

CVS Health: Quality Audit Program Guide

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1. INTRODUCTION

1.1 Quality Audit Program (QAP) Purpose and Expectations

- 1.2 A core priority of the QAP is to ensure factories and products comply with all applicable laws, regulations, QAP requirements, and Current Good Manufacturing Practices (cGMPs).
- 1.3 Factories are expected to foster a culture of integrity, ethics, and compliance at all levels of interaction with CVS.
- 1.4 The QAP is built on processes designed to prevent, detect, and address potential noncompliance and quality issues across CVS' domestic and international supply chain.
- 1.5 To achieve these objectives, the QAP's intent is to partner with suppliers and factories who consistently demonstrate high performance.
- 1.6 Factories with sustained poor performance do not meet CVS' expectations and are not acceptable for ongoing business.
- 1.7 CVS partners with an independent third-party audit service provider to help ensure QAP principles are consistently applied across the Store Brands (SB) supplier network.
- 1.8 The audit partner supports audit scheduling and execution and assists with the review and closure of corrective and preventive actions (CAPAs) resulting from audits.
- 1.9 CVS' preferred audit partner is UL Verification Services, Inc.
 - 1.9.1 UL provides factory auditing services under the Retail Certification Program (RCP) and the CVS Technical Audit Program. UL is an ANSI/ANAB-accredited international provider of management system certification and registration services.
- 1.10 Secondary Audit Service Provider
 - 1.10.1 In certain cases, CVS may require a factory to be audited by an alternate third-party audit service provider.
- 1.11 **Attachment 01: Audit Costs** outline the estimated costs associated with audit services.
- 1.12 **Attachment 02: Fines & Penalties** outline the estimated cost of noncompliance with the QAP requirements.
- 1.13 Questions about the QAP can be sent to: qafactoryaudit@cvshealth.com.

2. SCOPE

- 2.1 Sites supplying CVS SB regulated and non-regulated items.
 - 2.1.1 Factories that perform manufacturing and/or packaging activities.

3. GENERAL

- 3.1 CVS conducts two types of quality audits based on the product's regulatory classification: Regulated and non-regulated Technical audits.
 - 3.1.1 **Regulated Audit Program:** GMP audits for factories of FDA-regulated products
 - 3.1.2 **Technical Audit Program:** Technical audits (TA) for factories of non-FDA-regulated products.
- 3.2 Multiscope audits are conducted against all applicable standards.
- 3.3 For combination products, CVS determines the audit scope using the most stringent applicable standard to ensure product safety and quality.
- 3.4 **Table 01: Audit Requirements** outlines the product category, standard, and areas of focus for regulated and non-regulated audits.

Table 01: Audit Requirements

Product Category	Standard	Areas of Focus
Medical Devices (Regardless of Class or Exemption Status)	21 CFR Part 820	<ul style="list-style-type: none"> - Personnel qualification and responsibilities - Building and facilities infrastructure
Dietary Supplements	21 CFR Part 111, 117, 121	<ul style="list-style-type: none"> - Equipment control (including qualification, maintenance, cleaning, calibration)
OTC Drugs	21 CFR Part 211	
Infant Formula	21 CFR 106, 117, 121	
Cosmetics	ISO 22716, ANSI 455-3 FDA MOCRA	<ul style="list-style-type: none"> - Material procurement and handling - Production and process controls - Packaging and labeling - Laboratory Controls, Test methods - Holding and distribution - Complaint handling - Management responsibilities - Records and document control - Change Control - CAPA - Regulatory Event
Food (Including Medical Foods)	21 CFR Part 117	<ul style="list-style-type: none"> - Sanitation and Sanitation Controls - Pest Control - Personnel Practices - Traceability, Recall and Coding - Facility, Grounds & Equipment - Control of Inspection, Measuring and Test Equipment - Maintenance - Utilities/ Product Contact - Crisis Management - Food Safety & Security - HACCP - Allergen Control - Contamination Prevention - Good Laboratory Practices / Inspection & Testing - Regulatory Event - Food Defense - Quality System - Management Responsibility - Corrective Action / Root Cause Analysis - Training - Document and Data Control - Production and Process Control - Supply Chain Control - Conformance to Spec / Continuous Improvement. - Customer Service - Intentional Adulteration

Table 01: Audit Requirements

Product Category	Standard	Areas of Focus
General Merchandise	Technical Audit Program	<ul style="list-style-type: none"> - Quality Management System (QMS) - Facilities - Supply Management - Equipment Control and Maintenance - Contamination Control - Production Set Up - Product Conformity - Administration and Training - Hazard and Risk Management System

4. NEW FACTORY

- 4.1 All suppliers are required to identify the manufacturing and packaging sites for all potential new SB items on the Product Kickoff (PKO) form.
- 4.2 A factory may prequalify as an authorized factory by submitting a current third-party audit report and certificate demonstrating compliance with applicable product category requirements.
 - 4.2.1 The audit must have been conducted within 12 months of the product’s scheduled arrival at CVS’ Distribution Centers (DCs), referred to as the IN-DC Date, regardless if the product is regulated or non-regulated.
- 4.3 A factory that does not prequalify must be audited within 60 days of issuing the PKO.
- 4.4 **Table 02: Acceptable Certification Bodies and Reports** list the acceptable Certification Bodies (CB) and documents used to determine prequalification status.
- 4.5 **Table 02** is not an exhaustive list. CVS may accept documents from CBs not listed on Table 02 so long as the submitted documents provide evidence of a robust quality system and the CB’s credentials can be verified.

Table 02: Acceptable Certification Bodies and Reports

Certification Body	Product Category	Audit Report
Bureau Veritas BSI Eurofins Intertek NSF SGS UL US FDA USP	Non-Regulated	ISO 9001, 13485, Technical Quality Audit
	Food	GFSI, GMP, FDA EIR
	Cosmetic	ISO 22716, Cosmetic GMP, FDA EIR
	Dietary Supplement	Dietary Supplement GMP Registration, Dietary Supplement GMP, FDA EIR
	Infant Formula	Infant Formula GMP, FDA EIR
	Medical Device	ISO 13485, Medical Device GMP, FDA EIR
	OTC Pharmaceuticals	OTC GMP, FDA EIR

5. EXISTING FACTORY

- 5.1 Existing factories are required to undergo audits conducted by UL to remain authorized.
- 5.2 Third-party audit reports may not be used in place of hosting an onsite UL audit.
- 5.3 Based on audit results, a factory may be required to complete a follow-up audit or reaudit until an acceptable level of conformance is achieved.
- 5.4 Factories are expected to maintain a consistently high level of quality.
- 5.5 Declines in performance or repeated poor audit outcomes may result in additional remedial actions or loss of business.
- 5.6 Remedial actions may include, but are not limited to, audits for cause, additional product testing, or targeted retraining.

6. SEASONAL FACTORY

- 6.1 A seasonal factory provides CVS SB products for a specific season, seasonal events, or holiday (e.g., Christmas, Back-to-School, Summer) and does not conduct year round business with CVS.
- 6.2 A seasonal factory providing FDA-regulated products must meet the qualification requirements outlined in the New Factory section.
- 6.3 A seasonal factory providing non-FDA-regulated products is not required to undergo a quality system audit.
- 6.4 If a seasonal factory begins producing products for CVS on an annual basis, the factory will transition to an existing factory status and is subject to annual quality audits, regardless of product regulatory status.

7. APPLICATION REVIEW AND SCHEDULING

- 7.1 A UL Client Services (CS) representative collects site details required for audit quotation.
- 7.2 The quotation includes UL Terms and Conditions and must be signed by UL and the factory, or the party responsible for audit payment.
- 7.3 UL CS coordinates the audit date with the factory and assigned UL auditor.
- 7.4 An audit agenda is issued no later than 14 days prior to the audit and outlines the processes to be evaluated.

8. AUDIT EXECUTION

- 8.1 To ensure maximum value from the audit, UL requires that the product under scope be in active production.
- 8.2 If production is not occurring, similar or “like” products must be running to demonstrate the applicable manufacturing and/or packaging processes.
- 8.3 UL must be granted access to all relevant facility areas, documentation, and personnel within the audit scope.
- 8.4 Objective evidence may include, but is not limited to:
 - 8.4.1 SOPs and records supporting qualification of non-direct vendors
 - 8.4.2 SOPs and records supporting quality systems, complaints, and investigations
 - 8.4.3 Master Manufacturing Records and production batch records
 - 8.4.4 Validations, test methods, and test records
 - 8.4.5 SOPs and records demonstrating compliance with QA requirements

- 8.5 The auditor reviews nonconformances during the closing meeting.
- 8.6 An Audit Summary is sent within 4 business days of the audit end date.
 - 8.6.1 The Audit Summary is a preliminary report and may be subject to change. The report indicates whether a follow-up audit is required.
- 8.7 A Corrective Action Request (CAR) is available on the myUL Portal.
- 8.8 Refer to **Attachment 03: Audit Process** for the audit process flow.
- 8.9 **GMP Audit**
- 8.10 The GMP audit is managed under UL's Retail Certification Program (RCP).
- 8.11 The RCP is divided into two subcategories:
 - 8.11.1 **Full Scope RCP Certification:** The audit scope encompasses the factory's entire operation. This is reflected in the final report and certificate. The certificate can be leveraged by other customers and retailers.
 - 8.11.2 **Limited Scope RCP Certification:** The audit scope is limited to products produced by the factory for CVS. The final report and certificate list the specific products evaluated. The certificate cannot be leveraged by other customers or retailers.
- 8.12 Approved GMP factories are audited at least every 12 months, but no more than 13 months since the previous annual audit. Therefore, the CVS factory audit due date equals 13 months from the previous annual audit.
- 8.13 UL may schedule an audit sooner if required to align with the expiration date of the factory's certification.
- 8.14 Food factories are audited against GMP standards.
- 8.15 **CVS Food Addendum Audit**
- 8.16 A food factory certified to a GFSI recognized scheme may undergo a one-day CVS Food Addendum Audit.
- 8.17 GFSI recognized schemes include:
 - 8.17.1 SQF Code (current version)
 - 8.17.2 BRC Global Standard for Food Safety (current version)
 - 8.17.3 FSSC 22000
 - 8.17.4 IFS Food (current version)
- 8.18 Factories not certified to a GFSI recognized scheme are required to undergo a full 21 CFR Part 117 food audit.
- 8.19 FDA does not regulate products with secondary contact with food, for example, disposable dishware.
 - 8.19.1 Factories that make these products can choose between a GMP audit or TA.
- 8.20 The CVS Food Addendum Audit evaluates facilities that manufacture, process, and package SB products.
- 8.21 The audit assesses key areas, including prerequisite programs, food safety and security, and quality systems, and is conducted in conjunction with a third-party or GFSI audit.
- 8.22 Facilities must provide objective evidence demonstrating compliance and maintain a minimum of three months of records to confirm full implementation of the program.
- 8.23 CVS products must be in production during the audit.
- 8.24 If production is not occurring, the factory must demonstrate that equivalent processes, materials, and production lines are in operation.

- 8.25 Each audit item must be graded and supported with auditor comments detailing what was reviewed and observed.
- 8.26 Compliance verification includes review of prior CVS product batches.
- 8.27 UL issues a Certificate of Compliance for all GMP Audits except for audits under the CVS Food Addendum scope.
- 8.28 **Technical Audit**
- 8.29 A TA is based on industry best practices for Quality Management Systems.
- 8.30 UL does not issue a Certificate of Compliance for TA.
- 8.31 Approved TA factories are audited at least every 12 months, but no more than 13 months since the previous annual audit. Therefore, the CVS factory audit due date equals 13 months from the previous annual audit, unless the factory qualifies for a biennial audit schedule.
- 8.32 The factory can qualify for a biennial audit schedule if the following criteria are met:
 - 8.32.1 The previous annual audit score is $\geq 80/100$
 - 8.32.2 No critical nonconformance was issued during the previous audit
 - 8.32.3 No product recalls have occurred over the last two years
 - 8.32.4 All CVS corrective action requests must have been satisfactorily closed
- 8.33 If eligibility for biennial audits is lost, the factory must achieve a score of $\geq 80/100$ on two consecutive audits to regain eligibility.
- 8.34 **Table 03: Audit Result Outcome** outlines the actions required for each audit result outcome.

Table 03: Audit Result Outcome

GMP Audits	
Audit Result	Actions
≥ 1 Critical NC Issued	Auto Fail
≥ 1 Major NC Issued	CAPA Follow Up Audit required
Minor NCs, when issued in sufficient number to result in a marginal or noncompliant rating	
Technical Audits	
≥ 1 Critical NC Issued	CAPA Follow Up Audit required
Final score $<80/100$	

- 8.35 All other results not outlined in **Table 03** will be verified during the next audit.
- 8.36 Auto Fail applies only to GMP Certification Audits and is triggered when an audit results in a score of $\leq 65/100$.
 - 8.36.1 CAPA responses are not required.
 - 8.36.2 The factory may dispute the result.
 - 8.36.3 In these cases, UL’s Certification Committee conducts a review and issues the certification decision.
- 8.37 CVS Food Addendum audits are not subject to Auto Fail criteria as they are non-certified.

9. CAPA SUBMISSION, REVIEW, AND APPROVAL

- 9.1 CAPA plans not submitted within required timelines are subject to a CVS late fee of \$1,000 per late submission.
- 9.2 UL escalates CAPA delays or issues to CVS.

- 9.3 Requests for CAPA due date extensions must be communicated promptly to UL.
- 9.4 See *Attachment 04: Developing CAPA Plans* for guidance on developing a robust CAPA plan.
- 9.5 **GMP Audit**
- 9.6 Nonconformances are issued to the factory during the closing meeting.
- 9.7 There are 3 types of nonconformances: Minor, Major, and Critical.
- 9.8 All nonconformances require CAPA plans.
- 9.9 CAPA plans must be submitted to UL within 30 calendar days of the audit end date and include:
 - 9.9.1 Immediate correction
 - 9.9.2 Root Cause Analysis
 - 9.9.3 Corrective Action
 - 9.9.4 Expected completion date
 - 9.9.5 Responsible personnel
- 9.10 UL reviews CAPA plans to confirm that corrective actions address the identified root causes.
- 9.11 Incomplete or insufficient CAPAs are rejected and returned for revision.
- 9.12 All CAPA plans must be approved within 45 calendar days of the audit end date. Failure to meet CAPA submission and approval timelines may result in denial of certification.
- 9.13 As an accredited third-party audit firm, UL maintains an independent and publicly available disputes and appeals process.
- 9.14 Factories may dispute an audit finding and request modification or reversal through an independent review by the UL Dispute Committee.
- 9.15 Disputes must be submitted to UL within 14 calendar days of the audit end date to be considered. Additional details are available in UL's Procedure for Complaints, Disputes, and Appeals.
- 9.16 CAPA plans must be submitted and approved before a certification decision is issued and the Final Audit Report is released.
- 9.17 **Technical Audit**
- 9.18 Nonconformances are issued to the factory during the closing meeting.
- 9.19 There are 3 types of nonconformances: Discussion Points, Major, and Critical.
- 9.20 Factories are expected to address Discussion Points prior to the next audit, however, formal written CAPA plans are not required to be submitted.
- 9.21 Major and Critical nonconformances require CAPA plans.
- 9.22 CAPA plans must be submitted to UL within 30 calendar days of the audit end date and include:
 - 9.22.1 Immediate correction
 - 9.22.2 Root Cause Analysis
 - 9.22.3 Corrective Action
 - 9.22.4 Expected completion date
 - 9.22.5 Responsible personnel
- 9.23 UL reviews CAPA plans to confirm that corrective actions address the identified root causes.
- 9.24 Incomplete or insufficient CAPAs are rejected and returned for revision.

- 9.25 All CAPA plans must be approved within 45 calendar days of the audit end date.
- 9.26 Factories that fail to meet CAPA submission and approval timelines may be considered to have a lack of commitment to CVS requirements that could impact the factory's ongoing business relationship with CVS.
- 9.27 Factories may dispute an audit finding and request modification or reversal by requesting a review by CVS.
- 9.28 Disputes must be submitted to UL within 14 calendar days of the audit end date to be considered.

10. RELEASE OF FINAL AUDIT REPORT

- 10.1 UL's Technical Review team reviews audit results prior to issuing the Final Audit Report.
- 10.2 This review occurs immediately following the audit.
- 10.3 Any changes to audit results are communicated by UL CS.
- 10.4 Reports from the GMP audit program are available within 60 calendar days of audit execution.
 - 10.4.1 The release of the final audit report and certificate of compliance is dependent on the approval of factory CAPA plans.
- 10.5 Reports from the TA program are available within 10 calendar days of audit execution.
 - 10.5.1 The release of the final audit report is not dependent on the approval of factory CAPA plans.

11. AUDITS FOR CAUSE (AFC)

- 11.1 CVS determines when an AFC is necessary based on information from, but not limited to:
 - 11.1.1 Significant issues reported by the auditor
 - 11.1.2 Severity and number of NCs
 - 11.1.3 Lack of factory commitment to implement corrective action plans
 - 11.1.4 Regulatory action: Form 483s, Warning Letters, Consent Decrees
 - 11.1.5 Media reports
 - 11.1.6 Product complaint or recall
- 11.2 CVS notifies UL, requesting an AFC of the factory to ensure resources are available.
- 11.3 CVS notifies the factory that an AFC is necessary.
- 11.4 If the factory refuses to host an AFC, the issue is escalated to the QA Director of SB and the PDM.
- 11.5 Refer to *Attachment 05: Auto Verification of FDA Regulatory Activity* for details regarding AFC resulting from regulatory activity.

12. CAPA FOLLOW UP AUDITS

- 12.1 A CAPA Follow Up Audit is *scheduled* within 90 calendar days of the end date of the annual audit.
- 12.2 The CAPA Follow Up Audit is *executed* within an appropriate timeframe based on the expected completion date of the factory's CAPA plan.
- 12.3 Corrective actions requiring significant resources, financial commitment, structural change, etc., may require longer target completion dates.

- 12.4 The CAPA Follow Up Audit should be targeted for completion no longer than 6 months from the corresponding end date of the annual audit. This is to avoid performing the follow-up audit close to the next annual audit.
- 12.5 The CAPA Follow Up Audit should be onsite unless the nature of verifying implementation and effectiveness of corrective actions can be performed virtually.
- 12.6 UL Program and QAP Managers use good judgment when determining if the CAPA Follow Up audit should be onsite or virtual.
- 12.7 Existing factories can remain certified during the CAPA Follow Up Audit process if the factory is acting in good faith to comply with the QAP. Otherwise, certification may be suspended or withdrawn.

13. INFORMATION SHARING

- 13.1 UL shares information pertinent to the execution and evaluation of the QAP with CVS.
- 13.2 This includes proactively sharing required information and documentation, including, but not limited to, recent regulatory activity since the last audit, unresolved debt, and any other issues that could impact CVS' business relationship with the supplier and factory.
- 13.3 Audit information is maintained in a secure online dashboard with access limited to authorized CVS users.
- 13.4 Information available on the dashboard includes:
 - 13.4.1 Current audit workflow status (e.g., scheduling, audit execution, CAPA)
 - 13.4.2 Audit dates and audit due date
 - 13.4.3 Audit score and associated risk level or range
 - 13.4.4 Audit type (e.g., initial, surveillance, recertification)
 - 13.4.5 Number and severity of NCs
 - 13.4.6 CAPA status
 - 13.4.7 Final audit report
 - 13.4.8 Certification status (e.g., current, suspended, withdrawn)

14. CONTRACTOR POLICY

- 14.1 Under the SB QAP, a contractor is defined as a party engaged by a supplier to:
 - 14.1.1 Manufacture or package finished goods distributed by CVS
 - 14.1.2 Produce consumer ready products used as components of finished goods
- 14.2 Subcontracted factories that provide raw materials or interim products are out of scope for this audit program.
- 14.3 Factories and their contractors are responsible for maintaining their own supplier qualification programs, which are evaluated during the audit.
- 14.4 Contractors that manufacture and/or package finished SB products on behalf of the primary factory are subject to audit.
- 14.5 Suppliers must disclose the use of any contractor to UL and the supplier must notify CVS SB Product Manager and QA Manager prior to any change in manufacturing or packaging sites.
- 14.6 Failure to disclose contractor use may result in fines, cancellation of existing orders, and potential termination of the business relationship.

15. DEFINITIONS

- 15.1 **CVS Store Brand:** All products distributed by CVS meeting the following criteria: Product is labeled as “Distributed by: CVS Pharmacy, Inc.” or Product is labeled as “Distributed by: Advanced Healthcare Distributors, LLC”.
- 15.2 **Manufacturer:** Factory that will be combining raw materials into bulk finished product.
- 15.3 **Nonconformance (NC):** A failure to meet defined requirements.
- 15.4 **Packager:** Factory involved in the packaging of bulk finished product into the primary container (e.g., filling, blister packaging, bottling, etc.).
- 15.5 **Seasonal Factory:** A factory that provides CVS Store Brand products for a specific season, seasonal event, or holiday (e.g., Christmas, Back-to-School, Summer), and does not conduct annual business with CVS.
- 15.6 **Factory:** A facility that manufactures or packages CVS Store Brand products.
- 15.7 **Supplier:** A company identified as the provider of finished products by the Merchandise unit. The supplier may be involved directly in the production of the finished product or may contract the production out to a contractor.

Attachment 01: Audit Costs

GMP Certification Audit Program

RCP Certification	Limited RCP Certification
Audit Per Day Fee \$2250 – \$2500 This is a range, and is dependent on region in which audit will occur	Audit Per Day Fee \$1400 – \$1800 This is a range, and is dependent on region in which audit will occur
Auditor Expenses are charged at Cost Estimated range from \$300 – \$500 per day Average daily expenses varies based on region	Auditor Expenses are charged at Cost Estimated range from \$300 – \$500 per day Average daily expenses varies based on region
Accreditation Fee No additional charge, <i>Waived for all CVS factories</i>	Accreditation Fee No additional charge, <i>Waived for all CVS factories</i>
UL CAPA Fee No additional charge	UL CAPA Fee No additional charge
CVS Administrative Fee \$1000 or \$1500 Dependent on audit scope \$500 for Food Addendum audits (all follow up audits - \$500 administrative fee) Covers activities done by the CVS Quality Vendor Audit Team, who verifies factory adherence to CVS requirements	CVS Administrative Fee \$1000 or \$1500 Dependent on audit scope \$500 for Food Addendum audits (all follow up audits - \$500 administrative fee) Covers activities done by the CVS Quality Vendor Audit Team, who verifies factory adherence to CVS requirements
CVS CAPA fee (per audit) \$200 Only charged if nonconformances are issued The CVS CAPA Fee refers to the time spent by CVS in working with factories in relation to corrective actions.	CVS CAPA fee (per audit) \$200 Only charged if nonconformances are issued The CVS CAPA Fee refers to the time spent by CVS in working with factories in relation to corrective actions.

Technical Audit Program

Audit Per Day Fee \$850 – \$2050 This is a range, and is dependent on region in which audit will occur
Auditor Expenses are charged at Cost Estimated range from \$300 – \$500 per day Average daily expense varies based on region
UL CAPA Fee \$200 Only charged if nonconformances are issued
CVS Administrative Fee \$500 (follow up audits - \$500 administrative fee) Covers activities done by the CVS Quality Vendor Audit Team, who verifies factory adherence to CVS requirements
CVS CAPA fee (per audit) \$200 Only charged if nonconformances are issued The CVS CAPA Fee refers to the time spent by CVS in working with factories in relation to corrective actions.

Attachment 02: Fines & Penalties

Noncompliance	Fine or Penalty
Late submission of CAPA plans	\$1000
Failure to disclose appropriate factory or change in factory	Expedited Audit Expense / Potential Test For Cause Expense
Late scheduling & completion of quality system audit due to factory	\$250/Month, Expedited Audit Fees
*Confirmed falsified audit report and/or business license	Expedited Audit Expense, Potential Test For Cause Expense, Potential Termination or Loss of Business
*Evidence of the factory bribing or attempting to bribe the auditing team in any manner	Expedited Audit Expense, Potential Test For Cause Expense, Potential Termination or Loss of Business
*Evidence of either sexual, psychological, physical, verbal harassment, abuse, intimidation and/or bullying the auditing team in any manner	Expedited Audit Expense, Potential Termination or Loss of Business
*Repeat Non-compliance Issues, including but not limited to: - Non-compliance with Audit Schedule - Late or Insufficient CAPA response - Failure to Identify All factories	Additional Audits, Potential Test For Cause Expense, Potential Termination or Loss of Business
Audit postponement or cancelation	Within 4 weeks of confirmed audit dates: \$2000 Within 1 week of confirmed audit dates: Up to 80% of UL contract value, plus incurred nonrefundable expenses

*CVS reserves the right to terminate business immediately when any of these conditions are encountered.

Attachment 03: Audit Process



Attachment 04: Developing CAPA Plans

The audit program is designed to drive continuous improvement, ensuring factories maintain high quality standards, improve efficiency, reduce costs, and support on time product delivery. Continuous improvement is achieved through effective Corrective and Preventive Action (CAPA) development based on sound root cause analysis.

Effective root cause analysis and CAPA implementation support continuous improvement by:

- Preventing recurrence of issues
- Reducing potential risk to personnel
- Minimizing rework and scrap
- Improving overall competitiveness

Root Cause Analysis

Root cause analysis ensures that corrective actions address the underlying cause, not just the symptoms. Insufficient or superficial root cause analysis will be rejected and returned for revision and may result in repeat nonconformances in future audits.

Key principles of effective root cause analysis include:

- Assigning responsibility to knowledgeable personnel (or a team, as appropriate)
- Clearly defining the problem being analyzed
- Identifying potential causes through structured analysis
- Collecting and evaluating data to confirm or eliminate potential root causes

Common root cause analysis methods include:

- 5-Why Analysis
- Fishbone (Ishikawa) or Cause-and-Effect Diagrams
- Kepner-Tregoe Problem Analysis
- Fault Tree Analysis

CAPA Plan Development

CAPA plans must be based on the results of root cause analysis and include:

- Correction (immediate containment)
- Corrective action to prevent recurrence
- Consideration of potential impact to related systems or processes

CAPA plans must also identify responsible personnel and include a realistic implementation timeline. Approved timelines are used to determine appropriate follow-up and verification activities. If timelines or actions change, the factory must notify UL so verification can be appropriately planned.

Attachment 05: Auto Verification of FDA Regulatory Activity

It is the responsibility of the auditee to inform both UL and CVS Quality Assurance when a regulatory activity occurs.

Overview

An Audit For Cause (AFC) is required for the following FDA regulatory activities:

- Form 483
- Warning Letter
- Consent Decree

An AFC is not required for:

- Import alert or Import Refusals. In these cases, UL notifies CVS QA for further direction

An AFC may not be necessary if the site provides an FDA Establishment Inspection Report, as this is evidence that the agency has accepted the auditee's corrective actions, and the inspection is closed.

AFC Methodology

The default AFC format is a desktop audit. If a desktop audit is not feasible, an onsite AFC must be conducted.

The AFC focuses on, but is not limited to, the following:

- Confirming evidence of CAPA implementation
- Verifying CAPA effectiveness
- Ensuring supporting records are complete and demonstrate compliance with FDA expectations
- Reviewing any additional documents from the FDA since the original regulatory action took place

Post Audit Process

UL submits AFC results to CVS QA. CVS QA evaluates results to determine if additional actions are required. CVS QA informs QA business partners of any quality concerns discovered during the AFC and the AFC is closed once all actions are completed.