as well as applicable local or destination market requirements and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives.

3.20 Major equipment - equipment specified in production and laboratory documents which is considered essential to the process.

3.21 Manufacturing processes -a series of process steps that transform raw materials or components into finished goods, compliant with specifications and standards.

3.22 Non-conformance - information claiming a product does not meet defined acceptance criteria.

3.23 Out-of-specification - test results that fall outside established specifications or acceptance criteria.

3.24 Packing material - materials used to pack packaging components or accessories, to protect them from damage during transportation.

3.25 Packaging components - any material employed in the packaging of a cosmetic product, excluding any outer packaging used for transportation. They are referred to as primary or secondary, depending on whether they are intended to be in direct contact with the product.

3.26 Preventive maintenance - The care and servicing of equipment at established intervals to assure equipment is in satisfactory operating condition. Maintenance, including tests, measurements, adjustments, and parts replacement is performed to prevent faults from occurring.

3.27 Plant - location where components are delivered or further handled.

3.28 Premises - physical location, buildings and supporting structures used to conduct receipt, storage, manufacturing, packaging, control and shipment of product, raw materials and packaging components or accessories.

3.29 Quality Assurance - an independent function within the organization with an aim to create and manage quality processes predominantly focused on proactive identification and management of risks to the production process and finished product.

3.30 Quality Control - a process to ensure that goods meet defined quality requirements.

3.31 Quality Notification (QN) - An electronic document created in SAP that records activities related to discrepant material disposition.

3.32 F2 Quality Notification (QN) - A specific Quality Notification used to document rejected material due to supplier issues in the SAP system.

3.33 Q2 Quality Notification (QN) - A specific Quality Notification used to request an investigation and corrective action from a supplier.

3.34 Raw material - any substance or ingredients which are part of component formulation.

3.35 Recall - decision made by a company to call back a product batch that has been put on the market.

3.36 Return to vendor (RTV) - sending packaging components back to component vendor.

ESTĒE LAUDER COMPANIES

3.37 Rework - Performing one or more additional operations, e.g. sorting, inspecting, relabel, repackage etc. for a specific attribute found to be non-conforming, on all or part of a lot of packaging components.

3.38 Sample - one or more representative elements selected from a set, to obtain information about that element or set.

3.39 Sampling - set of operations relating to the drawing and preparation of samples.

3.40 Sanitization - The process utilized to eliminate or reduce viable microbial contaminants to an acceptable level on equipment and surfaces. Surfaces must be clean for the sanitization procedure to be effective.

3.41 Scrap - any residue of a production operation, transformation or use, any substance, material, product that its holder intends for disposal.

3.42 Shipment - set of operations relative to the preparation of an order and its putting in a transport vehicle.

3.43 Abbreviations

- AQL - Acceptable Quality Level
- BOM - Bill of Materials
- CAPA - Corrective and Preventive Action
- CoA - Certificate of Analysis
- COO - Country of Origin
- CPP - Critical Process Parameters
- CQA - Critical Quality Attributes
- ELC - The Estee Lauder Companies Inc.
- FDA - Food and Drug Administration
- FMEA - Failure Mode & Effect Analysis
- FQC - Final Quality Control
- GDP - Good Documentation Practices
- GLP - Good Laboratory Practices
- GMP - Good Manufacturing Practices
- IDN - Internal Distribution Network
- IPQC - In-Process Quality Control
- IQC - Incoming Quality Control
- ISO - International Organization for Standardization
- KPI - Key Performance Indicator
- OTC - Over the Counter
- PTP - Packaging Test Procedure
- QA - Quality Assurance
- QMS - Quality Management System
- QN - Quality Notification
- RCA - Root Cause Analysis
- RDP - Regulated Drug Products
- RTV - Return to Vendor
- SKU - Stock Keeping Unit
- SOP - Standard Operating Procedure
- SPC - Statistical Process Control
- TPM - Third Party Manufacturer
- UPC - Universal Product Code

ESTĒE LAUDER COMPANIES

4. Introduction

4.1. The Estée Lauder Companies (ELC)

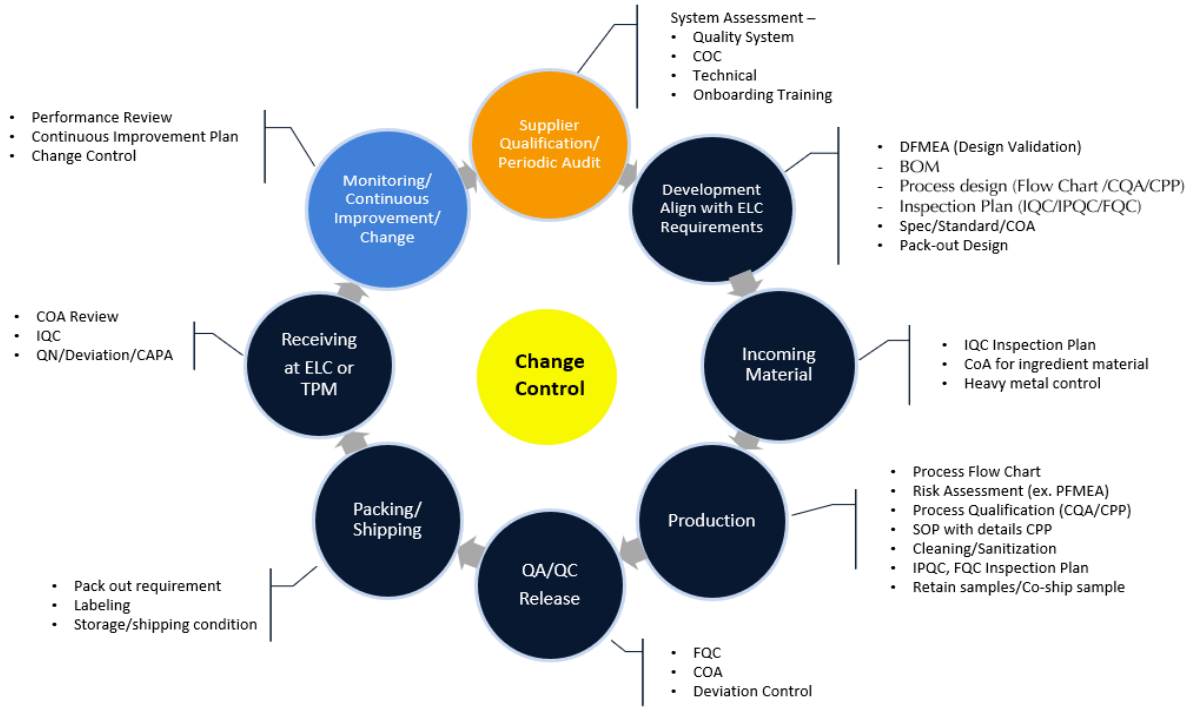
Founded in 1946, this technologically advanced, innovative company has gained a worldwide reputation for elegance, luxury, and superior quality. ELC products come with a promise to uphold the finest standards of excellence. Through extensive research and stringent product evaluation, we are pleased to offer skincare, makeup, haircare and fragrance products that are both gentle and highly effective. For additional information, please visit our website at http://www.elcompanies.com

4.2. ELC Functions Related to Suppliers

- ELC Procurement (GSR), in charge of collaborative relationship with suppliers, supplier selection, finance audit, business award, cost approval, commercial matters and performance management.
- SQA - Supplier Quality Assurance, in charge of oversight of supplier quality onboarding, supplier quality performance and drive quality improvement with suppliers.
- PKG - Packaging Development team, accountable for the packaging design, development, and specifications.
- Category Technical Packaging Engineering - responsible for the technical assessment for packaging suppliers, review and approval drawings and specifications.
- R&D - Research and Development, accountable for the formulation design, development, and specifications.
- CVE - Commercialization and Validation Engineering, in charge of filling process review and validation through line trials.
- Material Planning - in charge of material orders and delivery scheduling.
- ELC Global Quality Audit - responsible for scheduling and conducting audits of supplier's quality management system.

4.3. Supplier Quality Management

Supplier quality management covers the entire processes in below graph.



ESTĒE LAUDER COMPANIES

4.3.1. Mission

Our goal is to cultivate a top-tier supplier network that provides a competitive advantage for our brands and delivers prestigious quality to our consumers.

4.3.2. Vision

Our aim is to implement the best-in-class quality management program that ensures zero recall and critical reject by using effective risk management processes, capable associates, engaged suppliers, and efficient tools**.**

4.3.3. Strategy

Our supplier quality strategy is structured with four pillars.

4.4. Supplier Qualification

Audit and approved by GSR through the supplier qualification process. When a subcontractor is selected by ELC supplier to produce a sub-component or raw material, the supplier is responsible for audit and qualification of the subcontractors for quality assurance. When required by ELC SQA or audit team, the supplier should provide audit reports for their subcontractors.

4.4.1. Audit Checklist

The audit checklist includes general requirements from Good Manufacturing Practices, industry standards, and any applicable regulatory requirements, as well as ELC's specific needs based on the items to be supplied to ELC.

4.4.2. Audit Process

4.4.2.1 Audit Request

ELC Procurement (GSR) works with the supplier to complete an audit request form and submits it to the ELC Global Audit Group.

4.4.2.2 Audit Scheduling

The ELC Global Audit Group schedules the QA audit with the supplier and arranges for a regional auditor or external audit agency to perform an onsite or desk audit.

4.4.2.3 Audit Report

After the audit is completed, the ELC regional auditor issues an audit report to the supplier. If the audit is passed, the global auditor requests the supplier to submit a CAPA plan. If the audit is failed, the global auditor works with GSR to determine if a CAPA plan is needed. In case a CAPA plan is needed, GSR will work with the supplier to ensure agreement and commitment from the supplier.

ESTĒE LAUDER COMPANIES

4.4.2.4 Audit CAPA Plan Approval

Suppliers must submit a CAPA plan for all areas identified as non-compliant within the timeframe given by the regional auditor, even if the audit is passed. The CAPA plan must address the root cause of the non-compliance with corrective and preventive actions. The regional auditor approves the CAPA plan and provides feedback to the supplier.

4.4.2.5 Audit CAPA Implementation

After the audit CAPA plan is approved by the regional auditor, the supplier must complete all CAPA actions within the specified timelines and submit evidence to regional SQA for verification.

4.4.2.6 Audit CAPA Verification

After CAPA implementation, the supplier shall send evidence to local ELC SQA. ELC SQA verifies the evidence and provides feedback to the supplier for further improvement, if applicable.

4.4.3. Periodic Audit

The regional manager of the ELC Global Audit Group will determine the frequency of periodic audits for a facility based on a risk matrix. If a periodic audit fails, GSR will work with the Global Audit Group, SQA and the supplier to align an action plan.

4.4.4. Audit Performance Improvement

Suppliers are expected to continually improve their audit score to 90 or above. The audit score may impact their future business opportunities with ELC. To improve the audit score, suppliers are expected to incorporate the requirements in ELC's audit checklist into their internal audit checklist, so that compliance with these requirements can be audited during their internal audits.

4.5. Supplier Onboarding Training

Prior to starting business with ELC, a new supplier must contact ELC GSR for onboarding training to understand ELC's requirements. ELC GSR will work with related functions (GSR, PKG, SQA, Supplier Support, etc.) to provide an onboarding training to the new supplier. After the training, the supplier should incorporate the requirements into their internal process and procedures for training, execution, and compliance.

Process for Supplier Quality Onboarding Training.

- Plan the Training - ELC SQA works with the supplier to schedule the onboarding training.
- Execute the Training - ELC SQA conducts the onboarding training with the new supplier.
- Self-Learning - The supplier is provided with the ELC quality manual and procedures for self-learning.
- Q&A Session - ELC SQA holds a Q&A session to answer any inquires from the supplier.
- Gap Assessment by Supplier - The supplier conducts a gap assessment with support from SQA on process mapping and gap analysis against ELC requirements provided during the training.
- CAPA Plan - The supplier submits a CAPA plan to ELC SQA for alignment.
- CAPA Verification - ELC SQA verifies the implementation of CAPA at the supplier.

4.6. Quality Agreement

A Quality Agreement describes the quality responsibilities between ELC and its suppliers and helps to establish a mutual understanding of expectations. It defines the terms and responsibilities for managing the quality of goods produced for ELC. The Quality Agreement is an integral part of the ELC Supplier Qualification Program and must be in place before starting any business with ELC.

Supplier senior management must ensure that all terms are integrated into the supplier's internal quality system and that compliance with these terms is maintained.

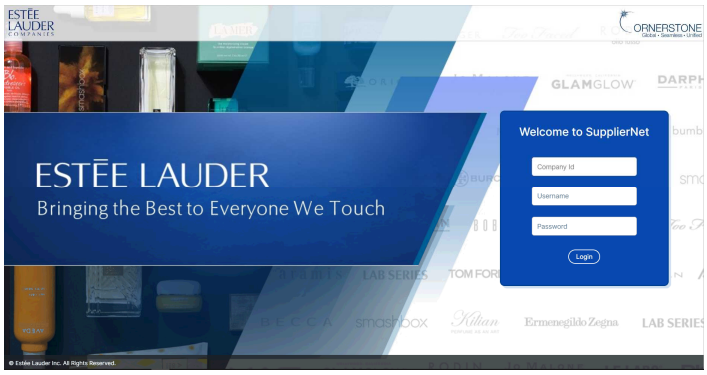
The Quality Agreement sign-off process is managed by GSR. Any specific questions about the contents can be answered and discussed with SQA.

4.7. Communications

We encourage open and active communication between ELC and our suppliers to achieve our mutual goals by working closely together and establishing open lines of communication.

4.7.1. Supplier Net

The Supplier Net is a dedicated supplier website located at http://suppliernet.elcompanies.com
It allows packaging suppliers to upload and consult packaging specifications, including drawings and artwork. Once all specifications are approved, the packaging supplier can download and print the approved specifications. It also allows suppliers to download ELC packaging procedures and Packaging Testing Procedures (PTP). For access to the system and training, please contact the Supplier Support Team at suppliersupport@estee.com.



4.7.2. Supplier Portal

The Supplier Portal is located at https://supplierportal.elcompanies.com
Supplier Portal provides you access to the following information or activity. You can contact Supplier Support Team at suppliersupport@estee.com for access and training.

- Purchase orders (with Assembly Instructions)
- Bill of Materials (BOMs) when applicable
- Perform supplier transactions within SAP
- Review and respond to Quality Notifications (QNs)
- Review Supplier Quality Rating
- Download documents: Supplier Quality Manual, Procedures, Shipper Label Manual, etc.

ESTĒE LAUDER COMPANIES

4.7.3. Contact Persons

4.7.3.1 Supplier Contacts

The supplier shall submit contact information (name, phone, and email address) for the primary quality contact and technical/regulatory contact for each applicable manufacturing site that supplies products or materials to ELC. If there is a significant change in the primary contact, the supplier must promptly update ELC GSR, SQA, and the supplier support team. The supplier is expected to proactively review access to the Supplier Portal and deactivate user accounts linked to departed personnel.

4.7.3.2 ELC SQA Contacts

We encourage suppliers to contact our local SQA directly for any questions or concerns related to the quality of products made for ELC. This includes, but is not limited to, the events listed below 4.7.4. Suppliers can contact GSR when they don't have local SQA contact information.

4.7.4. Notifying ELC of significant Events

The supplier shall immediately notify ELC SQA of any of the following events, including but not limited to:

a) Regulatory agency visits (notify within 24 hours) - If a violation is reported or recorded that potentially or specifically impacts ELC, the supplier must notify ELC GSR/SQA within 24 hours and provide ELC with a copy of any regulatory agency establishment inspection report and responses.
b) Notification by law enforcement or other authorities of a potential product security event.
c) Non-routine regulatory agency investigations, testing, sampling, reporting, or other contact or action that could affect material produced for ELC.
d) Inability to deliver materials that meet ELC specifications.
e) Out-of-specification (OOS) results identified on products produced for ELC. ELC SQA and PKG must be notified to make the final usage decision.
f) Any event that leads the supplier to suspect that a non-conformance exists in the product already shipped to ELC.
g) Discovery of potentially defective or adulterated ingredients or packaging materials associated with the product in distribution.
h) Systematic product quality defect or process control deviation that could lead to a recall or withdrawal of a finished product of ELC.
i) Product tampering or threat of tampering.
j) Any changes, such as ELC-approved suppliers, ELC-approved facility or equipment, ELC-approved manufacturing procedures, processes and/or tooling, design, specification, testing methods, sampling plan, etc., that could impact materials/products manufactured for ELC, whether planned or unplanned. Changes must be approved by ELC SQA prior to implementation. See change control in section 5.7.

5. General Requirements

Suppliers are responsible for the quality management of all activities that occur in their facility and ensuring that the product quality meets ELC's requirements and applicable regulatory requirements.

5.1. Management Responsibilities

5.1.1. General

Senior management shall demonstrate leadership and commitment concerning the quality management system by:

ESTĒE LAUDER COMPANIES

a) ensuring that ELC Quality Agreement is signed, effectively communicated and it's requirements implemented internally,
b) ensuring that GMP, regulatory and customer requirements are identified and communicated as appropriate to each level of the organization,
a) taking accountability for the effectiveness of the quality management system,
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization,
c) ensuring the integration of the quality management system requirements into the organization's business processes,
d) promoting the use of the process approach and risk-based thinking and decision-making;
e) ensuring that the resources needed for the quality management system are available,
f) communicating the importance of effective quality management and of conforming to the quality management system requirements,
g) ensuring that the quality management system achieves its intended results,
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system,
i) promoting continuous improvement culture and initiatives across the entire organization to drive Reject Reduction and Defect Decrease (R2D2) towards the long-term goal of Zero Defect,
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2. Customer Focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) Customer and applicable statutory and regulatory requirements are determined, understood, and consistently met.
b) The risks and opportunities that can affect the conformity of products and services, and the ability to enhance customer satisfaction are determined and addressed.
c) The focus on enhancing customer satisfaction is maintained and regularly measured. Remedial actions will be taken if customer satisfaction falls below the established threshold.

5.1.3. Quality Management System

The supplier's top management shall ensure the following:

a) A Quality Management System (QMS) is established with reference to ISO9001. The company's quality objectives, policy, procedures, work instructions, and forms are appropriately documented, communicated, understood, and adhered to throughout the organization.
b) The organizational structure is documented in organization chart. The responsibilities and authorities for relevant roles are adequately assigned through job description, communicated, and understood within the organization. Sufficient resources are provided to consistently produce products meeting predefined requirements, including regulatory, GMP, and customer requirements.
c) A periodic management review of the quality management system is established, implemented, and maintained to ensure its continuing adequacy, suitability, and effectiveness. This periodic review shall include, at a minimum, training effectiveness, internal and external audits, quality problems and complaint investigations, and corrective and preventive actions (CAPAs). Reports are approved and retained.
d) Top management is notified of quality critical situations in a timely manner.

ESTĒE LAUDER COMPANIES

5.1.4. Good Manufacturing Practice (GMP)

The suppliers should comply with relevant GMP requirements applicable to the types of activity and products provided to ELC, which include personnel, buildings and facilities, equipment, raw materials, packaging components, production & process control, finished goods, quality control laboratory, and records.

5.2. Quality Assurance / Quality Control

The supplier shall ensure that the QA/QC unit has the responsibility/authority:

- to approve or reject all procedures or specifications impacting the quality of products or regulatory compliance
- to approve or reject materials and finished products
- to stop production activities if an issue impacting product quality occurs
- to independently check, date and sign master productions instructions, when regulatory required
- to review production records to ensure that no deviations have occurred or if deviations have occurred, they have been thoroughly investigated and documented, including deviations of yield
- to review batch documentation in order to release the batch
- to approve or reject products manufactured, processed, packed or held under contract by another company
- to review and approve (or reject) GMP-relevant changes
- to evaluate the established retest date or expiry date for packaging components
- to oversee the verification of effectiveness after implementation of a change or CAPA (e.g., evaluation of the first batch produced)
- to confirm the certificate of analysis (CoA) that a lot or batch has been produced, packed, labeled, tested, and stored in accordance with the procedures described in the master production documents.

5.3. Personnel Management

5.3.1. Principle

Personnel involved in implementing the activities described in this manual shall be appropriately trained and qualified to conduct activities related to the design, development, manufacturing, control, storage, and distribution of products in accordance with defined quality requirements.

5.3.2. Organization

5.3.2.1 The organizational structure should be defined in a way that makes the organization and functioning of the company's staff understandable. It should be appropriate for the company's size and the diversity of its products.

5.3.2.2 The supplier should ensure adequate staffing levels across different scopes of activity, based on the diversity of its production.

5.3.2.3 The organization chart should demonstrate the independence of each quality unit, such as the quality assurance unit and the quality control unit, from other units in the plant. Quality assurance and quality control responsibilities can be carried out by a separate quality assurance unit and a quality control unit, or by a single unit.

5.3.2.4 The company should have an adequate number of properly trained personnel for the defined activities.

ESTĒE LAUDER COMPANIES

5.3.3. Key Responsibilities of Personnel

All personnel should:

a) be aware of their position in the organizational structure.
b) be aware of their defined responsibilities and activities.
c) have access to and comply with documents relevant to their areas of responsibility.
d) comply with personal hygiene requirements and all requirements outlined in this manual.
e) be encouraged to report irregularities or other non-conformities that may occur within their areas of responsibility.
f) possess adequate education, training, and skills to perform their assigned responsibilities and activities.

5.3.4. Training

5.3.4.1 Personnel involved in production, control, storage, and shipment should have skills that are appropriate to their responsibilities and activities, based on relevant training and experience acquired, or any combination thereof.

5.3.4.2 The supplier shall have a documented training program that ensures all employees (existing, newly hired, or temporary) engaged in product design and development, manufacturing, processing, packing, and holding of products have the appropriate education, experience, and training to perform assigned tasks.

5.3.4.3 Training shall be organized prior to the issuance of new or revised quality system documents, including manuals, procedures, work instructions, and forms.

5.3.4.4 GMP and safety training (initial and refresher) shall be included in the training program.

5.3.4.5 An adequate number of trained and qualified personnel shall be available.

5.3.4.6 Training records shall be kept, and qualification statuses shall be up to date.

5.3.4.7 There shall be evidence of verification of the effectiveness of the organized training.

5.3.5. Personnel Hygiene and Health

5.3.5.1 Requirements for maintaining hygiene and avoiding contamination should be understood and followed by every person whose activities take them into production, control, and storage areas.

5.3.5.2 Personnel should be instructed to use hand washing facilities with automatic dispensers for liquid soap and sanitizer.

5.3.5.3 Every person entering production, control, and storage areas should wear appropriate personal protective equipment (PPE) to avoid contamination of cosmetic products.

5.3.5.4 Eating, drinking, chewing, smoking, storing food/drink, or smoking materials or personal medication in the production, control, and storage areas should be avoided.

5.3.5.5 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.

5.3.5.6 Operators are not allowed to touch surfaces that will contact cosmetic products (for example, the inside surface of a jar, bottle, tube, cap, disc, applicator, etc.) with bare hands because it may cause risks for microbiological contamination. Accordingly, operators are not allowed to contact the surfaces on tooling that contact directly with these above surfaces on the components.

5.3.5.7 Personnel health - Steps should be taken to ensure, as far as practicable, that any person affected by an apparent illness or having open lesions on exposed body surfaces should be excluded from direct contact with the product until the condition is corrected or determined by medical personnel that the quality of products will not be compromised. Personnel shall be instructed to report to their supervisor any health or safety conditions that could adversely affect products.

5.3.5.8 When operators are injured, they shall be removed from the production line for primary

healthcare. The products made before the injury must be verified for contamination by blood stains and body fluid.

5.3.6. Visitors and Untrained Personnel

Visitors or untrained personnel should 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 required PPE. They should be closely supervised.

5.4. Premises (Facility)

5.4.1. Principle

Premises should be designed, constructed, and utilized based on the type of packaging component produced to:

a) ensure the protection of product quality and eliminate the risk of contamination.
b) allow for efficient cleaning, sanitizing, and maintenance.
c) minimize the risk of mix-up between products, starting materials, and packing materials.

5.4.2. Types of Areas (Zoning)

5.4.2.1 Separate or defined areas should be provided for storage, production, quality control, and ancillary areas such as restrooms, pantries, and canteens.

5.4.2.2 Changing rooms must have lockers, shoe cabinets, non-hand-contact automatic washing, and disinfectant. If necessary, a second changing room should be provided based on the needs of environmental control.

5.4.2.3 The supplier must implement a zoning concept in their manufacturing site to control contamination risks. Zones must be defined based on a risk assessment that takes into consideration potential risks, product exposure, surface contact with products and ingredients. Defined personnel practices, control, transitions of personnel and materials, and gowning per zone must be documented and monitored.

5.4.2.4 Manufacturing sites should set up the manufacturing floors with zoning requirements and environmental control that ensure the proper flow direction of materials and personnel to avoid cross-contamination. Where applicable according to local regulatory requirements, environmental monitoring for airborne particulates must be in place. Any production that generates dust should be in a separate production area.

5.4.3. Space

An adequate amount of space should be available to facilitate operations such as receiving, storage, and production.

5.4.4. Flow

To prevent mix-up and contamination, the flow of materials, products, and personnel through the building or buildings should be clearly defined.

5.4.5. Floors, Walls, Ceilings, Windows

5.4.5.1 Floors, walls, ceilings, and windows in production areas should be designed or constructed for easy cleaning and, if necessary, sanitization, and kept clean and in good repair. Brick, cement blocks, and other porous materials should be sealed, and surface materials that shed particles should be avoided.

5.4.5.2 Windows should be designed as non-opening or kept closed whenever good ventilation is present. If an open window is necessary, a curtain or screen should be used.

ESTĒE LAUDER COMPANIES

5.4.5.3 New construction of production areas should incorporate considerations for proper cleaning and maintenance. The new design and construction should include smooth surfaces, where appropriate, to resist corrosive cleaning and sanitizing agents.

5.4.6. Washing and Toilet Facilities

Adequate clean washing and toilet facilities should be provided for personnel, and these facilities should be differentiated from but accessible to production areas. When appropriate, sufficient facilities for showering and changing clothes should also be provided.

5.4.7. Lighting

Adequate lighting that sufficient for operations should be installed in all areas. Lighting should be installed in a manner that ensures the containment of any debris from potential breakage. Alternatively, measures should be taken to protect the product. Lighting fixtures over areas where exposed products or open containers are staged should be covered, unbreakable, or impact resistant.

5.4.8. Ventilation

5.4.8.1 Ventilation should be sufficient for the intended production operations, or specific measures should be taken to protect the product.

5.4.8.2 Ventilation, temperature, humidity, dust, and micro-organisms should be monitored and controlled according to established ranges and limits, where appropriate.

5.4.8.3 Dusty operations should be suitably contained and ventilated. If fans are used, they should be properly cleaned and positioned to prevent potential contamination. Ventilation and air conditioning systems should be qualified, appropriately monitored, and actions should be taken when limits are exceeded. The preventative maintenance program should include the systems with periodic filter replacement, such as heating, ventilation and air conditioning (HVAC), and online compressed air.

5.4.9. Pipework, Drains and Ducts

5.4.9.1 Pipework, drains, and ducts should be installed in a manner that prevents drip or condensation from contaminating materials, products, surfaces, and equipment.

5.4.9.2 Drains should be kept clean and should not allow backflow. Floor drains should be screened, trapped, and regularly cleaned and sanitized.

5.4.9.3 Design considerations should be given to the following:

- Exposed overhead roof beams, pipes, and ducts should be avoided.
- Exposed pipes should not touch walls but should be suspended from or supported by brackets with sufficient separation to allow thorough cleaning.
- Alternatively, specific measures should be taken to protect the product.

5.4.10. Cleaning and Sanitization

5.4.10.1 The supplier should have a documented cleaning and sanitation program in place that includes cleaning procedures for the premises to ensure a clean and sanitary condition corresponding to the specific needs of each area, based on good manufacturing practices (GMPs) and other applicable regulatory standards.

5.4.10.2 Cleaning and if necessary, sanitization should be carried out to protect product quality.

5.4.10.3 The cleaning and if necessary, sanitizing agents to be used should be specified and effective.

5.4.10.4 The supplier should implement continuous surveillance to ensure that deviations are timely identified and quickly corrected.

5.4.10.5 Clean and sanitary conditions should be always maintained and in all areas of the plant and warehouse facilities and meet or exceed all applicable government regulatory standards.

ESTĒE LAUDER COMPANIES

5.4.10.6 5S factory management should be implemented at the factory and shop floor. For example, refer to website https://www.5stoday.com/what-is-5s/

5.4.11. Maintenance

The premises used for activities described in this manual should be maintained in good repair, and repair and maintenance activities should not affect product quality. Records of maintenance activities should be kept, and a set of technical documentation for quality-critical equipment and installations should be maintained.

5.4.12. Consumables

5.4.12.1 Consumables used for the premises should not affect product quality.

5.4.12.2 The supplier should maintain records of the assessment of all utilities (e.g. air, gases, steam, water, and other fluids like lubrication fluids, cooling fluids, and hydraulic oils that may accidentally come into contact with the product) for their potential impact on product quality and any associated risks.

5.4.12.3 The supplier must set up specification and label identification for chemicals used at the facility, including but not limited to insecticides, herbicides, lubricants, water additives, and any potentially hazardous substances. All chemicals must be regulatory approved and applied by authorized persons in accordance with chemical usage instructions on the label.

5.4.12.4 All chemicals must be labeled and stored in a secured location with an absolute low possibility of direct or indirect contamination by leakage, accidental or unauthorized use by any means.

5.4.12.5 The supplier must contact the local ELC SQA when product quality is at risk due to any condition.

5.4.13. Pest Control

5.4.13.1 The supplier should have a documented pest control program to monitor and control pest activity in their facilities and surrounding areas. This program should, at a minimum, include maps showing the location of different pest control devices, schedule and method to follow, and pest control agent to use. Pest control activities should be performed by certified contractors or trained personnel. Effective measures should be taken to keep buildings free of infestation by rodents, birds, insects, and other vermin, preventing contamination of equipment and materials. Logs of pest activities should be maintained and verified for trending, and corrective actions should be defined for increased activities and trends.

5.4.13.2 The storage and use of pesticides and herbicides must be strictly controlled by authorized personnel. They should be clearly labeled to avoid misuse.

5.4.13.3 Pesticides should be used in compliance with all applicable local environmental regulations. A chemical usage log should be maintained with minimum information, including the chemical username/identity, chemical usage quantity, usage time, and usage location.

5.4.13.4 Premises should be designed, constructed, and maintained to restrict access to insects, birds, rodents, pests, and other vermin. Measures should be taken to control the exterior of the premises to prevent attracting or harboring pests.

5.4.14. Process Air, Heating and Cooling Systems

5.4.14.1 To prevent contamination, process air should be filtered to be free from particulates (verified through testing) when used with direct contact to interior surfaces of the packaging component. A maximum micron filter size of 0.2 microns is required, in order to filter the microorganisms in air.

5.4.14.2 Environmental heating and cooling systems should utilize filters, which should be cleaned and

ESTĒE LAUDER COMPANIES

replaced at regular intervals. Cleaning and replacements of filters should be maintained and documented in a logbook or computerized maintenance program.

5.4.15. Security

The supplier should ensure proper security to prevent unauthorized entry and access throughout the facility, including manufacturing and processing areas, raw material and component (including printed materials) storage areas, hazardous chemical storage areas, shipping and receiving areas.

5.4.16. Water

If water is used to contact the inside surface of packaging component that contacts cosmetic products, the water system should be validated to be free of microbiological contamination and free of dead legs. The equipment for purification, storage, and distribution should be operated in a manner that ensures a reliable source of water with appropriate chemical and microbial purity as per ELC specifications. Approved procedures for routine sanitization and maintenance of the water system should be in place. The quality of the water should be defined and controlled if the water comes into direct contact with primary packaging components or their starting material or is used for cleaning any equipment in contact with primary packaging components or their starting material.

5.4.17. Waste Disposal

The supplier shall have a procedure detailing the process for general and hazardous waste disposal, including assurance for proper destruction of bulk and printed materials with adequate control. The waste disposal process shall not cause contamination of finished components. Dusty operations shall be suitably contained and ventilated.

5.5. Process Engineering

The supplier shall ensure the following is implemented.

5.5.1. Cleaning and Sanitizing

5.5.1.1 Written procedures should be established and followed for cleaning and sanitizing each piece of equipment used in the production process, including assisting equipment. These procedures should detail cleaning and sanitizing frequency requirements and include methods to disassemble and reassemble equipment.

5.5.1.2 Cleaning and sanitizing activities should be recorded in the Equipment Cleaning and Use log, including the date, time, product, and batch number of each batch processed.

5.5.1.3 Residues from the cleaning process should be removed.

5.5.1.4 Cleaned equipment should be protected from contamination.

5.5.2. Process Qualification

5.5.2.1 A master validation plan, including equipment qualification, utility qualification, process validation, test method validation, and computer system validation, should be available, reviewed, and approved by Quality, Manufacturing/Operations, and other applicable units.

5.5.2.2 Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) should be performed on all critical equipment that manufactures or controls products, including QC laboratory equipment.

5.5.2.3 Qualification/validation documentation should meet GMP requirements.

5.5.2.4 The process validation approach should be defined (prospective, concurrent, or retrospective validation).

5.5.2.5 Procedures should be in place to ensure a continued state of control over a qualified process (calibration, preventive maintenance, change management, training).

5.5.2.6 Cleaning procedures should be validated.

5.5.2.7 Dirty and clean hold times should be validated.

ESTĒE LAUDER COMPANIES

5.5.2.8 Routine cleaning and storage should not allow microbial proliferation.

5.5.3. Equipment Control

5.5.3.1 Equipment surfaces should be non-reactive, non-absorptive, corrosion-resistant, non-toxic, and free from additives.

5.5.3.2 Design and operational precautions should be taken to ensure that lubricants, coolants, or other operating substances do not come into contact with materials or products.

5.5.3.3 Equipment should be maintained in accordance with a written preventative maintenance program that is compliant with ELC procedure (QA-SOP-00286 - Supplier Preventive Maintenance Procedure for Equipment Mold and Tooling) for equipment, mold, and tooling.

5.5.3.4 Usage and maintenance records should be kept.

5.5.3.5 A process should be in place to identify any defective equipment, prevent it from inadvertent use, and isolate it if possible.

5.5.4. Equipment Calibration

5.5.4.1 Procedures should be in place for checking and calibrating each piece of equipment used in the manufacturing, processing, packing, holding, or testing of a product. Schedules should be defined, and records should be kept.

5.5.4.2 Measuring devices should be of an appropriate range, precision, and accuracy.

5.5.4.3 A procedure should be in place to define corrective actions should an instrument be found out of calibration.

5.5.5. Computer Systems

5.5.5.1 Computer systems are controlled in such that way only authorized personnel can access production records.

5.5.5.2 When regulatory-required, computerized systems to automate production activities are validated.

5.6. Deviation Control

5.6.1 A deviation is a departure from an approved procedure, instruction, or specification. Deviation control is the process of identifying, assessing, and correcting deviations.

5.6.2 The supplier is expected to implement a quality system for deviation and CAPA management.

5.6.3 Deviations from specified requirements should be reviewed and authorized with sufficient data to support the decision.

5.6.4 Corrective actions and preventive actions should be taken to prevent recurrence of the deviation.

5.7. Change Control

5.7.1. Change Control Procedure

The supplier shall implement a change control procedure that defines how to log, assess, approve, implement, and verify the effectiveness of changes impacting product safety or quality. Packaging suppliers must notify ELC GSR and/or relevant functions of their intention to make any change that may affect product safety or quality (such as appearance defects outside the approved standard or range boards approved by ELC PKG, average value of critical dimension with deviation of 1-sigma from the target nominal value, Cpk values below the Cpk value approved by PKG, additional safety or functional risks, or any inconveniences to consumer use, etc.). ELC shall review and approve the requested change before the supplier implements it.

Any planned or unplanned changes that might impact the safety and quality of products manufactured for ELC must be evaluated and approved by ELC SQA prior to implementation. This includes but is not limited to the following.

- Changes to facilities: transferring of manufacturing operations from one site to another,

ESTĒE LAUDER COMPANIES

manufacturing environment, laboratories, internal campus or facility change, structural changes like walls, doors or ceilings, construction, facility maintenance, utilities, warehouse storage conditions, etc.

- Changes to equipment and tooling: equipment/tooling change, equipment/tooling validation status, equipment/tooling configuration settings, equipment calibration, tooling qualification, tool refurbishing or duplicate tooling, equipment/tooling maintenance, equipment/tooling moves, decommissioning, equipment parts changes that are not considered “Like for Like”, hardware and software changes, changes to computer hardware, software, or upgrades (for validated software systems), etc.
- Changes to processes: manufacturing procedure change, cleaning and sanitation procedure, hygiene practices, GXP data, records retention or archived documentation, environmental control program, training, GMP certification.
- Changes to specifications: material code, any specification parameters, for instance, artwork, dimensions, UPC, construction material, pack-out change, testing specifications, sub-supplier change, updated physical standards, product safety changes, color changes, test methods, regulatory requirements, etc.
- Changes to test methods: sample preparation, type of technique to be used, equipment and technology upgrades, reagents, process steps details, etc.
- Changes to materials: material supplier or material specifications of resins, pigments, paints, decoration foil, etc.

5.7.2. Change Control Form

Suppliers have the option to use their internal change control form. Below key information should be included in the Change Control Form.

Section 1: CHANGE REQUEST

- Change Request #
- Date Requested
- Requester Name / Dept
- Department (where change is needed)
- Product Information (if appliable) – i.e. Material Code, Material Description, Batch #,
- Manufacturing Site Name/Address
- Change Control Type
- Description of Proposed Change including description of the current state
- Reason for Change (to be completed by the Change Requestor)
- If Change is Temporary, Permanent, or Emergency
- If temporary, define the time period (start and end date)
- Proposed Date of Implementation

Section 2: IMPACT ASSESSMENT & IMPLEMENTATION PLAN

- Assessment of Impact/Risk to product safety and quality
- Assessment of Impact/Risk to storage and transportation
- Assessment of Impact/Risk to customer (for example, ELC fill/assembly sites)
- Assessment of Impact/Risk to consumer
- Risk Control Plan
- Change Implementation Plan (must have Required Tasks, Task Owner, and Due Date)
- Review by the Subject Matter Expert (SME)

Section 3: CHANGE REQUEST APPROVAL

- Change Request Approval (Approved or Reject to implement)

- Sign-off by all relevant stakeholders/approvers

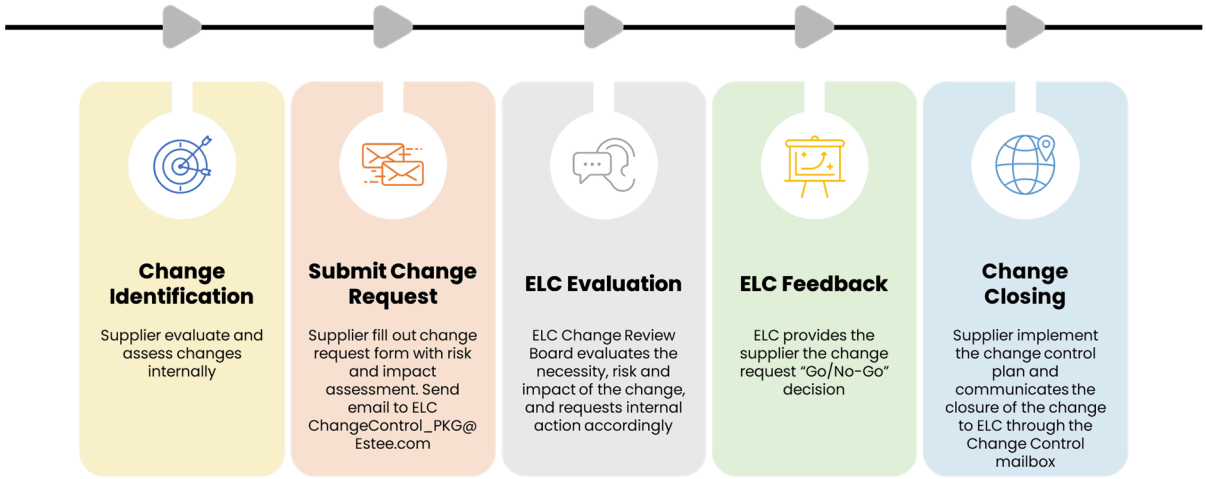
Section 4: CHANGE IMPLEMENTATION FOLLOW-UP & VERIFICATION
- Implementation tasks are complete / task completion date

Section 5: CHANGE CLOSE OUT
- Final Close out Approvals

5.7.3. Change Notification to ELC

Suppliers are responsible for communicating changes and submitting a change request form to an ELC designated email: ChangeControl_PKG@estee.com

Suppliers should follow the steps in below flow chart to notify ELC about the change request/risk assessment/change control and implementation plan, obtain ELC approval, implement the change control plan and update change closing to ELC.



5.7.4. Change Notification from ELC

For changes initiated by ELC, the supplier should also manage them through their internal change control procedure and provide progress updates and results to the change requester. The supplier must initiate internal change control process immediately upon receiving a change notification from ELC and must process it immediately to avoid being overlooked or neglected over time.

5.8. Traceability Control

The supplier should establish and implement a written procedure to assure top-to-bottom and bottom-to-top traceability of people, equipment, materials, processes and processing parameters, facilities, and measurements used in the production of ELC products. When a quality issue is identified, the supplier should be able to quickly identify related batches that potentially have the same issue within 48 hours after notification. A traceability drill, both top-to-bottom and bottom-to-top, should be part of the supplier's Quality Management System and should be performed on an annual basis. Any findings from the traceability drill should be treated as non-conformance, supplier should run full investigation with RCA and CAPAs to avoid reoccurrence.

For batch definition, supplier is recommended to break down production batches based on the consistency or variation of all process elements (man, machine, material, method, measurement, environment). A batch can be the components produced by one shift of operators on specific machine or line with a specific process/parameter and using a specific batch of materials in same environment.

ESTĒE LAUDER COMPANIES

It is not recommended to combine productions of different days into one batch, which means maximum batch size is the units produced in one day.

5.9. Records Control

Supplier shall establish procedure to manage record control, define critical quality records and their retention period, and define good documentation practices. Supplier must keep accurate records for design, development, supplier audit, incoming inspection, manufacturing, testing, release, storage, and delivery operations performed at their facility. The records must comply with Good Documentation Practices (GDP) and Good Manufacturing Practices (GMP). The records retention must follow any applicable local regulation and be kept on file for 5 years and made available for review by ELC upon request, within 48 hours.

5.10. Testing Laboratory Qualification

The supplier must qualify their testing laboratory to ensure compliance with Good Laboratory Practices (GLP) requirements and ELC Packaging Testing Procedures (PTP).

- Testing equipment should be qualified through best practices Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ). Testing equipment must be qualified by supplier qualification program, which aim to meet any applicable local regulation and gives high confidence on testing accuracy.
- Testing equipment must be calibrated on a regular basis. The calibration points must cover the whole range required in product specifications.
- Testing equipment must be maintained on a regular basis according to equipment maintenance procedures.
- Testing methods must be validated, compliant with ELC PTP. If supplier testing method is not aligned to ELC PTP, supplier shall request and get approval from PKG, and documented in component specification before it will be used for packaging component testing. Local SQA should be notified.
- Testing personnel must be trained and qualified.
- Testing records must be maintained according to Good Documentation Practices.

5.11. Testing Laboratory Certification

5.11.1. Certification by ELC Packaging Testing Lab for Development Lab at Supplier

When applicable, ELC Packaging Testing Lab can work with the supplier to certify their in-house testing lab which will be used to test component quality during development.

5.11.2. Certification by ELC SQA for QC Lab at Supplier

To ensure the reliability of supplier testing results against ELC specifications, the supplier is required to apply ELC PTP in their quality control for all ELC packaging components. The supplier shall verify equivalence of their internal testing procedures against ELC PTP and review findings with ELC local SQA then implement actions to close the gaps.

5.12. Data Integrity

Data integrity is the maintenance of, and the assurance of, data accuracy and consistency, over the entire product life cycle. It is a critical aspect to the design, implementation, and usage of any system that stores, processes, or retrieves data. It is essential to ensure that data is reliable, trustworthy, and appropriate for its intended use.

Data integrity is fundamental for ensuring product quality, safety, and regulatory compliance. Data integrity requirements apply equally to paper records, electronic records, and data throughout its life cycle, regardless of how the data has been generated or the format in which it is stored.

Data Integrity principles apply to all GXP data generated for making products for ELC. Data generated through these processes should meet Data Integrity criteria for:

- Raw data capture / initial generation
- Processing (transformation/migration)
- Review
- Use (product traceability)
- Archiving
- Retrieval
- Destruction

Suppliers are accountable for the integrity of the data they create and are involved with, including the generation, recording, reporting, and retention of all GXP data. All GXP data must be retained for a minimum of 5 years or as outlined in records retention requirements.

Software applications used to generate, process, and store GXP data must be validated in accordance with Computerized System Validation requirements.

5.13. Mix-up Control

Mix-up is one of the top issues that can occur with packaging materials delivered by packaging suppliers. This includes incorrect materials, colors, parts, components, artwork, product labels, shipper labels, etc. Mix-up can cause quality and safety issues, as well as concerns for our consumers and damage to our brand reputation. All suppliers are required to implement a mix-up prevention program, develop and implement procedures to prevent mix-up at each step of the product realization process, use a mix-up checklist to assess end-to-end processes, identify gaps that may cause mix-up issues, and implement CAPA to mitigate risks. For best practices, please refer to the mix-up checklist from supplier portal, or contact to your local SQA for support.

5.14. Contamination Control

Contamination is another one of the top issues that can occur with packaging components delivered by packaging suppliers. This includes contamination on the inside or outside of packaging components, which may lead to contamination of our products or production lines, resulting in quality or safety issues, concerns for our consumers, and damage to our brand reputation. All suppliers are required to implement a contamination prevention program, develop, and implement procedures to prevent contamination at each step of the product realization process, use a contamination checklist to assess end-to-end processes, identify gaps that may cause contamination issues, and implement CAPA to mitigate risks. For best practices, please refer to the contamination checklist from supplier portal, or contact to your local SQA for support. Refer to section **6.11 Pack-out Development and Qualification** for packing material selection, pack-out design and qualification.

6. New Product Quality Development

6.1. General Requirements

Suppliers should implement procedures to manage new product/process design, development, verification and validation to identify/manage quality risks and comply with ELC coporate specifications and packaging specifications. The suppliers are recommended to refer to APQP (Advanced Product Quality Planning) which is the best-in-class methodology for new product quality management.

Regardless if the product is designed by ELC or supplier, ELC PKG will work with packaging suppliers to manage product/process design, development, verification and validation to ensure that product quality can meet ELC requirements. Supplier should take lead to initiate technical readiness review and quality risk review with local ELC SQA when required by local SQA.

6.2. Notification to ELC SQA

Suppliers should notify the local ELC SQA immediately after receiving business award, work with ELC PKG and SQA to assess quality risks and take actions to eliminate or mitigate qulaity risks.

6.3. Quality Plan for Technical Readiness

Suppliers should implement a Quality Plan for new product/process design, development, verification and validation. All key applicable items on the Packaging NPL Technical Readiness Checklist should be planned to be completed during development and be ready prior to startup of the first production.

6.4. Product Design, Development and Verification

During product design phase, supplier should consider the requirements in ELC Corporate Specification for the subject commodity to be developed, material specification template and PTP, work with ELC PKG and SQA to identify CQA to fulfill consumer expectation/use, customer expectation/use, and transportation. When required by ELC PKG, supplier should apply DFMEA to identify potential failure modes against each identified and aligned CQA, effects on customer/consumer, corresponding severity rankings, occurrence ranking, detection method and detection ranking, RPN (Risk Priority Number) rating and associated CAPA to improve RPN for failure modes identified with medium or high risk.

When supplier designs the products, the supplier shall assess the risks of mix-up with other similar products and take actions to prevent mix-up with a systematic approach.

- For example, two or more products that have the same design and color, but different artwork can be easily mixed during BOM setup, production, or storage. The different artwork can be shade difference or COO difference.
- For example, two or more products that have the same design and artwork, but different colors can also be easily mixed during BOM setup, production, or storage.

Success plan criteria, risk mitigation and/or CAPA plans are required to be properly documented, tracked, and shared upon request.

6.5. Artwork Management

Artwork must be properly managed to ensure the latest version is linked to the correct material code in supplier BOM, specification, and inspection plan so that the latest artwork is correctly used in production and inspections to prevent mix-up which may cause huge loss to supplier and ELC. To avoid mix-up of artwork or artwork revision, supplier shall ensure to:

- Manage each revision of artwork AI file and artwork PDF file via document control system, assign a unique ID (for example: ELC material code and revision sequential#) to each artwork revision, name the artwork soft copy with it.
- Mark the unique # on the printing tool as the unique # for the printing tool to avoid mix-up of printing tools.
- Mark the unique # on the hard copy of PDF artwork attached to the internal spec so that production can check the unique # on printing tool to match the unique # on the hard copy of PDF artwork.

ESTĒE LAUDER COMPANIES

6.5.1. Artwork Receipt and Verification

After receiving the final artwork from ELC packaging, suppliers are strongly recommended to verify it using digital inspection and confirm that the received final artwork is identical to the artwork attached in the approved specification of the ELC material code.

6.5.2. Artwork Transfer to supplier internal artwork

When supplier transfers ELC artwork into their internal working artwork, supplier must review the complexity of the artwork and access their process capability to duplicate it in their manufacturing process. When necessary, vendors should arrange for line trials to verify their process capability, collect defective samples, and prepare a range board for approval by the ELC PKG.

When supplier transfers ELC artwork into their internal working artwork, supplier should always start from the original artwork instead of taking an existing internal working artwork to modify it because it can easily cause mix-up. Supplier needs to ensure the latest artwork is linked to the correct material code (supplier material code and ELC material code) in supplier BOM as well as other documentation.

After transfer in their internal artwork system, supplier should submit a copy of the artwork to PKG. Work orders for the related component cannot start before the approbation from PKG.

6.5.3. Artwork Storage

Suppliers must store all artwork of the latest version in a secured database with limited access for non-essential employees. This applies to ELC original artwork as well as supplier's internal working artwork transferred from ELC original artwork.

6.5.4. Artwork Version Control

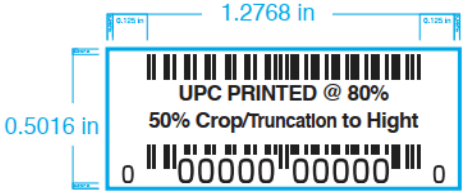
Suppliers must apply proper version control to prevent the misuse of old versions. The old version must be deleted or archived from the artwork storage immediately after receiving the new version.

6.5.5. Artwork Change Control

Suppliers must create an artwork change control checklist that includes all categories related to the change, such as old artwork (ELC original artwork + supplier internal artwork), old printing tools, old standard samples, etc. The checklist must include an assigned person responsible for destruction, as well as a review and approval process. Change requests must be documented immediately after receiving a change notification and must be finished as soon as possible. Otherwise, they might be ignored or forgotten.

6.5.6. UPC (Universal Product Code)

Based on the ISO standard, the smallest UPC should not be reduced to less than 80% magnification.



When the blank space is not sufficient, suppliers must not shrink the UPC magnification smaller than 80% to fit the blank space. Instead, the supplier shall raise it to ELC PKG for a solution.

The supplier shall generate the right size (length and height) of the UPC directly from the barcode software and shall not adjust its length after the UPC is generated. Otherwise, the barcode grade may be impacted. The height can be adjusted but needs to follow the minimum height requirement.

When generating a barcode from the barcode software, both the barcode and the human readable code below or above the barcode shall be generated by the barcode software based on the human readable code input into the barcode software. This can help ensure the barcode reading result is certainly aligned to the human readable code below or above the barcode. Some suppliers may generate barcode then manually add human readable code below or above the barcode. This is incorrect, may cause discrepancy between the barcode and the human readable code.

6.6. Printing Tool Management

Suppliers must ensure that the final artwork is used to make the printing tools. If the size permits, the ELC material code and/or supplier material code (must be a unique code) must be clearly marked on the printing tools. The printing tools must be verified by a second qualified person against the ELC specification. The printing tools must be strictly controlled to prohibit access by unauthorized persons and must be verified by a second person each time they are released to the production floor. Old versions or worn tools must be destroyed immediately, and the destruction must be documented at the time when destruction occurs.

- When supplier design the procedure for artwork printing tool management, supplier shall assess the risks of mix-up with other similar products and take actions to prevent mix-up from a systematic approach.
- When operator makes a new printing tool, they shall ensure to use the latest version of artwork (such as Adobe Illustrator file) and check it against the latest version specification upon receipt of PO and prior to production.
- Supplier shall implement robust inspection of new printing tools to ensure mix-up will not be caused by the tool.
- Supplier shall have a unique ID for each tool, which corresponds to only one revision of the artwork. ELC material code and artwork ID are also recommended to be marked on the tool as a double check for product identification.
- The printing tools shall have special identification of its approval status (for example, "SAMPLE ONLY", plus artwork revision date or #) before final approval of the samples, to avoid mix-up of the different versions or mix-up with other approved tools.

6.7. Bill of Materials (BOM)

For each product developed for ELC, supplier shall set up a unique material code and respective BOM. It is not allowed to assign only one internal material code for multiple ELC material codes. ELC material code and supplier material code must have unique 1:1 relation, and ensure correct artwork is linked to each material code without mix-up issue.

Suppliers should include the ELC material code in their internal BOM, either assign a specific field or column for the ELC material code or assign it at beginning of the material description. This will ensure that the ELC material code appears on the supplier's internal Production Order, Process Order, or Work Order, allowing supplier operators to verify the ELC material code printed on the shipper label against the ELC material code printed on the Production Order, Process Order, or Work Order. By incorporating the ELC material code in the Bill of Materials, suppliers can establish a connection with the ELC Purchase Order, ELC specification, and supplier's internal specification, to help avoid mix-up.

ESTĒE LAUDER COMPANIES

6.8. Outsourced Material Qualification

6.8.1. Materials Sourced by ELC

6.8.1.1 Supplier Management

ELC is responsible for the qualification and management of material suppliers sourced by ELC.

6.8.1.2 Material Specification

ELC Packaging Development is responsible for issuing material specifications, standards, color range boards, and defect range boards. The material supplier is responsible for distributing approved standards and range boards to the receiving company (the supplier) prior to or at the same time as the first delivery. The supplier should contact the ELC PKG or SQA if they do not have the standards or range boards available for incoming inspection or for reference during production.

6.8.1.3 Material Inspection Protocol

During development, the supplier should work with ELC PKG/SQA to align inspection plan for the materials supplied by ELC from a supplier selected/qualified by ELC.

6.8.2. Materials Sourced by Supplier

6.8.2.1 Supplier Management

Supplier shall establish a procedure for subcontractor qualification to define the selection, evaluation, approval, and monitoring of subcontractors that provide materials or services affecting finished product quality. It should include the alignment of quality agreements to define subcontractor responsibilities.

For any outsourced/subcontracted materials or processes that directly affects quality of products produced against a purchase order from ELC, ELC's supplier should notify ELC GSR and SQA in advance so that ELC GSR can work with SQA and Global Audit Group to determine whether the outsourced process is critical and if ELC needs conduct an audit at the outsourcing/subcontracting facility or if ELC's supplier needs organize an audit. CAPA follow-up remains ELC's supplier's responsibility.

6.8.2.2 Material Specification

Suppliers should develop material specifications for incoming materials and work with the subcontractors to review manufacturing process qualification.

6.8.2.3 Material Inspection Protocol

The supplier should work with their subcontractor to align inspection plan against material specification. Upon request from ELC local SQA, suppliers should provide the material specification and inspection plan to ELC SQA for review.

6.9. Tool Qualification and Tool Age Management

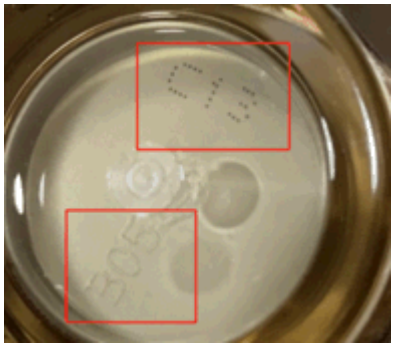
Packaging suppliers must ensure tools are properly qualified according to ELC “TPP-001-03 Tool Qualification Procedure” and are approved by ELC Category Technical Packaging Engineering prior to production runs.

- Error-proofing techniques should be applied for tooling design to reduce the risk of non-conformance during development and mass production.
- For injection or other plastic molding process, supplier should evaluate the change of critical dimensions at 48 hours after molding.

- The extreme samples (maximum and minimum dimensions) found during tool qualification (TQ) should be identified and used to perform fitting tests with other extreme samples to evaluate the performance at worst case.

When supplier design the tooling, supplier shall assess the risks for mix-up with other similar products and take actions to prevent mix-up from a systematic approach. For example, when multiple products or components share the same main structure of the tools, the core part shall be changed for each product or part, it is easy to mix up.

Tooling identification is a process or action used to easily identify tools. Supplier must ensure proper identification of tooling to avoid mix-up. When different cavities or sets of tooling are needed, each cavity or set should be identified with a unique number for easy identification and traceability. When the cavity number can be seen by consumers, the cavity number must not contain three characters starting with a letter, for example A15 or B09, because it may cause confusion with ELC batch coding. It is recommended to use a number containing 1-2 digits, for example, 6, 12, 32, etc.



Here is an example which caused confusion to consumers. This is the bottom view of a jar with an inner cup. The cup cavity number is B05 while the finished goods batch coding is C13. The jar supplier was required to modify its cavity number to two digits.

The tools shall have special identification of its approval status (for example, "SAMPLE ONLY", plus artwork revision date or #) before final approval of the samples, to avoid mix-up of the different versions or mix-up with other approved tools.

Packaging suppliers must have proper inspection and maintenance procedures to ensure the quality of tools throughout the entire committed tooling life span. Where applicable, suppliers should implement procedures with proper measures (for example, tooling should be equipped with an automatic counter to count the number of shots or open/close cycles, so that the tooling age can be precisely recorded and monitored.) to manage tooling ages to prevent poor performance caused by aged tooling and take preventive actions to mitigate quality risks due to aged tooling. This will help ensure that the tooling remains in good condition and performs effectively over time. For details, the supplier may refer to ELC procedure “QA-SOP-00286 Supplier Preventive Maintenance Procedure for Equipment, Molds, and Tooling”.

6.10. Process Design, Development and Verification

The supplier is responsible for design, development, and verification of the manufacturing process with proper validation prior to or through the first production runs. Where applicable, suppliers should complete a P-FMEA for new products and review it with ELC PKG. CPP are process variables that have an impact on a product's CQA. Both CQA and CPP should be well-defined and verified during process design and development and verification, and well-controlled to ensure the packaging component fulfills its specification with high confidence and reliability. When required by ELC local SQA, suppliers should provide the manufacturing process SOP and inspection plans to ELC local SQA for review.

- Supplier should establish process flow chart, review with ELC PKG and SQA
- Supplier shall identify CQA and CPP, review with ELC PKG and SQA,
- Supplier shall perform P-FMEA to evaluate potential risks and take actions to mitigate risks.

ESTĒE LAUDER COMPANIES

- The production process shall be qualified through line trials with enough running time to confirm process capability. Data on critical functions and dimensions shall be collected and analyzed to confirm process capability can meet expectation.
- Supplier should verify sample quantities with PKG and submit the samples to the ELC PKG testing lab or an ELC qualified lab for testing and approval.

When supplier design the management processes or production processes, supplier shall assess the risks of mix-up with other similar products or its own semi-finished products (for example, printed vs non-printed) and take actions to prevent mix-up with a systematic approach.

6.11. Pack-out Design, Development and Verification

Suppliers should implement a written procedure to manage pack-out design, development, and qualification. Suppliers are recommended to use ELC's "Pack-out Checklist and Action Plan" to assess their internal process, identify gaps, and develop an action plan for improvement.

Suppliers are responsible for the design, development, and qualification of their pack-out to protect components from physical damages (scratches, scuffing, hit marks, etc.), physical contamination, microbiological contamination, as well as water condensation during transit. The final pack-out used by the supplier must pass the Packaging Testing Procedure "Transit Testing - Vibration and Drop Test Procedure" prior to the first production run. Suppliers are responsible for verifying that transit testing is completed prior to first production and submitting transit testing report to ELC PKG for review and copy local SQA. If transit testing is not complete, the packaging supplier must alert ELC PKG and SQA on time prior to first production. Any questions concerning transit testing should be directed to ELC PKG and copy local SQA.

When an ELC special requirement exists for a pack-out (for example, the pack-out requirement in ELC corporate specification, a special tray is designed for an automatic loading at fill/assembly site), suppliers need to ensure compliance with the special requirements to ensure the pack-out can support the specified purpose.

Packing materials used shall not be a source of contamination for final components. Suppliers should set up procedures or specifications for packing materials, ensure to set up inspection plan for incoming inspection of the packing materials and accordingly apply incoming inspection.

Suppliers should consider the potential impact of humidity or water condensation on product quality during production, storage, or transportation, and take appropriate action to protect products from water marks. For example, use a big polybag to protect the components from contaminations, seal the polybag to prevent moisture from affecting the packaging component, or add desiccants if the destination regulation allows to use desiccants.

6.12. Line Trial at Supplier and Fill/Assembly Site

Line trial of the final packaging components are required at the fill/assembly sites prior to the first production run to evaluate how packaging components go through production process at fill/assembly site and whether there are quality issues happened during transit or production process at fill/assembly site. Hence packaging supplier must verify the packaging components quality to confirm conformance with the specification prior to shipment.

When packaging suppliers produce components samples for line trial at fill/assembly site, the supplier should take this opportunity to verify production process capability, quality controls, packing method and set up range boards where needed for approval by ELC PKG. All quality requirements for normal production, quality controls, pack-out and final release shall be strictly applied following the supplier's internal procedures to ensure the samples for line trial can meet all quality requirements.

If quality issue is identified due to the packaging components during the line trial, the supplier will be informed by ELC PKG and required to take CAPA prior to the first production run. Suppliers should keep local SQA informed about the CAPA status.

Supplier shall control production to avoid mix-up, manage line clearance, tools, production, samples, inspections, etc. just in the same way as normal production. The tools shall have special identification of its approval status (for example, "SAMPLE ONLY", plus artwork revision date or #) before final approval of the samples, to avoid mix-up of the different versions or mix-up with other approved tools.

6.13. Specifications, Standards, Range Boards, Inspection Plan

6.13.1. Specifications

Prior to final specification approval, packaging suppliers are required to include detailed dimensional and functional requirements on the specifications and drawings. The critical dimensions must be circled in red circles.

When adhesive is used to glue the components, we also require detailed adhesive information documented on the specifications and drawings. Details are to be inclusive of (but not limited to) the following:

- Type of adhesive (manufacturer and grade)
- Amount of adhesive (pattern, total weight, and tolerance)
- Location of adhesive (target zone, prohibit zone)
- Adhesive application process (application and curing parameters, dwell time to bond, etc.)

Packaging suppliers shall view and download the most updated versions of corporate specification, packaging specification, drawing, artwork, and Packaging Test Procedures (PTP) through SupplierNet and incorporate the requirements in supplier internal documents. **Any change to the packaging specifications must be reviewed and approved by ELC PKG.**

- Supplier shall ensure that appropriate personnel at manufacturing locations have access to the latest corporate specification, packaging specifications, drawing, artwork, Packaging Testing Procedures (PTP) for all products produced or to be produced for ELC, and ensure related personnel are well trained about the requirements in these documents. The supplier can contact ELC PKG or SQA if any questions about these requirements.
- Supplier shall ensure that the most updated corporate specification, specification, drawing, artwork, and Packaging Test Procedures (PTP) are fully implemented at the manufacturing locations by incorporating the requirements in these documents into supplier’s internal specifications and Standard Operating Procedures.
- Supplier is required to test products made for ELC with ELC PTP listed in the specification. If supplier wants to use an internal testing procedure to test products made for ELC, the supplier must perform an equivalence study to qualify the equivalence of their internal testing procedures against ELC PTP. Any discrepancy must be properly addressed/fixed and communicated with ELC local SQA.
- ELC material code is the only connector among ELC specification, artwork, standard and PO. This connection shall be extended to supplier internal documents until shipment to ensure the correct product is produced and shipped. When supplier transfer ELC spec into their internal spec, supplier shall keep ELC material code so that production and QC can check the ELC material code correctness against spec. to ensure they produce the correct product matching the material code on ELC PO. And this is the only way to link their internal spec with ELC spec.
- Any required cross reference of ELC material code, with Supplier's internal material code is carried out using a validated system and is sufficiently verified for correctness (4 eyes principle applied or validated scanning system).

ESTĒE LAUDER COMPANIES

6.13.2. Standards

During development, supplier shall work with ELC PKG to approve adequate copies of standards so that the supplier has enough copies for internal use, backup, and submission to receiving sites.

Supplier shall ensure to have respective standard per each finished product ordered by ELC, marked with ELC material code on them. When ELC only issue generic standard or cannot sign respective standard due to any reason, supplier shall issue respective internal standard for each finished good ordered by ELC and always use respective standards in production and inspections.

ELC material code must be marked on the approved standard so that production and inspection can use the standard to check the material code on shipper label for QC check purpose, and to check the material code on production order to ensure the correct product is produced against ELC PO.

6.13.3. Color Range Board

During development, supplier shall work with ELC PKG to approve color standard and color range board, then ensure to use them in production controls. During production, the supplier should always target to achieve the standard color as close as possible.

6.13.4. Defect Range Board

During development, supplier shall work with ELC PKG to approve defect range boards for defects discovered in development or potential defects that may happen in production. **Any defect range board that will be used by supplier in production control for ELC products must be approved by ELC PKG prior to use in production control**. Supplier should request enough copies of approved range boards so that the supplier has enough copies for internal use in production, backup, and submission to the receiving sites.

Prior to submitting a request for a range board, supplier shall make every effort to improve the manufacturing process. When supplier submits a defect range board for ELC PKG approval, they should estimate the defect rate and include that information on the board so that the PKG can make an appropriate decision based on the defect severity and percentage.

6.13.5. Deliver Approved Standards and Range Boards to Receiving Sites

Before the first delivery arrives at each receiving location, supplier must distribute the approved standards and range boards to each receiving location (Supplier can check with ELC PKG to get a list of the receiving locations for the subject packaging component being developed. Supplier can also find the receiving locations via purchase orders.), as outlined in the Packaging Operation Procedure "Approval, Distribution and Documentation of Component Standards and Range Boards Procedure." The receiving sites' QA/QC will need these to perform incoming inspections. Any delayed submission may potentially cause delays to the production schedule at the receiving sites. Supplier needs to ensure it requests enough copies of approved standards and range boards so that supplier can send one set to each receiving location, keep some sets for internal use and backup for potentially added fill/assembly sites.

6.13.6. Inspection Plan

Supplier shall establish inspection plan for IQC, IPQC and FQC, and review them with ELC local SQA. The inspection plan should include inspection items, inspection method, acceptance criteria, and sampling plan.

- Inspection Item - The inspection items should cover at minimum the following: appearance, color, odor, noise in use, critical dimensions, functional tests, fitting test with other

components, customer or consumer usage test, and transit test. The supplier inspection plan shall include the inspection items required in the ELC Procedure “QA-SOP-001003 Procedure for Inspection of Packaging Materials" and the “Defect Reference Guide” applicable to the commodity made by the supplier for ELC.

- Inspection Method - The inspection method must be fully aligned with ELC PTP. Otherwise, the supplier should communicate with ELC PKG/SQA and get their alignment.
- Sampling Plan - Use Single Normal Inspection Level 2 to determine sample size and accept/reject criteria for aesthetic attributes, use Single Normal Inspection Level S-2 to determine sample size and accept/reject criteria for functional and dimensional attributes.

6.13.7. Defect Classification

Suppliers shall comply with the defect classification in ELC Procedure “QA-SOP-001003 Procedure for Inspection of Packaging Materials" and the “Defect Reference Guide” applicable to the commodity made by the supplier for ELC. This applies to all packaging components made for ELC, regardless of the language used in the artwork.

6.13.8. CoA Template

During development, supplier should establish a CoA template for the item to be developed and share it with ELC SQA for review/approval. Please refer to 9.17.3 for details about CoA requirements.

6.14. Pre-Production Run

For medium and high complexity/risk new packaging, the supplier is recommended to run pre-production runs in sufficient quantity to verify/validate the manufacturing processes. This is typically done after successful line trials at supplier and fill/assembly sites and after specification approval by PKG. If pre-production run is not planned, the activities described below in 6.14.1, 6.14.2 and 6.14.3 should be performed in the first production run.

6.14.1 Before a pre-production run, the following need to be reviewed for technical readiness.

- Customer approved specification, standards and range boards are available and incorporated to internal system.
- People are properly qualified.
- Equipment and tools are properly qualified to be effective.
- Facility is properly qualified.
- Materials are properly qualified with approved inspection plans.
- SOP for each manufacturing process is approved with clear critical process parameters (CPP).
- Inspection plan and measurement methods are qualified for all critical quality attributes (CQA). An intensive sampling plan need to be aligned for pre-production run.

6.14.2 During a pre-production run, the following need to be reviewed for technical readiness, any gaps should be identified for further improvement prior to first production.

- Review people performance to ensure they follow the approved SOPs and are familiar with their job.
- Review facility, equipment, and tools to ensure they are effective to produce the required quality of product.
- Review process capability data (CPK) to ensure consistency of CQA.
- Review materials quality to ensure it can fulfill production needs.
- Review SOPs to ensure they cover all required details with clear critical process parameters (CPP) and can be easily followed by operators or equipment during pre-production run.

ESTĒE LAUDER COMPANIES

- Review inspection plans to ensure they cover all required details and critical quality attributes (CQA), can be easily followed by the inspectors.
- Review customer approved specification, standards and range boards to ensure they are suitable and can be met.
- Review internal component specifications and drawings to ensure all critical dimensions and functions are included.
- Review fitting function with other components, especially when the minimum or maximum of critical dimensions are found close to the lower or upper specification limits.
- Review the pack-out method, ensure it doesn't generate damage, scratch and scuff.
- Review defects found during pre-production runs and check if they are covered in the range boards approved by ELC PKG. If not, new range boards need to be approved by ELC PKG.

6.14.3 After a pre-production run, the identified gaps need to be reviewed for further improvement prior to the first production.

6.15. Shipper Label Format

Please refer to "ELC Supplier Shipping Component/ Raw Material Label Manual".

All new suppliers to Estée Lauder Companies are required to submit sample master carton shipping labels for approval before making their first shipment. Suppliers are urged to prepare carton labels in accordance with the formats outlined hereafter and submit them for approval upon receipt of their Estée Lauder Companies Supplier Guide. Review of labels submitted for approval may take 5-7 business days. For status on your submission please email shippinglabel@estee.com

Additional Requirements:

- Font type: Please use the font type that most closely matches the attached example (see below)
- The below markings must be printed on a label with white backing.
- All bar codes must be scannable with an ANSI rating of no less than "B"
- All human readable fields must be legible.
- Each container must contain a label designating the amount in that container (i.e., Shipper quantity, drum quantity, bag quantity).
- For shippers the single label should be placed on the carton side with the shortest width dimension at no more than a 30-degree tilt from the center.
- To ensure the barcode matches the human readable code above the barcode, the barcode application must create the barcode based on the human readable code input/displayed above the barcode, rather than a separate input.

The ELC label template only contains information required by ELC. Some suppliers want to apply internal labeling as well on each shipper to ensure effective internal control and traceability. In this case, supplier is recommended to combine them into one label instead of putting two labels (one for internal use and another for ELC), put ELC required information on the top and include internal control information on the bottom of the label. Below is an example. For traceability purposes, supplier is also recommended to include a sequential number on each shipper and record them in production record. This will help supplier segregate specific shippers when an issue is identified for a specific period of production.

First Part – ELC Labeling

1. ELC material description
2. ELC material code, **10 characters without "-"**
3. Quantity per carton
4. Vendor name
5. Vendor lot#
6. ELC PO#
7. Production Date, format YYYY-MM-DD
8. COO: Country of Origin, where component is made.

Second Part – Supplier Internal Labeling

1. Internal material code
2. Internal production/process order
3. Carton # for good traceability
4. QR code containing vendor lot and carton#

6.16. Technical Readiness Review

During NPL development, supplier should use a Packaging Technical Readiness Checklist to plan, monitor, and record progress on technical readiness. When required by ELC local SQA, supplier shall submit the completed Technical Readiness Checklist and required documents to the local SQA for review. Please refer to the Technical Readiness Checklist template created by ELC SQA and contact the local SQA if you have any questions. All items on the checklist should be completed before the first production run unless it is not applicable.

6.17. First Production Startup Notification

The supplier should inform ELC SQA of the schedule for the first production start-up. ELC SQA will determine whether an on-site start-up verification is necessary and if pre-shipment or co-shipment samples are required to be sent to ELC local SQA for review in case ELC local SQA cannot be on-site for startup verification.

7. ELC Purchase Orders

The supplier shall implement procedures for managing the receipt, verification, and conversion of ELC purchase orders to ensure that the correct product, quantity, and delivery date are input into their internal system for production orders.

When receiving an ELC PO, the responsible supplier person shall verify the PO information to confirm the material code and description against ELC-approved specifications. If there are any questions, concerns or doubts, the supplier shall verify them with the ELC material planner.

When transferring ELC purchase orders to the supplier's internal production or process orders, an independent person or function must verify and cross-check the ELC material code with the supplier's internal material code. The PO information shall be audited frequently and thoroughly to always ensure accuracy. If the supplier detects incorrect PO information that could impact product quality, they must inform ELC SQA immediately. Investigations and CAPAs must be implemented to minimize the risk of incorrect PO information in the future.

As good practice, the supplier's system should allow operators to input the ELC material code and automatically find the corresponding supplier internal material code. Manual searches for corresponding internal material codes can easily lead to mistakes. The supplier's system should also allow for scanning of ELC PO information or copying and pasting it into the supplier's system instead of typing it to avoid typing errors.

8. Incoming Material Quality Management

8.1. General Requirements

The supplier shall implement procedures to properly manage the quality of incoming materials used to manufacture components for ELC, ensuring compliance with material specifications.

8.2. Material Sourced by ELC

8.2.1. Material Receipt

Upon receiving the packaging materials, the supplier's warehouse operator should verify the material code, lot number, and quantity labeled on the containers against the purchase order and packing list. They should also verify the container integrity status to ensure that each container is visually examined for appropriate labeling, wet shipper, damage, broken seals, and contamination. The supplier should report any discrepancies to ELC Planning and SQA.

The containers should be cleaned where necessary, handled in a manner to prevent contamination, kept closed and stored off the floor. They should be correctly labeled with prescribed data (lot control/traceability). When materials are repacked, they shall be relabeled to maintain the same labeling information as originally marked.

The materials shall be held in quarantine until tested and released by the quality control unit. Physical quarantine areas shall be well identified, and access shall be restricted to designated and authorized personnel. When electronic quarantine is used, electronic access shall be restricted to designated and authorized personnel.

8.2.2. Material Inspection

The supplier should inspect incoming materials to ensure conformance with the specification.

The supplier shall install a sampling and testing program for the inspection of incoming materials that will be used during product realization. A separate sampling area is recommended. If sampling is performed in the storage area, it shall be conducted in a way that prevents mixing, contamination or cross-contamination. Containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their contents and other components. Sampled containers shall be marked to show that samples have been taken. Samples shall be properly identified with material code, lot

number, date sampled, initials of the sampler, and sample identity number. If a delivery or shipment of material is made up of different batches, each batch shall be considered as separate for the purpose of sampling, testing, and release.

Records indicating receipt, examination, testing, and disposition shall be maintained for at least 5 years.

8.2.3. Non-Conformance

For material purchased by the supplier as "Directed-Buy Material", the supplier should inform the material supplier of any non-conformance found during incoming inspection or production and work with the supplier to improve it. Any rejected material must be clearly labeled, segregated in a quarantine area, and protected from contamination and damage.

For material purchased by ELC as "Free-Issue Material", the supplier should inform ELC's local SQA of any non-conformance found during incoming inspection or production, and ELC's local SQA will work with the material supplier to improve it. Any rejected material must be clearly labeled, segregated in a quarantine area, and protected from contamination and damage.

8.3. Material Sourced by Supplier

8.3.1. Material receipt

Same as above 8.2.1

8.3.2. Material inspection

Same as above 8.2.2

8.3.3. Non-Conformance

The supplier should inform their subcontractor of any non-conformance found during incoming inspection or production and work with them for quality improvement. Any rejected material must be clearly labeled, segregated in a quarantine area, and protected from contamination and damage.

8.4. Material Storage

All components must be stored under sanitary conditions, with appropriate temperature and humidity control. Each pallet must be properly identified and protected from damage and contamination. Materials must not be stored in any area where they could be contaminated with foreign material or odors. Inventory control of materials must allow for a First-In, First-Out (FIFO) basis.

The supplier shall ensure that:

- A material system is applied to manage material storage to avoid mix-up. A stock locator system is required, and a barcode system is recommended.
- There is enough space for material quarantine, storage, or picking to avoid mix-up in the warehouse.
- Only one material is allowed to be stored on one pallet.
- The warehousing environment is acceptable for product and material storage. Receiving, staging, and shipping areas shall be clean and dry. When applicable, according to regulatory requirements, the supplier shall perform temperature mapping in warehouses to identify critical locations for monitoring. The supplier shall ensure that temperature monitoring is in place accordingly, and that limits are installed, with action plans for out-of-limit excursions defined.

ESTĒE LAUDER COMPANIES

- Pallets are stacked properly and not causing potential damage. All components and materials shall be stored off the floor (on pallets) and in a manner to prevent contamination.
- All pallet locations shall be identified in a suitable stock locator system.
- All labels and other labeling material are suitably identified and stored in a secure location with restricted access. This material shall be withdrawn against a packaging order, issued, and checked.
- Rejected materials are identified and controlled under a quarantine system designed to prevent their unintended use.
- Materials carrying an expiration date shall require the item to be retested before use when exceeded. ELC approbation from SQA is needed to use an expired material. Expired materials shall be segregated from non-expired materials.
- Inventory correctness audits are carried out frequently and are monitored as key performance indicators.
- There is a documented procedure for investigating items found in the warehouse with a missing label.

9. Production Quality Management

9.1. General Requirements

The supplier should implement procedures to manage production quality to ensure compliance with ELC approved specifications.

9.2. Standards

The purpose of an approved standard is to facilitate the visualization of the BOM and assembly instructions. The supplier must maintain standard samples under controlled and secured storage conditions to prevent any degradation or deterioration. For example, color standard and color range boards should be stored in the dark to avoid color degradation. Expired standards should be replaced in a timely manner. When generic standard is approved by ELC, supplier shall establish an assembly reference standard sample at the start-up of all new items with new material code.

9.3. Production Order

Production orders are used to manage the conversion of purchased materials into manufactured items to fulfill customer purchase orders at the requested quality, quantity, and timeline. Production orders route through various work centers on the shop floor.

The ELC material code should be correctly included in the production order so that production operators can check the ELC material code printed on shipper labels against the ELC material code on the production order. Therefore, the ELC material code is required to be included in the supplier's internal bill of material.

The supplier shall implement a procedure to ensure that the ELC material code on the purchase order is correctly transferred to the supplier's internal material code on the production order and verified by a second person to confirm that the conversion is correct.

When converting an ELC purchase order to a supplier production order in the supplier's production management system, the supplier's system should allow the operator to input the ELC material code and automatically find the corresponding supplier internal material code. Manually finding the corresponding internal material code can easily cause mistakes. It is expected that the supplier's system allows the use of a scanner to scan ELC PO information to input it into the supplier's system

or simply copy and paste ELC PO information to the supplier's system instead of typing the PO information to avoid typing mistakes.

9.4. Material Preparation

9.4.1. Material Pickup and Verification in Warehouse

The supplier's warehouse should prepare materials based on the picking list in the production order, verify each pallet or container for material code and lot number against the picking list, and ensure that there is no mixing of materials. The picked materials should be grouped and segregated according to the production order to prevent confusion with other production orders. As a best practice, the supplier is advised to use material barcode system to control materials and minimize errors in manual control.

9.4.2. Material Verification on Production Line

The supplier's operator, line leader, or material setup person shall perform an identification check when receiving materials from the warehouse and check each container prior to using it in production. The identification check should cover, at minimum the following: material code, color, artwork, and appearance of at least one piece. As a best practice, supplier is advised to use material barcode system to control materials and minimize errors in manual control.

9.4.3. Shipping Label Preparation

Supplier shall implement a procedure to manage shipping label preparation, verification, and application to eliminate the possibility of incorrect labels or label mix-up.

- Supplier shall ensure label printing request contains correct information for label printing.
- Supplier should follow the shipper label template aligned with ELC, refer to section 6.15.
- Supplier is recommended to print or manually write the carton number # on each label for good traceability control.
- The label printing operator should setup the printing machine, print sample labels and check the sample labels against the label printing request to ensure that the contents are all correct, including ELC material code, quantity, batch number, production date, vendor lot number, etc. It is recommended to use barcode scanner to check the correctness of ELC material code.
- A second person checks label contents against the label printing request to ensure they are all correct.
- The label printing operator packs out labels and transfers them to the production floor.
    - During label transfer, proper segmentation and identification with the production order must be applied to avoid mix-up.
    - On the production floor, the labels should be stored together with the other materials that are prepared for the same production order, and all materials shall be managed and segmented per the production order. Avoid storing labels for different products in the same location.

9.5. Line Clearance

Mix-up is one of the top three quality issues. Line clearance is essential to preventing mix-up. The supplier must implement a procedure and checklist to manage line clearance and prevent mix-up.

The checklist should include all the points that need to be checked and cleared, along with instruction on how to do it and how to verify it. It should be specific to each production line and designed based on risks. Here is an example for a printing line.

ESTĒE LAUDER COMPANIES

Checking Points	Line Clearance Operation	Operator	Checker
1) Incoming material storage area	Remove all materials remaining at the incoming material area, pack them well, count and label them properly, and remove them from the production line.		
2) Feeding machine	Remove all materials remaining in the feeding machine, and pack them back into the incoming boxes.		
3) Conveyor	Remove any product remaining on the conveyor, and beside the conveyor.		
4) Printing machine	Stop feeding materials, continue running for X minutes to ensure all products come out of the machine, stop machine and stop conveyor, 1) Verify inside of the machine step by step to clear all remaining products, 2) Verify the table to remove any remaining products. 3) Remove printing tools		
5) Conveyor	Remove any product remaining on the conveyor and beside the conveyor.		
6) Packing station	Remove any product remaining at packing station; Remove remaining labels		
7) FG storage area	Remove any product remaining in FG storage area, put them to the buffer area, then return them to warehouse.		
8) Blue boxes	Remove any product remaining in the blue boxes.		
9) Red boxes	Remove any product remaining in the red boxes.		
10) Floor	Remove any product remaining on the floor		
11) Inspection table	Remove any product samples, destroy or retain them; remove all documentations of previous run.		

Before the new production starts, the production staff must clean up all materials and documentation left over from the previous production against a checklist, and have it double-checked by a second person. Leftover materials or documentation should not be kept in the production area, even temporarily. They must be returned to the warehouse promptly to avoid mix-up.

A documented verification of proper line clearance is necessary for all items produced for ELC, with double verification and signature required.

9.6. Line Cleaning and Sanitization

The supplier should clean and sanitize the production line prior to production startup, especially the tools that contact the surfaces that will contact the cosmetic product. There should be a written procedure for cleaning and sanitization, in which the sanitizer and frequency are defined.

9.7. Line Setup and Startup Verification

It has happened many times that line/machine setup samples were mixed in deliveries and caused rejection or quality complaint. Once the production line/machine setup is completed and First Article Inspection confirms that the product quality meets the specification, the production line must be properly cleared and verified to ensure that all line/machine setup samples are removed from the production line prior to production startup. If the supplier wants to use the line/machine setup sample

in deliveries, the supplier must perform 100% inspection and ensure that all samples comply with the specification.

The supplier should create a startup checklist and use it to perform and document the startup verification prior to production. The checklist should include the following items, to verify:

- Line clearance has been properly completed after line/machine setup.
- Standards, specifications, drawings, and range boards are accessible to production floor personnel.
- Appropriate equipment and tooling for the production are in place.
- Machine and tooling settings are properly input and set.
- All equipment and the production area have been cleaned and sanitized.
- All materials brought to the line are approved by QA with green QC release labels and that they match the current BOM and standards.
- Product is being produced according to the SOP.
- All required information is correctly printed on shipper labels.
- First Article Inspection is performed to ensure that components match the approved ELC specifications, drawings, artwork, and standards/range boards. It is recommended that suppliers build digital artwork comparison capability.

9.8. Process Control

9.8.1. General Requirements

Suppliers are expected to manufacture defect-free components compliant with the regulations, specifications, and quality requirements. During the product development stage, the supplier should define the manufacturing process, identify CPP to ensure consistent CQA and satisfy customer and consumer expectations. The manufacturing process and related CQA/CPP should be clearly defined in the SOP and monitored, verified, and recorded on a regular basis during production. These data should be analyzed on a regular basis to monitor process capability.

9.8.2. In-Process Quality Control (IPQC)

IPQC should be performed following SPC approach with an approved quality inspection plan determined during development stage. Please refer to section 6.13.6 for detail requirements (inspection items, method, acceptance criteria, sampling plan).

- In-process controls and their acceptance criteria should be defined.
- In-process controls should be performed according to a pre-defined program.
- Any result outside the acceptance criteria should be reported and appropriately investigated.
- CQA - Refer to ELC packaging corporate specification, ELC material specification, ELC Defect Reference Guides in QA-SOP-001003_PROCEDURE FOR INSPECTION OF PACKAGING MATERIALS.
- Sample representativity - It must be representative to production cycle. For example, one injection shot, one printing cycle, etc.
- Sample quantity - The sample quantity for visual inspection must be equal to or above the sampling quantity required for Single Normal Inspection Level 2 for the subject batch.
- Sampling frequency - It must be sufficient to monitor process consistency.
- Preferred Process Control Inspection methods include:
  - In-process SPC - Supplier is recommended to use IPQC data to monitor Cpk for critical dimensions and functions per shift or day of production.
  - In-process Integrated Vision System - Supplier is recommended to apply automatic inline inspection using image comparison technology.

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- Suppliers are required to perform functional testing and dimensional analysis on their components per ELC PTP guidelines and Commodity Corporate Specification.
- Supplier shall perform identification check at each IPQC cycle. The identification check should cover at minimum the following: material code, color and appearance, artwork (pay attention to COO, ILN, UPC). For artwork inspection, suppliers must take at minimum representative samples of a full cycle at beginning of each shift and at end of each shift and at each time after changing the printing tool, perform QC inspection and keep the records and retains if applicable. It is recommended to perform the artwork inspection via Image Comparison by digital scanning the samples.
- IPQC should cover packing operations that may result in quality issues, such as mix-up, contamination, scratches, scuffs, or damage.
- IPQC records are required to be documented and retained along with the supporting data for ELC review upon request.

9.8.3. Production Stop and Restart

Supplier should establish a procedure to manage the stoppage and restart of production lines or equipment due to breaks, machine downtime, emergencies, problem-solving, power outages, etc., to ensure proper management of products on the production lines or equipment and avoid mix-up of semi-finished or incomplete products with finished products. A line clearance procedure must be defined and followed before restarting production to remove all products for which the required processes are not completed or potentially not completed. In the past, several rejections occurred due to insufficient line clearance after an emergency stop, where the equipment did not complete its work when resuming production.

9.8.4. Mix-up Prevention

Supplier should set up procedures to prevent mix-up during production and temporary storage in production floor. Please refer to the mix-up checklist and use it to check mix-up risks in production.

9.9. Packing & Labeling

Packing operation is a major source of quality issues that is often overlooked by in-process inspectors. Supplier should implement a procedure to manage the packing operations and ensure that the packing process is properly controlled by production team and inspected by IPQC inspector to prevent mix-up, scratches, scuffs, or damages, which are among the top 5 issues.

- Each loaded container must have the correct label before leaving the loading location for the next destination.
- Some suppliers may label many containers or all empty containers first and load them one by one. This is not allowed, as production may be stopped for any reason, leading to mix-up with these pre-labeled containers.
- Some suppliers may label the loaded containers after entering them into the warehouse. This is not allowed because it can easily cause mix-up.
- The packaging supplier should mark a sequential number on each carton label following the production sequence and maintain records for traceability.

For more details, please refer to the mix-up checklist prepared by ELC SQA for best practices in preventing mix-up.

9.10. Palletization

The supplier should implement an SOP to manage palletization operations. The following guidelines should be followed.

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- Pallet fumigation - The pallet for exportation must be fumigated with a fumigation certificate.
- Pallet length and width: 1.2m X 1.0m.
- Maximum height per pallet: maximum 1.35m.
- Maximum weight per pallet: 1000 kg.
- Pallet layout - it should be designed to allow interlaced layout from layer to layer to avoid splitting or falling. No cartons shall exceed the pallet.
- Pallet corner guards - Supplier should apply corner guards when needed.
- Pallet shrink-wrapping - Pallets need to be shrink wrapped when there is no cartons but only trays or when carton is not designed to be sealed (for example, a base and a cover which don't contact or overlap in final packing). The shrink wrap should exhibit adequate tension, must be free of holes or excessive wrinkling, and be closed over the entire surfaces including the bottom surface to avoid dusts or insects to go in the components.
- Pallet cello-wrapping - Supplier shall standardize the configuration for pallet wrapping to ensure that the entire pallet can be well wrapped to avoid loose wrapping. The cartons at bottom layer must be wrapped with the pallet so that the cartons will not move out of the pallet during transportation. Pallet should be wrapped tightly with plastic film from the pallet to the top layer of the shippers.
- Pallet stacking - Supplier need to confirm if pallet stacking is allowed for the components. If not allowed, supplier must label each pallet with "No Stacking". If allowed, suppliers should use a plywood board to segregate the stacked pallets to avoid damage of the top shippers.

9.11. Retain Samples

Retain samples are crucial for traceability and investigation of quality issues, and the supplier must keep retain samples from each production shift. It is recommended to keep at least one sample taken after a successful First Article Inspection at the beginning of each shift, one sample taken at the end of each shift, and one sample taken after a major change or adjustment, such as the adjustment of molding parameters or a change of decoration tooling like hot-stamping tool or silkscreen printing tool. Retain samples must be kept for a minimum of 5 years under suitable storage conditions, such as humidity, temperature, cleanliness, dimness/darkness to avoid color fading, etc.

Retain samples must be labeled with the following information at minimum:

- Supplier material code
- ELC Material Code
- Vendor Lot Number
- PO number
- Production date and shift (when applicable)
- Sampling point - beginning or end of production shift

9.12. Reconciliation

Reconciliation is a method used to verify the balance between the amount of material input to a process and the amount of output from it. At the conclusion of a manufacturing process, operations personnel should perform reconciliation calculations for the materials or components used in each completed batch. The calculation for reconciliation is as follows:

$$\text{Reconciliation \%} = \frac{Total\ units\ Produced + Scrap + Sample}{Quantity\ Used\ (Qty.issued - Returns)} X100$$

The result of the reconciliation calculation should be documented in the corresponding Batch Production Record. The Reconciliation (%) must fall within the documented acceptable limits. If the Reconciliation (%) is outside the acceptable limits, it may indicate a potential problem with the process. In such cases, operations personnel should investigate the result that fall outside the limits and provide explanations in the Batch Production Records. The Operations Supervisor or their designate should

review the Reconciliation (%) calculations as part of the Batch Production Records to ensure completeness and accuracy. They should also sign and date the records. If the Reconciliation results are outside the documented limits and no explanation is provided in the Batch Production Record, a Deviation Investigation should be initiated. Any open Deviation Investigations should be completed before the batch can be dispositioned.

9.13. Line Clearance After Production

Line clearance is a GMP requirement in manufacturing that ensures equipment and work areas are free of products, components, materials, labels, and documentation leftover from a previous production. The supplier must perform a full line clearance process at the start and the end of every production to reduce the risk of mix-up and cross-contamination.

9.14. Final Quality Control (FQC)

Finished goods inspection should be completed before sending the pre-shipment or co-shipment samples and the shipment. The finished goods inspection should include verifying compliance with the **ELC approved specification** and confirming that the shipper labels include the correct content and use the approved pack-out. Finished goods inspections are distinct from IPQC.

Some suppliers used to perform FQC against internal specification instead of the ELC approved specification. Discrepancies can occur when suppliers transferred ELC approved specification into their internal specification, resulting in rejected shipment at receiving site. It is best practice for supplier to use ELC approved specifications at FQC.

The sample quantity for visual inspection must be equal to or above the sampling quantity required for Single Normal Inspection Level 2 for the subject batch.

Please refer to section 6.13.6 for detail requirements (inspection items, method, acceptance criteria, sampling plan).

9.15. Non-Conformance Control

The supplier must establish documented procedures to manage nonconforming products and prevent their misuse or mix-up. Nonconforming products should be segregated and identified as "quarantine" both physically and in the supplier's inventory or quality management system. Placing nonconforming products in quarantine status is to prevent their unintended use or shipment and to ensure that they are properly investigated and disposed of according to the supplier's nonconforming product procedures.

9.16. Batch Release

Prior to batch release, all finished products should be inspected against **ELC approved specification**, and should comply with all acceptance criteria including correct labeling with ELC material code. Product release should be carried out by authorized personnel responsible for quality.

9.17. Sample Submission to ELC

9.17.1. Pre-shipment Samples

When required by receiving site QA or ELC local SQA, the supplier shall send pre-shipment samples to the receiving site QA or ELC local SQA prior to shipment. The pre-shipment samples must be representative of the beginning, middle (optional) and end of actual batch following AQL sampling plan aligned with receiving site QA or ELC local SQA.

ESTĒE LAUDER COMPANIES

9.17.2. Co-shipment Samples

Please refer to the communication letter for Component Standards and Co-shipment Samples for detail requirements. When required by receiving site QA or ELC local SQA, the supplier shall send co-shipment samples to the receiving site QA or ELC local SQA. Once all testing is approved, the supplier should send at least three co-ship samples (1B/1M/1E: one taken from beginning of production, one from middle of production, and one from end of production), along with a copy of the CoA and one shipper label to the receiving site QA or ELC local SQA. The shipment may be released to its destination when the co-ship samples are on their way. The co-ship samples will be inspected by receiving site QA or local SQA. In the event of a reject, a QN will be generated and the supplier will be notified.

9.17.3. Certificate of Analysis (CoA)

Packaging supplier must complete, retain and issue a **Certificate of Analysis (CoA) in English** for each shipment of component manufactured for ELC, where requested, and include all information required here below.

CoA header should include a table with following contents:

- Vendor name and address
- Manufacturer name and address
- Vendor material code # (optional)
- Vendor material description (optional)
- Vendor production order (optional)
- Vendor Lot #
- Vendor Lot Quantity
- Production date (YYYY-MM-DD)
- Final assembly line # (optional)
- ELC material code #
- ELC material description
- ELC PO #
- ELC Approved Specification Revision#
- ELC Approved Standard#
- ELC Approved Range Board#
- # of Cartons in total
- # of Cartons sampled
- # of samples pulled
- If an expiry date (or retest date) is required by regulations or recommended by the supplier, it shall be mentioned on CoA.

CoA body should include a table with following contents:

- Inspection items, acceptance criteria, inspection method, sampling plan, inspection results. The inspection items shall include all critical quality attributes required in ELC approved specification and corporate specification, including appearance, color, odor, sound (noise), dimensional, and functional requirements.
- All critical dimensions measurement results and their Cpk data.
- A summary of all Non-Conformances, Severity, and AQL
- A compliance statement: “We hereby certify that the product indicated above complies with all ELC approved packaging component specification requirements for appearance, copy, functionality, dimensions, and material used.”
- Attachment - When a contract lab is used for testing, the report issued by the contract lab shall be referenced on the CoA and attached to CoA.

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CoA footer should include a table with following contents:

- Name and title of the person authorized to release, signature of the person authorized to release, and date of release.

All supplier CoA template must be approved by ELC local SQA. For each commodity type, suppliers should send a blank copy of their CoA to the ELC local SQA for review. This is a one-time request to ensure that all critical quality attributes are documented in the CoA.

CoA must be stored at supplier for at minimum 5 years and be ready for random audit by ELC SQA. Refer to section 5.9 for detailed requirement.

Supplier is required to email CoA to this email address **COAPKG@ESTEE.COM** before or no later than the actual shipment arrival date.

- Email subject: CoA
- The CoA document must be named to include CoA, ELC material code, ELC PO#, Vendor lot#, Vendor name with COO. For example: COA-EWR0010061-PO450700839-VendorLot X1234-ABC China
- The CoA document must be attached to the email.

10. Storage of Finished Products

The supplier shall establish written procedures for storage management to ensure proper handling and storage conditions, including temperature, humidity, lighting, sanitation, pest control, and mix-up prevention, as well as any other precautions necessary to maintain product quality.

10.1 Warehouse shall check each container label for correct material code, batch, quantity to ensure to match the information in production order and material system.
10.2 When loading products to the racks, warehouse shall avoid putting together the products with similar material codes.
10.3 Palletization in warehouse:
10.3.1 Warehouse shall not mix different products on one pallet.
10.3.2 Warehouse should not redo palletization. If a situation arises where it becomes necessary, there shall be measures to avoid mix-up, such as clear segregation for repacking.
10.4 Finished products must be stored in defined areas under appropriate conditions for an appropriate length of time. If necessary, the storage environment condition and finished product quality should be monitored during prolonged stored.
10.5 Storage areas should permit organized storage. Supplier is recommended to apply a storage locator system to manage location of each pallet to minimize mix-ups.
10.6 When finished products are released, quarantined, or rejected, they should be stored in respective physical locations or by using any other system providing the same level of assurance.
10.7 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
10.8 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.
10.9 Periodic inventory checks should be performed to ensure the accuracy of inventory and that the acceptance criteria are met. Any significant discrepancy should be investigated.

ESTĒE LAUDER COMPANIES

11. Shipping

11.1. General Requirements

11.1.1 The supplier shall have documented procedures describing the distribution of products and the elimination of picking errors.

- A First-In, First-Out (FIFO) system shall be in place, whereby the oldest approved stock of product is used first, and that allows for the ready determination of the distribution of each lot of products.
- Records containing the name of the product, lot or control number, quantity and date shipped, and name and address of the consignee, shall be kept for at least 5 years.
- Transport conditions, including temperature, humidity, lighting controls, and any other precautions necessary to maintain product quality and ensure safe distribution, shall be established and maintained.
- Pallets shall be palletized according to specification/instruction.

11.1.2 The supplier shall ensure that an approved ELC Shipper Label submission form is on file. Verification of bar codes by scanner shall be organized. The supplier shall ensure that shipper labels are correctly and consistently applied to materials supplied to ELC and that labels meet ELC's Specifications in ELC Supplier Shipping Component/Raw Material Label Manual on shipper label content, symbology and layout.

11.1.3 The supplier is responsible for ensuring that the traceability of the distribution of the product by agents, brokers, traders, distributors, re-packers, and re-labelers is maintained.

11.2. Shipping Order

The supplier shall have the ELC material code printed on the shipping order and picking operators shall verify the ELC material code printed on the shipping label against the ELC material code in the shipping order to avoid mix-ups in picking.

11.3. Picking

Supplier shall implement a warehouse locator system and a barcode control system to avoid picking mistakes. FIFO (First-In, First-Out) shall be applied. Partial shipments shall be carefully managed to avoid mix-up. The products picked for each shipping order shall be segregated from each other to prevent mix-up.

11.4. Outgoing Quality Control (OQC)

Outgoing Quality Control (OQC) refers to an inspection carried out by the supplier in accordance with the quality agreement and specifications before the finished packaging component is shipped to the location appointed by ELC. OQC can result in mix-ups, damage, or contamination, so the supplier should implement procedures to manage OQC and prevent these issues.

11.5. Shipping Vehicles

All shipping vehicles must be cleaned and inspected for the following conditions prior to loading. If any of these conditions are identified, action must be taken to correct the condition and restore the vehicle to an acceptable status prior to loading.

- General cleanliness, foreign odors and dampness
- Foreign materials such as broken glass, oil, mold, dust etc.
- Insect, rodent or bird evidence
- Structural defects such as poorly fitting doors, inadequate latches, leaks, broken side panels, warped floors, miscellaneous protrusions, etc.

ESTĒE LAUDER COMPANIES

11.6. Loading

The supplier shall implement procedure to manage the loading operations to avoid mix-up or damage. When multiple material codes are combined in one shipment, the supplier needs to segregate them to prevent mix-up.

11.7. Shipping Documents

Supplier should provide all shipping documents required by the broker appointed by ELC. A copy of the CoA should be attached in the shipping document when it is required by receiving site QA or ELC local SQA.

12. Inspection at Receiving Site

Packaging supplier must conduct Visual inspection at IPQC/FQC with minimum sampling quantity of Single Normal Inspection Level 2. The receiving site QA performs inspections according to ELC procedure QA-SOP-001003, “Procedure for Inspection of Packaging Materials”.

13. Quality Notification (QN)

A shipment or lot of components can be rejected when the number of defective samples found during incoming inspection or production exceeds the AQL level defined in the statistical sampling plan. **ELC reserves the right to reject a shipment when a quality defect found during inspection or production, or distribution could result in consumer harm or a negative consumer experience.** Once a shipment is rejected, the ELC Quality Assurance department will issue a Quality Notification (F2 QN and Q2 QN) document in SAP system. When the total number # of defective samples falls within the acceptable AQL level, ELC has the option to issue an “Informational QN” which requires the Supplier’s root cause analysis RCA and CAPA response, without penalty to their quality score. Any questions or concerns regarding discrepancies with QN’s should be directed to the ELC QN initiator.

A QN includes following: ELC Material Code #, ELC PO#, ELC Batch #, ELC Inspection Lot #, F2 and Q2 #’s, Reasons for the reject, total number of defects found, tasks and required completion date.

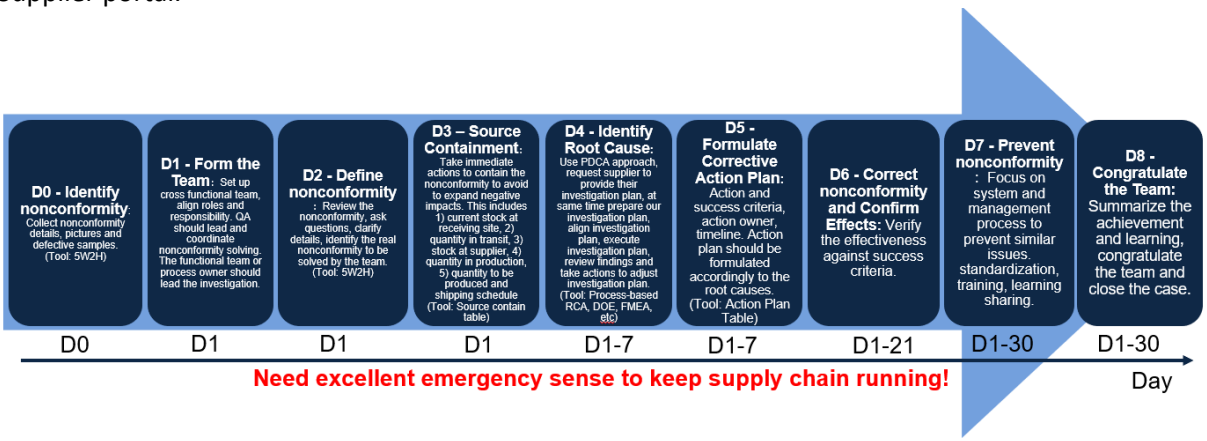
Samples from the rejected lot will be retained by the receiving site QA department for review with the supplier. The supplier must arrange for pick-up of these samples either by picking them up in person or by providing their FedEx or UPS account number to ELC QA. QN can be issued for components by ELC at any time, including:

- Incoming Inspection
- When a quality issue is detected during production of fill/assembly
- When a quality issue is found during the inspection of Finished Goods
- When ELC receives a complaint from the field

Supplier is responsible for accessing the Supplier Portal and completing the required actions assigned to QN. Failure to complete the actions within the required timeframe will result in a deduction of points from the monthly quality rating for quality performance. Upon request, the supplier task completion time can be extended for each timed task and must be negotiated with the ELC receiving plant. If a task time extension is granted, the supplier must complete the original tasks within the revised timelines in the Supplier Portal.

We strongly recommend our suppliers to apply 8D approach to manage an issue investigation, see below chart. When a QN is received, the supplier is responsible for providing an investigation plan, including immediate actions on source containment, potential RCA, and proposed CAPA, to the local ELC SQA for review and alignment. The supplier must then implement the investigation plan and update the local ELC SQA with a CAPA form or an equivalent supplier's form aligned with the ELC form.

The supplier must align the final RCA/CAPA with the local ELC SQA and update the RCA/CAPA in ELC Supplier portal.



We strongly recommend our suppliers to apply process-based investigation for RCA and CAPA. The supplier should identify all processes where the quality issue potentially occurred or where detection was missed, and verify relevant operations, people qualifications, machines, SOPs, process qualifications, process design, environment, and management. Please refer to the 'Quality Issue Investigation Form' for guidance. Supplier can use the ELC template or adapt their own internal form/template to ELC template.

14. Performance Review and Continuous Improvement

The supplier should review their quality performance on monthly, quarterly, and annual basis, then implement a Continuous Improvement Program (CIP) to improve their performance when needed. Continuous improvement Program should include data review, gap analysis, and CAPA plan, CAPA verification and performance monitoring. It should be reviewed with ELC local SQA. Any changes to ELC approved specification, processes, products, or equipment must go through the change control process. Here are the recommended KPIs (Key Performance Indicators) to be monitored by all suppliers.

14.1. Delivery Reject Rate (DRR)

ELC target for supplier-caused rejects is 0%. Each reject results in significant costs and wasted time for both the receiving site and the supplier. It is imperative that we work together to reduce rejects to zero.

14.2. Defect Parts Per Million (DPPM)

- Highly critical defect - target to be Zero.
- Critical defect - target to be Zero.
- Major defect - target to be within AQL and reduced continuously.
- Minor defect - target to be within AQL and reduced continuously.

14.3. New Product Right First Time (NPRFT)

New product launches often involve higher risks. NPRFT serves as a performance indicator to assess the supplier' effectiveness in new product development with right quality at the first time. Our objective is to achieve a 100% success rate.

14.4. Supplier Quality Performance Score

Please refer to the global SOP "QA-SOP-001002 Supplier Quality Performance Measurement Procedure". ELC evaluates each supplier's quality performance based on the following parameters:

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- % of rejected deliveries
- % of rejected units
- % of critical/highly critical quality notifications (QNs)
- Number of Level 3-6 issues (A Level 3-6 issue is defined as an issue found in a material that has been used and the finished product has shipped from the distribution center to customer. At this point, the product is beyond ELC's control and requires customer intervention.)

The supplier performance rating will be emailed to supplier at the beginning of every quarter. The email will include the performance scores for the past six quarters and a list of the quality notifications that impacted the supplier's rating over the same period. Suppliers with a poor/average (yellow) or very poor (red) rating must develop an action plan for improvement and review with their local ELC SQA contact. Failure to improve performance may impact future business with ELC.

Packaging Type	Performance Score Range	Performance Rating	ELC Requirement
All	95-100	Good/Excellent	Goal for All Suppliers
Secondary/Tertiary Packaging	80-94	Poor/Average	Need Improvement
Primary Packaging	75-94		
Secondary/Tertiary Packaging	0-79	Very Poor	Need Fundamental Improvement
Primary Packaging	0-74		

14.5. Audit Score

Audit observations are classified as critical, major, and minor or comments and the audit is scored based on the number of findings and their severity. A supplier passes the audit when the score is 70 or above. **All suppliers are expected to achieve an audit score of 90 or above.** It is highly recommended that the supplier includes the contents of ELC audit checklist in their internal audit checklist so that supplier's system can be assessed against ELC audit checklist on regular basis when conducting internal audits.

15. Reference Documents

15.1. QA-SOP-001002 Supplier Global Quality Measurement System Procedure
15.2. QA-SOP-001003 Procedure for Inspection of Packaging Materials
15.3. QA-SOP-00286 Supplier Preventive Maintenance Procedure for Equipment Mold and Tooling
15.4. QA-FRM-001001 Component Aesthetic Defects Estimation Template
15.5. SQP-FRM-001 CSAR Artwork Control Checklist and Action Plan
15.6. SQP-FRM-002 Mix-up Checklist and Action Plan
15.7. SQP-FRM-003 Pack-out Checklist and Action Plan
15.8. SQP-FRM-004 Contamination Checklist and Action Plan
15.9. SQP-FRM-005 Quality Issue Investigation Form
15.10. SQP-FRM-006 Packaging NPL Technical Readiness Checklist
15.11. ELC Supplier Shipping Component/Raw Material Label Manual
15.12. Advanced Product Quality Planning Manual

16. Revision History

VERSION NUMBER:	REASON FOR REVISION	EFFECTIVE DATE:
1	New Document	See Document Footer

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ELC Signing Page

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