Supplier Guide for Quality System Audits

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1. Introduction

Values – Integrity & Business Practices

The Quality Audit Program (QAP) strives to embrace the following values when conducting business:

- Innovation: Demonstrate openness, curiosity and creativity in the pursuit of delivering excellence
- Collaboration: Sharing and partnering with people to explore and create things that we could not do on our own.
- Caring: Treating people with respect and compassion so that they feel valued and appreciated
- Integrity: Delivering on our promises; doing what we say and what is right
- Accountability: Taking personal ownership for our actions and their results

A priority of the QAP is to ensure the supplier and product comply with all applicable laws and regulations and promote adherence to QAP requirements and Current Good Manufacturing Practices (cGMPs). The supplier should also be committed to creating an environment that promotes integrity, ethics, and compliance with applicable laws and regulations at all levels of interactions with the customer and client. The QAP is built on processes to help prevent, detect, and resolve instances of potential noncompliance and poor-quality issues within CVS' domestic and international supply chain.

Key Terms for this Guide

- **CVS Store Brand:** All products distributed by CVS that meets the following criteria:
  - Product is labeled as "Distributed by: CVS Pharmacy, Inc.".
  - Product is labeled as "Distributed by: Advanced Healthcare Distributors, LLC".
- **Direct Importer:** CVS is listed as the importer of record, purchasing directly from the factory with no domestic distributor involvement.
- **Manufacturer:** Supplier that combines raw materials into bulk finished product.
- **Nonconformance (NC):** A failure to meet defined requirements

- **Packager:** Supplier that packages bulk finished product into the primary container (e.g., filling, blister packaging, bottling, etc.)
- **Seasonal Supplier:** A supplier 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.
- **Supplier:** A facility that manufacturers or packages CVS Store Brand products.
- **Vendor:** A party in the supply chain that makes goods and services available to CVS

Quality System Policy

Policies include but are not limited to: 21 CFR 111 (Dietary Supplements), 21 CFR 117 (Foods), 21 CFR 211 (Finished Drug Products), 21 CFR 820 (Medical Devices) and Good Manufacturing Practices Guidelines for Cosmetics.

Suppliers of non-FDA regulated Store Brand (SB) items are required to have quality systems in place and improve their quality systems as outlined in the UL Technical Audit Program (TAP).

Program Intent

The QAP is designed to help ensure:

- Suppliers provide our customers with safe, effective products that meet specifications and are produced in compliance to all applicable regulations and standards.
- Suppliers appropriately address issues and improve processes to adhere to the CVS SB requirements.

To meet the objectives mentioned above, the overall intent of the QAP is to do business with continually high performing suppliers. A consistently poor performing supplier is not acceptable to CVS. See section 4 for details on audit result expectations.

Introduction to our Store Brand Audit Partners

Good Manufacturing Practice (GMP) is a philosophy ensuring products are consistently produced and controlled to the quality standards appropriate for their intended use and conform to the regulatory requirements stipulated by health authorities. GMPs are fundamental to any manufacturing industry and are often required to be implemented by national governments.

CVS partners with a 3rd party audit service provider to help ensure our philosophy is applied throughout our SB network. The 3rd party audit service provider participates in scheduling and conducting supplier audits. In addition, this audit partner helps to manage the review and closure of CAPAs resulting from the audit. CVS' current preferred audit partner is UL.

UL Verification Services, Inc. – Supplier Quality Audits & Certification
UL provides auditing services with regards to the Retail Certification Program (RCP) and the UL Technical Audits Program. UL is an ANSI/ANAB accredited international provider of management system certification and registration services.

Secondary Audit Service Provider
CVS may request that a supplier be audited by a different 3rd party audit provider.

2. Program Basics

What type of audit is required?

There are two types of quality audits based on the regulatory category of the product:

- Technical Audit Program (TAP): Technical audit for suppliers of non-FDA regulated products.
- Regulated Audit Program: GMP audit for suppliers of FDA regulated products.

Store Brand	Audit Type
Non-FDA Regulated	TAP
FDA Regulated (i.e., Food, OTC Drug, Cosmetic, Dietary Supplement, Medical Device)	GMP
*Combination Non-FDA Regulated & FDA Regulated (e.g., Blow-molded container & Food)	GMP

*Discretion will be utilized by the Manager of the QAP to determine the appropriate audit type. A GMP audit will be required, at a minimum.

UL Technical Audit Program (TAP)

The UL TAP is designed to cover a wide range of non-regulated consumer products. It is based upon the principles of Quality Management Systems. The UL TAP includes the following 8 core modules:

- 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

UL Good Manufacturing Practice (GMP) Audit

The UL Retail Certification Program (RCP) is utilized for cGMP audits and UL offers two options to CVS suppliers, both of which follow the standard audit process:

- **RCP Certification** – The scope of the audit encompasses the entire operations of the supplier, which are reflected in the report and certificate.
- **Limited RCP Certification** – The scope of the audit is limited to the product produced for CVS. The resulting report and certificate identify the specific products that were evaluated during the audit and specifically exclude any other product format and associated processes.

OTC Drug, Medical Device, Dietary Supplement, Cosmetic:
A GMP audit evaluating supplier systems and processes used to maintain and control product safety and quality. Areas evaluated include, but are not limited to:

- Personnel qualification and responsibilities
- Building and facilities infrastructure
- Equipment control (including qualification, maintenance, cleaning, calibration)
- 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
- Recall

Food:
A GMP audit evaluating systems and processes used to maintain and control product safety and quality. Areas evaluated include, but are not limited to:

- 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 Requirements
- 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

The table below outlines the types of GMP audits:

Store Brand Product Type	Basis for Audit Requirements
Medical Devices **(Regardless of Class or Exempt Status)**	21 CFR Part 820 – Quality System Regulations
Foods **(Including Medical Foods)**	21 CFR Part 117 – cGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, Global Food Safety Initiative (GFSI). Bottled Water (as applicable)
Dietary Supplements	21 CFR Part 111 – cGMP, Packaging, Labeling or Holding Operations for Dietary Supplements, applicable elements of 21 CFR Part 117 21, CFR Part 121, and the FSVP requirements.
OTC Drugs	21 CFR Part 211 – cGMP for Finished Pharmaceuticals
Infant Formula	21 CFR 106, 117 and 121 – Infant Formula Requirements Pertaining to cGMP, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications
Cosmetics	ISO 22716, ANSI 455-3, and FDA MOCRA Manufacturing Practice Guidelines/Inspection Checklist published by the FDA on February 12, 1997; and revised on April 24, 2008, and June 2013.
Multiple Products and Combination Products	Multiscope audits against applicable standards. The scope for combination products is determined by CVS based on the most stringent standard to ensure safety and quality.

3. Audit Process

New Supplier

The vendor must identify all manufacturing, packaging, warehousing, and contract suppliers for SB items. Suppliers may prequalify to be added to CVS' Approved Supplier List (ASL).

Prequalification:
A supplier can prequalify as an authorized supplier by submitting a current 3rd party audit report and certificate that demonstrates the supplier is meeting requirements for the product category. The 3rd party audit must have been executed within 12 months of when the product is scheduled to arrive at CVS Distribution Centers (DC). This is known as the, "IN DC Date".

The prequalified supplier must host an initial UL audit within 12 months of being added to the ASL.

If a supplier does not prequalify, then a successful audit must be completed before the supplier is added to CVS' ASL. The initial audit must be completed no later than 60 days prior to the IN DC Date.

An audit is successful if the supplier is operating under an acceptable risk level. The supplier is approved with respect to the new items.

An audit is unsuccessful if the supplier is operating at an unacceptable risk level. The supplier is rejected as a provider of the new item. The supplier is eligible for future consideration pending buyer interest and the verification of corrective actions taken to address the observations.

Existing Supplier

The QAP requires annual audits executed by UL for all suppliers on the ASL. Based on the audit findings, supply sites may be required to undergo a follow-up audit or re-audit until an acceptable level of conformance is achieved. Corrective action plans for observations noted during the annual audit are submitted – within the designated timeframe – to UL for review and approval. See section 4 for details on audit outcome next steps for GMP and Technical Audits.

Annual audits may be waived if the supplier meets the following criteria: Supplier produces non-regulated items, annual audit costs exceed 5% annual sales to CVS (unit cost x total units sold to CVS), and no more than two consecutive waivers have been issued.
Requests for a waiver should be submitted to the QAP team in writing. Waiving an annual audit is at the sole discretion of the QAP Manager.

A supplier is expected to continually operate at a high-quality standard. Reductions in performance and successive poor audit ratings may result is loss of business or additional remedial action – for example, hosting an audit for cause, additional product testing, or targeted retraining.

Seasonal Supplier

A season supplier is a supplier that provides CVS SB products for a specific season, seasonal event, or holiday (e.g., Christmas, Back-to-School, Summer), and does not conduct annual business with CVS.

A seasonal supplier providing an FDA regulated item is qualified as outlined under the New Supplier section above.

A seasonal supplier providing a non-FDA regulated item is not required to undergo a quality system audit.

A seasonal supplier will transition to an existing supplier and be subject to annual quality audits if the supplier begins to produce items annually for CVS – regardless if the items are regulated or non-regulated.

Food Supplier

A food supplier certified to one of the GFSI recognized schemes may undergo a one-day CVS Food Addendum audit. A supplier not certified to one of the GFSI recognized schemes must undergo a full 21 CFR Part 117 food audit.

GFSI recognized schemes include: SQF Code (Current Version), BRC Global Standard for Food Safety (Current Version), FSSC 22000, or IFS Food (Current Version).

CVS Food Addendum Audit:
The CVS Food Addendum Audit is designed to evaluate facilities that manufacture, process, and package SB products. The supplier may also warehouse and distribute the products.

Facilities are evaluated in key areas: Pre-requisites, Food Safety & Security, and Quality Systems. The addendum is intended to be interpreted alongside a third party, or GFSI audit. Facilities are required to provide objective evidence to demonstrate their level of compliance to the audit item. It is required that the facilities must have at least 3 months records to prove a full implementation of a program in terms of documentation. It is a requirement that CVS materials be in production during the audit, or if not possible, affirm that the same processes/ materials/ lines are running that would produce CVS product. It is a requirement that each audit item be graded, with comments included to describe what the auditor investigated and what was found. Confirmation of compliance must include a review of previous batches of CVS product. Pre-requisite program confirmation should be done on time periods when CVS product is running.

21 CFR Part 117 Food Audit:
If a food supplier is not certified to one of the GFSI recognized schemes, then a full regulatory food audit is executed.

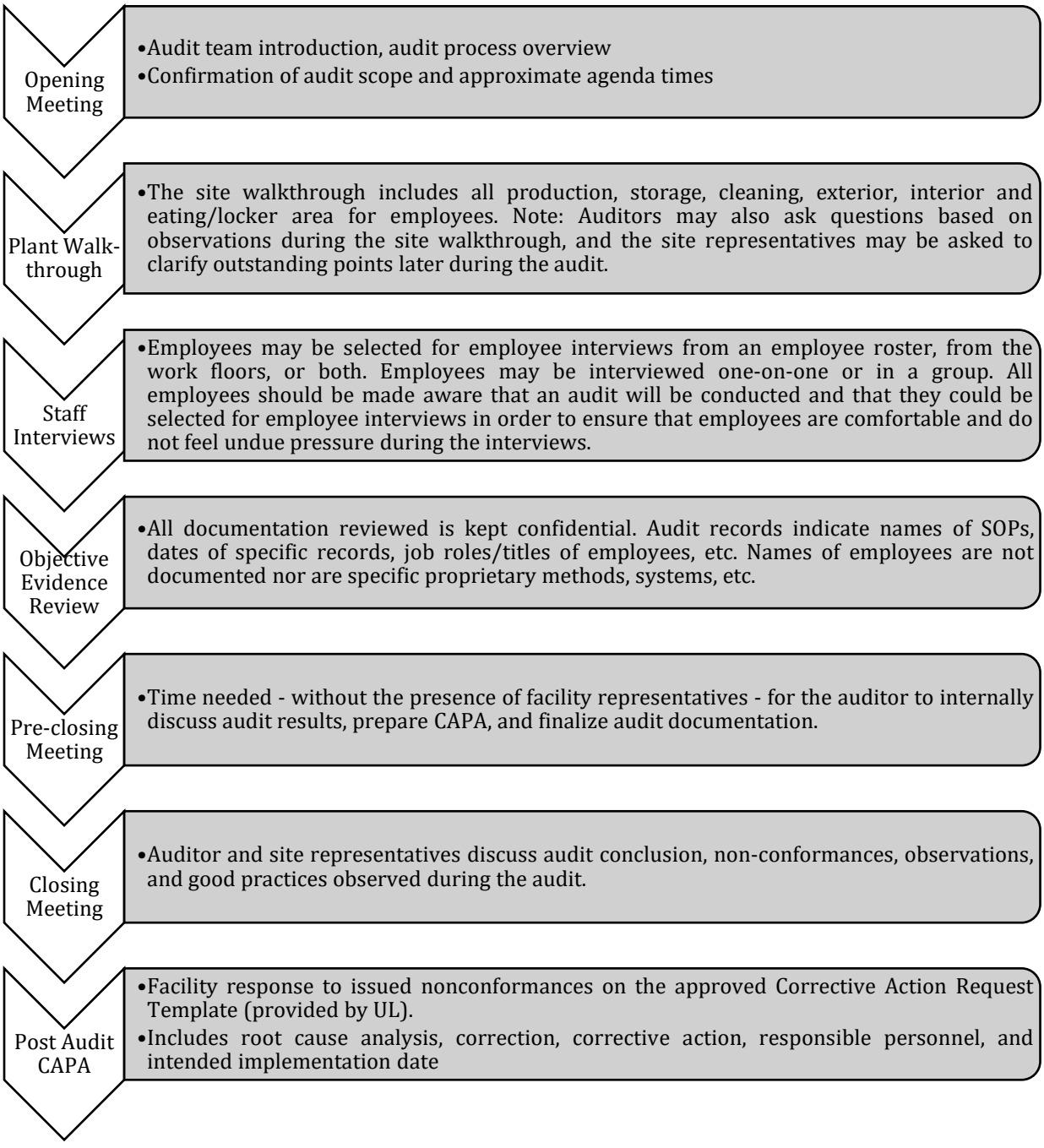
Audit Scheduling

Audit Scheduling

A UL Client Services (CS) representative sends the supplier an application form for completion. The application clarifies site details necessary for UL to quote the audit. The quotation includes UL Terms & Conditions and is signed by UL and the supplier or the party paying for the audit.

UL CS arranges an audit date agreed upon by the supplier and UL auditor. An audit agenda is sent no later than 14 days prior to the audit and provides a general overview of the processes that are evaluated during the audit.

Audit Process



Audit Requirements

Audit Evidence

To ensure the most value from the audit, UL requires that production be running on the product under scope – or that similar or 'like' products – are in production, demonstrating the manufacturing and/or packaging process. UL must be granted access to all applicable facility physical areas, documentation records, and staff under the scope of the audit.
Evidence typically includes, but is not limited to:

- SOP and documentation/records certifying non-direct vendors.
- SOP and documentation/records supporting Quality System, Complaints, investigations
- Master Manufacturing Records, Production Batch Records
- Validations, Test methods, Test Records
- SOP and documentation/records supporting QA Requirements have been met.

CAPA Dispute

As an accredited third-party audit firm, UL maintains an independent disputes and appeals process, which is publicly available. Any supplier under the audit program may request a dispute of an audit finding and request that it be modified or overturned through independent review by the UL Dispute Committee. The intent to dispute must be communicated to UL within 14 calendar days of the audit end date to be considered. Further details around the dispute process can be found in UL's Procedure for Complaints, Disputes and Appeals.

CVS Dashboard

Audit information is maintained in an online dashboard and access is restricted to authorized individuals.

The items that are visible include:

- Current status of audit workflow, e.g., scheduling, audit execution, CAPA
- Audit dates and audit due date
- Audit Score and risk level or range
- Audit activity, e.g., initial audit, surveillance audit, recertification audit, etc.
- Number and severity of NCs
- CAPA
- Final audit report
- Certification status, e.g., current, suspended, or withdrawn

4. Audit Results and Next Steps

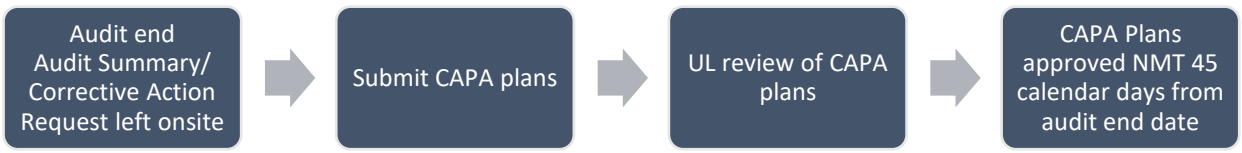
Audit Summary and Corrective Action Request (GMP Audit Program)

The auditor provides the site with an Audit Summary and a Corrective Action Request (CAR) form during the closing meeting. The Audit Summary is a preliminary report – subject to change – indicating if a follow up audit is necessary.

The UL Technical Review team reviews the audit results before approving the Final Audit Report. Technical review occurs immediately following the audit, and if there are any changes to results, these will be communicated by UL CS.

Overview of the CAPA Process (GMP audit Program)

1. The CAR is provided to the supplier during the closing meeting. The CAR details all NCs and includes instructions for submitting CAPA plans.
2. The supplier submits CAPA plans within 30 calendar days.
3. UL reviews CAPA plans to ensure the corrective action addresses the root cause of the non-conformance. Insufficient CAPA plans are rejected and returned to the supplier for revision. The supplier must resubmit CAPA plan revisions for approval.
4. All CAPA plans must be approved no more than 45 calendar days from the audit end date. Suppliers that do not complete CAPA submission and approval within 45 calendar days may be denied certification.



CAPA plans must be submitted and approved before a certification decision can be rendered and Final Audit Report released.

Note: Plans not submitted on time are subject to a CVS late fee of $1000 per late submission.

UL escalates delays or issues arising from the CAPA process to CVS. Requests to extend the CAPA Plan due date should be promptly communicated to UL.

Follow up Audit (GMP Audit Program)

The severity and number of NCs issued during an audit determines if a follow up audit is necessary. The UL certification committee determines the type of follow up activity based on the NCs and mechanism for verifying CAPA. Follow up audits ensure corrective actions are effective at remediating NCs.

TABLE: GMP Audit Results & Next Steps

Type of Nonconformance Received	Program required 'next steps'

One or more Critical (50 points each)	Results in an Auto-Fail decision and requires a new Initial audit to be conducted. No CAPA submission/response process is conducted. CAPA Disputes are permissible if received within 14 calendar days from the last day of the audit.
One or more Major (10 points each)	CAPA plan submission within 30 calendar days. Follow up audit within 90 days* of plan approval
Minor nonconformances issued to the extent that it results in a marginal or noncompliant score (3 points each)	CAPA plan submission within 30 calendar days. Follow up audit within 90 days* of plan approval
Minor Nonconformances issued, but score remains Compliant, or Reasonable or Low Risk	CAPA plan submission within 30 calendar days. Verification of CAPA plans at next annual audit.

*Where CAPA implementation may require follow up outside of the 90-day window, this may be permitted, provided UL approves and CVS agrees.

AUTO-FAIL

Auto-Fail applies to GMP Certification Audits. If audit non-conformances result in a High Risk threshold **score of 65 or less**, then supplier CAPA responses are not required. UL's Certification Committee conducts a review and a certification decision is rendered.

Follow up Audit (TAP)

The UL Technical Audit will result in a letter and color grade from A to D. Overall Rating is indicated in the table below, in relation to the letter grade achieved.

Overall Rating	
A	High Performance/Meets Expectations
B	Medium Performance/Further Improvement Needed
C	Low Performance/Significant Action Required
D	Very Low Performance/Urgent Action Required

Critical or Major nonconformances under the program will require objective evidence of closure to be submitted and reviewed. This may be done during the CAPA submission process.

CAPA Follow Up Audits are required for any audit that results in issuing ≥ 1 Major nonconformance. The follow up audit is scheduled within 90 calendar days of the annual audit end date. The follow up audit is executed within an appropriate timeframe based on

the expected completion date of the CAPA plan. The follow up audit should be targeted for completion no longer than 6 months from the corresponding annual audit end date. This is to avoid performing the follow up audit close to the next annual audit. Follow up audits do not impact the timing of annual audits.

If a follow up audit is failed, or the supplier is unable to demonstrate closure of the CAPA, then a re-audit may be required. CVS is made aware of the failure and indicates to UL the required next steps.

Expectations for Developing CAPA Plans (GMP and TAP)

The audit program is designed to drive continuous improvement. The continuous improvement ensures suppliers continue to increase quality, drive lower costs, and ensure on-time delivery of products. Continuous improvement starts by developing effective corrective action and preventive action plans (CAPA) through effective root cause analysis (also known as cause analysis).

Root cause analysis and implementation of effective CAPAs help ensure continuous improvment by:

- Preventing problems from recurring
- Reducing possible injury to personnel
- Reducing rework and scrap
- Increasing competitiveness

Root Cause Analysis

The fundamentals of Root Cause Analysis are as follows:

- Assign the task to a person (team if necessary) knowledgeable of the systems and processes involved.
- Define the problem to ensure you understand what you are analyzing.
- Develop theories about possible causes (brainstorm).
- Collect data and evidence that can help you systematically to rule in or rule out potential root causes.

Determining the root cause for an observation is important to ensure we are not just addressing a symptom. Analyze the situation through cause analysis to ensure you define the problem and address the condition (nonconformity, defect, undesirable situation). Root Cause found to be insufficient will be rejected and returned for revision. Improper or shallow root cause may lead to repeat nonconformances in subsequent audits. Where care is taken to develop insightful root cause, this will help avoid nonconformances issued for the same area in future.

There are several methods that can be utilized in the process of Cause Analysis.

- 5-Why
- Fishbone/Ishikawa/Cause-and-Effect Diagrams
- Kepner Tregoe Problem Analysis
- Fault tree analysis

CAPA Plan Creation

The CAPA plan should consider the items identified as part of the Cause Analysis. CAPA will require an immediate Correction (containment activity), as well as an action that is intended to prevent the item from recurring. Consideration should be taken around whether other related systems or processes could be impacted.

Plans should also include the personnel responsible, as well as the intended implementation timeframe. It is important to indicate a realistic implementation timeframe. This will be used as a guide to determine appropriate follow up timelines, and UL will anticipate that the plan has been carried out in accordance with the deadline set by the facility for its completion. Where a site decides that an updated timeline or action is needed, UL should be contacted and updated, so verification can be properly planned.

Contractor Policy

Under the Store Brand Quality Systems Audit program, a contractor is defined as a party hired by a supplier to:
- Manufacture or package any *finished* good(s) that will be distributed by CVS
- Produce any *consumer ready product(s)* used as a component in any finished goods

Subcontracted suppliers who provide raw materials and interim product(s) to suppliers or contractors are outside of the scope of the Store Brand Quality System Audit Program. Suppliers and their contractors are responsible for maintaining their own supplier qualification programs and this quality system activity will be evaluated during the audit conducted. Audits will be required for contractors who manufacture and/or package finished Store Brand products under the direction of the primary supplier.

Vendors must **disclose** the use of any contractor as defined above when filling out the UL Audit Application Package/Questionnaire. Vendors must notify CVS Store Brand QA Management and/or CVS Store Brand QA Audit Manager prior to any transition of manufacturing or packaging sites.

Failure by the vendor to disclose the use of a contractor will make the vendor subject to fines (refer to appendix I) and may result in termination of the business relationship. Any existing orders with that supplier may be cancelled.

5. Appendices

Appendix I: Vendor Fines & Penalties

Vendor fines and penalties may be necessary to ensure suppliers are providing appropriate support to ensure timely delivery of safe and quality products to market. Below is a list of fines and penalties that may be applied for program non-compliance:

Non-Compliance Type	Fine or Penalty
Late Submission of CAPA (Corrective and Preventive Action) plans	$1000
Failure to Disclose Appropriate Supplier Site or Change in Supplier Site	Expedited Audit Expense / Potential Test For Cause Expense
Late Scheduling & Completion of Quality System Audit Due to Supply Site	$250/Month, Expedited Audit Fees
Late Submission of New Product Information	$1500
*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 supply site 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 Suppliers	Additional Audits, Potential Test For Cause Expense, Potential Termination or Loss of Business

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

Appendix II: Audit Costs

GMP Certification Audit Program

Audit Fees Option 1 RCP Certification	Audit Fees Option 2 Limited Scope 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 expense varies based on region	**Auditor Expenses** are charged at Cost Estimated range from $300 – $500 per day *Average daily expense varies based on region
Accreditation Fee No additional charge, *Waived for all CVS suppliers*	**Accreditation Fee** No additional charge, *Waived for all CVS suppliers*

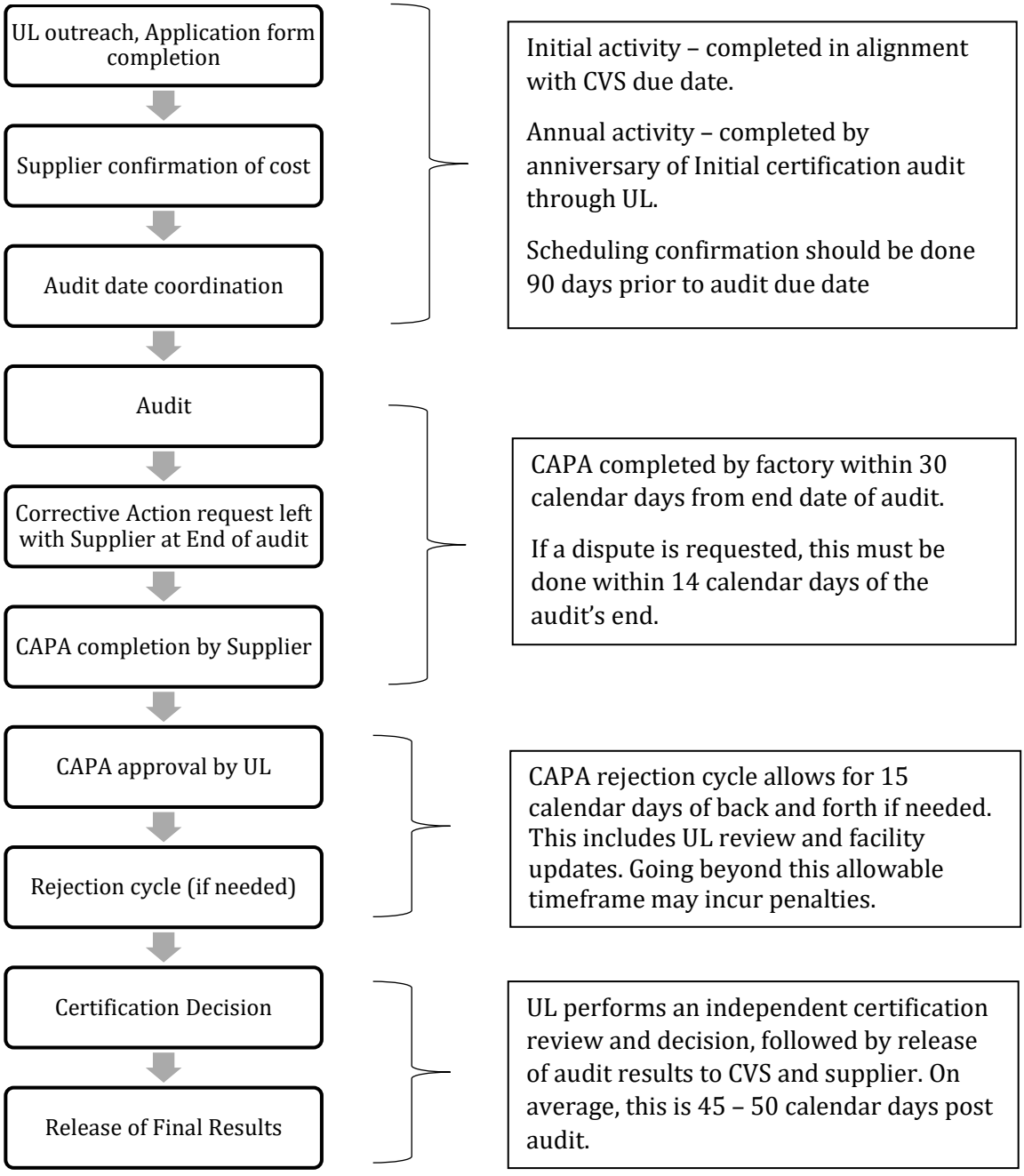
UL CAPA Fee No additional charge	**UL CAPA Fee** No additional charge
CVS Administrative Fee $1000 or $1500 Dependent on audit scope $500 for Food Addendum audits (all follow up audits - $500 administrative fee) Covers activities done by the CVS Quality Vendor Audit Team, who verifies supplier adherence 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 supplier 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 suppliers 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 suppliers in relation to corrective actions.

Technical Audit Program

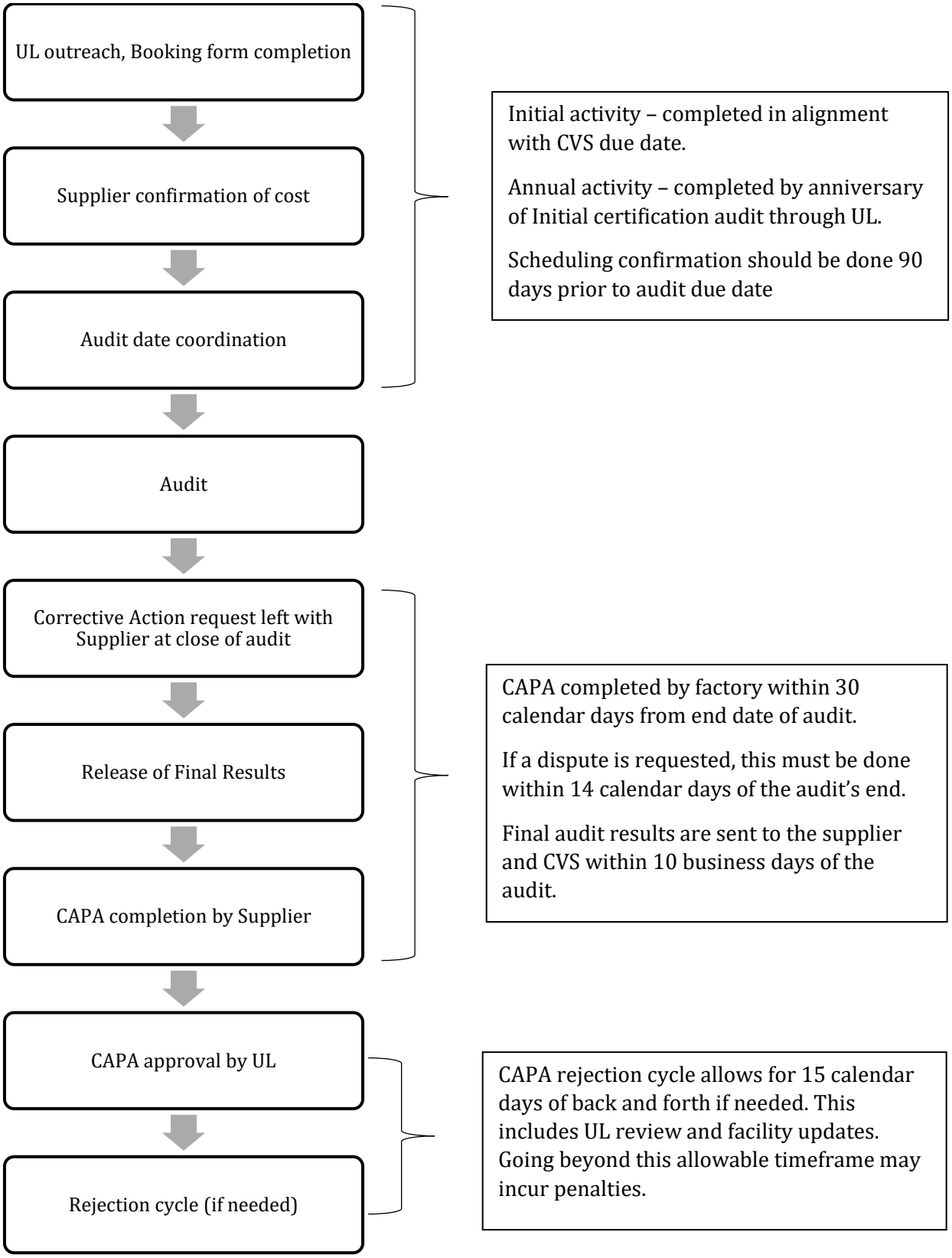
Audit Fees
Audit Per Day Fee $850 – $2050 *This is a range, and is dependent on region in which audit will occur
Auditor Expenses are charged at Cost Estimated range from $300 – $500 per day *Average daily expense varies based on region
UL CAPA Fee $200 *Only charged if nonconformances are issued
CVS Administrative Fee $1000 (follow up audits - $500 administrative fee) Covers activities done by the CVS Quality Vendor Audit Team, who verifies supplier 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 suppliers in relation to corrective actions.

Appendix III: Audit Process Timeline Summary

UL GMP Program Process Overview



UL Technical Audit Process Overview



Appendix IV: Pertinent Contact Information

UL Quality System Audit Program (GMP and TAP)

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UL Support Team: qafactoryaudit@CVSHealth.com

CVS Health Quality System Audit Program (GMP and TAP)

Ryan Glin | Sr. Manager, Factory Audit Compliance, CVS Health Store Brands
ryan.glin@CVSHealth.com

Appendix V: Auto Verification of FDA Regulatory Activity

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

UL automatically executes an Audit For Cause (AFC) once informed of recent regulatory activity.

An AFC is required for the following FDA regulatory activities:
- Form 483 classified as Voluntary Action Indicated (VAI) or Official Action Indicated (OAI)
- Warning Letters
- Consent Decrees

An AFC is not required for:
- Form 483 classified as No Action Indicated (NAI)
- Import Alerts or Import Refusals
    - In these cases, UL notifies CVS QA for further direction

An AFC may not be necessary if the auditee provides an FDA Establishment Inspection Report (EIR), 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 virtual/desktop audit. If a virtual/desktop audit is not feasible, an onsite AFC must be conducted.

The AFC focuses on:
- Confirming evidence of CAPA implementation
- Verifying CAPA effectiveness

POST-AUDIT PROCESS
UL submits AFC results to CVS QA. CVS QA evaluates results to determine if additional actions are required. The results and subsequent actions of the AFC are escalated to internal CVS stakeholders by CVS QA.