Supplier Guide for Quality System Audits

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1. Introduction

Values – Integrity & Business Practices

The Quality System Audit Program 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 Quality System Audit Program is to ensure suppliers and products comply with all applicable laws and regulations and promote adherence to Quality System requirements and Current Good Manufacturing Practices (CGMPs). Suppliers 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 suppliers, customers, and clients. The Quality System Audit Program is built on processes to help prevent, detect and resolve instances of potential noncompliance and poor quality issues within our 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.
- **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

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

Suppliers of non-FDA regulated Store Brand items are required to have in place and improve their quality systems as outlined in the UL Technical Audits program.

Program Intent

The intent of CVS Health Quality System audit program is to ensure all Store Brand Suppliers are held to and achieve the same standards and requirements regarding quality systems used to produce the products provided. The Quality Systems Audit Program in place 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
- Suppliers appropriately address issues and improve processes to adhere to the CVS Health store brand requirements.

In order to meet the objectives mentioned above, the overall intent of the audit program is to do business with continually high performing supply sites. Suppliers and/or their contracted sites consistently performing poorly within the program are not acceptable to CVS Health. In section four of this document, specific expectations regarding audit results will be discussed in more detail.

Introduction to our Store Brand Audit Partners

Good Manufacturing Practice 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. Good Manufacturing Practices are fundamental to any manufacturing industry and are often required to be implemented in plants and factories by national governments.

CVS Health partners with a 3rd party audit service provider to help ensure our philosophy is applied throughout our Store Brand network. The 3rd party audit service provider participates in scheduling and conducting facility audits. In addition, this audit partner helps to manage the review and closure of CAPAs resulting from the audit. CVS Health's 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
From time to time, CVS Health may request that a supplier be audited by a different 3rd party audit provider, at their discretion. This will be determined by CVS Health and such request made through them when applicable. The secondary service provider utilized will be approved by CVS.

2. Program Basics

What type of audit is required?

Before presenting the details of how the auditing program works, it is important to first understand what type of Quality System audit(s) will most likely be required at your production facilities. There are two types of quality system audits that may be conducted, both of which are listed below:

- TAP - Technical Audit Program (Quality System Audit for sites where non-FDA regulated products are manufactured)
- GMP - Good Manufacturing Practices (Quality System Audit for sites where FDA regulated Items are manufactured)

The quality system audit requirement is applied based on the type of product manufactured. The table below outlines the minimum quality system audit requirement for each.

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 Quality System Audit Program to determine the appropriate audit type. A GMP Quality System Audit will be required, at a minimum.

UL Technical Audit Program (TAP)

The UL technical audit program is designed to cover a wide range of non-regulated consumer products. It is based upon the principles of Quality Management Systems. The UL Technical Audits Program 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

This GMP audit is conducted by UL. UL's Retail Certification Program (RCP) will be utilized, and UL may offer two options to CVS suppliers, both of which follow the standard audit process:

- **RCP Certification** – under this option, the scope of the audit will encompass the entire operations of the supplier, which will be reflected in the report and certificate.
- **Limited RCP Certification** – under this option, the scope of the audit will be limited to the product(s) produced by supplier for distribution and/or sale by CVS. The resulting report and certificate will identify the specific product(s) that was/were evaluated during the audit and specifically excluding any other product format and associated processes.

OTC Drug, Medical Device, Dietary Supplement, Cosmetic:
A Good Manufacturing Practice (GMP) audit involves an evaluation of the systems and processes used by a company to maintain and control quality of items regulated by the FDA. Areas that are 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 Good Manufacturing Practice (GMP) audit involves an evaluation of the systems and processes used by a company to maintain and control safety and quality of items regulated by the FDA. Areas that are 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

There are five (5) types of GMP audits that are performed based on the type of product the facility manufactures, which are listed in the table below:

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 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, Global Food Safety Initiative (GFSI)
Dietary Supplements	21 CFR Part 111 – Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements, applicable elements of 21 CFR Part 121, 21 CFR Part 117 and the FSVP requirements.
OTC Drugs	21 CFR Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
Infant Formula	21 CFR 106 – Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications
Cosmetics	Systems and processes evaluated during a cosmetic audit can be found in the Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist originally published by the FDA on February 12, 1997; and revised on April 24, 2008 and June 2013

Multiple Products and Combination Products	In situations where products falling under multiple regulatory categories are being produced, multiple audits may be necessary depending on the combination of products and the potential risks. In situations where the site is producing a combination product, such as a drug delivery system, the scope will be determined and agreed upon with CVS. Discretion will be utilized by the Manager of the Quality System Audit Program to determine the appropriate audit path.

GMP audits will be performed at all supply sites that manufacture and/or package store brand items such as food, cosmetics, over-the-counter medications, medical devices, other FDA regulated store brand items.

3. Audit Process

New Suppliers

All suppliers are required to identify the production site(s) - manufacturing / packaging / holding and contract sites for all potential new Store Brand items. Suppliers must be pre-qualified by submitting a previous 3rd party audit report for an audit that evaluated quality systems compliance at the site(s) manufacturing and/or packaging the potential new item, or the supply site will be required to undergo an audit (conducted by the approved Audit Partner) no later than 60 days prior to the "in DC date" (date scheduled to arrive in distribution centers).

Pre-qualification audit reports must be submitted to the Store Brands QA Audit Manager for acceptability. The audit referenced in the submitted report must have taken place within the 6 months prior to the "in DC date" and have been performed by a qualified and competent audit body, as determined by the Store Brand Quality Audit Manager. If the audit was conducted as part of a certification program, within the last 12 months is acceptable. (An example of this would be an ISO or GFSI recognized scheme.)

If an acceptable report is provided, the supplier (and the supply site/contractor, as applicable) will be added to the list of qualified suppliers. The supplier's production site(s) will be required to undergo an audit utilizing CVS Health's approved audit partner approximately 12 months (+ 1 month) from the date of the pre-qualification audit. This is done to ensure that no supply site goes more than 13 months between quality systems audits.

If an acceptable report is not provided (or available), the supply site will be required to undergo an audit no later than 60 days prior to the "In DC" date. If the audit report indicates that the production site is operating under an acceptable Risk Level, the supplier/supply site will be approved with respect to the new item(s) and added to the list of qualified suppliers.

The supplier will be responsible for ensuring appropriate corrective actions are implemented in response to the site's observations.

If the audit report indicates that the production site is operating at an unacceptable Risk Level, the supplier will be rejected as a provider of the new item. Suppliers whose production sites are not approved may be eligible for future consideration pending buyer interest and the verification of corrective actions taken to address the observations noted in the pre-qualification audit report. Once a new supplier has been approved the production sites will be required to be audited on an annual basis. **Late scheduling and completion of Quality System audit due to supply site, will result in a $250 fee/month and potential termination of business.**

Existing Suppliers

Suppliers currently providing Store Brand items will have their production sites audited by the approved audit partner on an annual basis. Based on the audit findings, supply sites may be required to undergo follow-up audit or re-audit until they maintain an acceptable level of conformance under the Audit Program. All supply sites must prepare plans of corrective action for observations noted during any audit within the program-designated timeframe. Plans must be submitted to the audit partner for review and approval.

GMP suppliers will be required to abide by the provisions of the UL Retail Certification Program. Where a follow up audit is unsuccessfully accomplished, a re-audit will be necessary as defined by the program. Similarly, where UL Technical audit scores indicate poor performance, re-audit may be required to verify implementation and effectiveness of proposed actions. Based on this, poorly performing suppliers may be required to undergo more than 1 audit per year. Additional detail on audit outcomes and the associated next steps may be found under section 4.

Suppliers whose audit costs are greater than 5% of their sales revenue, may be eligible for a waiver of the audit requirement. This is only an option for suppliers of non-FDA regulated items. Suppliers who wish to apply for this exemption must submit their request in writing to the Store Brands QA Audit Manager. The submission for an exemption must be accompanied by a copy of an independent 3rd-party audit report from a qualified audit body. The scope of the audit must address compliance to applicable regulations and/or be an overall assessment of the quality systems used by the supplier to produce Store Brand items. Suppliers will be notified regarding the granting of the audit exemption.

As previously indicated, suppliers are expected to continually operate as High Performing suppliers and supply sites. Reductions in performance and successive poor audit ratings may result is loss of business or additional remedial action (e.g., product test for cause, audit for cause).

Seasonal Suppliers

Seasonal suppliers who are being used to provide a FDA regulated item for the first and only time, must provide a quality systems audit report or undergo an audit before they can be approved, as with other new suppliers. If they are unable to provide an acceptable report, UL will be required to audit them prior to approval.

Seasonal suppliers who are providing non-FDA regulated items on a one-time basis are not required to undergo a quality system audit.

Seasonal suppliers of FDA regulated and non-FDA regulated items who are being used repeatedly (year to year) will be considered to be an Existing Supplier and will audited annually.

Suppliers of Food Items

In addition to the quality systems audit requirement, all food suppliers are expected to be certified to one of the GFSI recognized schemes including, but not limited to: SQF Code (Current Version), BRC Global Standard for Food Safety
(Current Version), FSSC 22000, and IFS Food (Current Version).

Existing suppliers of food items who are certified to a recognized GFSI scheme will ONLY be required to undergo an abbreviated one-day audit by UL, under the CVS Food Addendum.

Full Food:

For those suppliers without an existing GFSI audit report, UL offers two program options:

Retail Certification Program audit under 21 CFR Part 117 scope
Suppliers who opt for this option will be registered under UL's accredited GMP certification program, and audited against the applicable standard for Human Food production. This will result in an audit report and certification against 21 CFR Part 117, and requires adherence to the elements of the certification program.

Safe Quality Food (SQF) Certification with CVS addendum
Suppliers who opt for this option will be registered under UL's SQF Certification Program, and will be audited against the current edition of the SQF scheme. The program timelines and certification requirements, including the use of the SQF Assessment Database, will apply in this case. A one-day CVS Food addendum will also be required.

CVS Food Addendum:

The UL CVS Addendum Audit is designed to provide an evaluation of facilities that manufacture, process, package CVS branded food products. The site 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.

Audit Scheduling, Process and Cost

Supplier information on existing and new production sites will be provided to UL for the purpose of scheduling the necessary audits. A UL representative will reach out to the supplier designate to:

1. Obtain additional Supplier Information
2. Provide a quotation for services
3. Schedule an Audit

Audit Scheduling

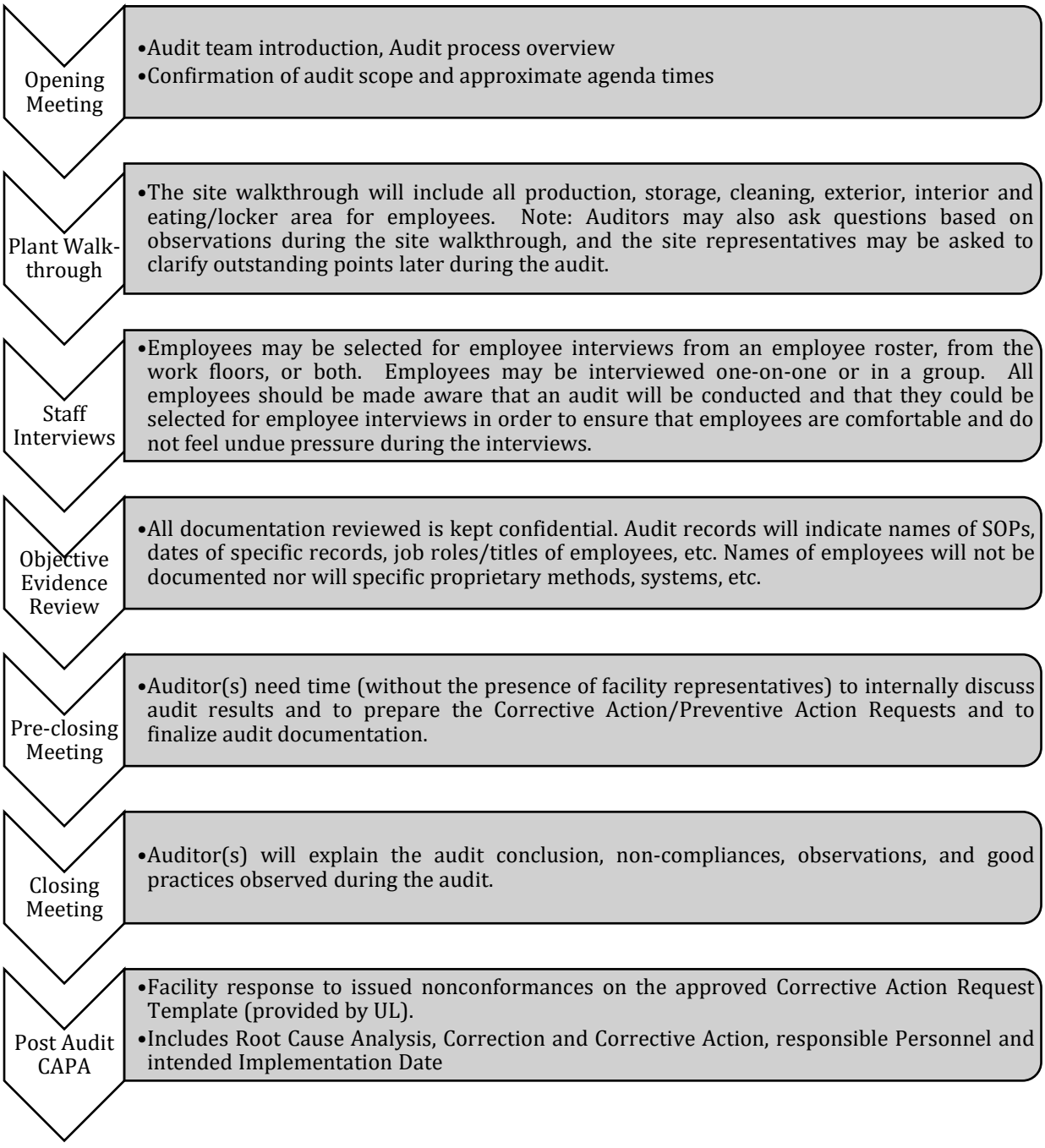
When scheduling an audit, a local UL Client Services representative (CS) will contact the supplier (or supply site as directed) and request that an Application Form be filled out and returned. This document clarifies the site's details and allows for UL to provide the necessary Quotation for services. The Client Services staff member will provide the appropriate party with the quotation, including UL Terms and Conditions for agreement and sign off.

UL Client Services will then arrange an audit date with the supply site that is agreeable to both the production site and the auditor. UL will send the production site a copy of an audit Agenda. This is sent no later than 14 days prior to the audit. This audit plan is a general overview of the quality system areas that will be evaluated during the audit.

Audit Process

Audit Activity

An audit activity consists of the following process:



Audit Requirements

Audit Evidence

In order 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.
The type of evidence typically requested 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 facility 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 in order to be considered. Further details around the dispute process can be found in UL's Procedure for Complaints, Disputes and Appeals.

CVS Dashboard

It is a requirement of the CVS program that audit information is maintained in an online dashboard that is visible only to CVS audit program Staff.

The items that are visible to CVS via this method are as follows:

- The current 'step' of the process in which the auditee is engaged (e.g., scheduling, Review, CAPA, etc.)
- Audit dates assigned, or audit due date
- The Audit Score/risk level or range
- The Audit activity (whether initial, surveillance or recertification, etc.)
- Nonconformances issued during the audit and their severity
- Status of certification (current, suspended or withdrawn)

Reports are also directly released to CVS through UL's Path SmartSuite system.

UL maintains a series of policies and procedures that cover all constituents — employees and authorized contractors, business partners and clients. Policies have been developed to

cover such aspects as IT Security, Encryption, Privacy, SDLC, and Records Management. Network access is restricted to authorized individuals, and network availability is monitored.

4. Audit Results and Next Steps

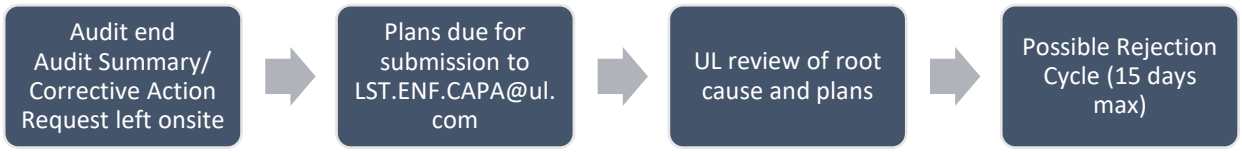
Audit Summary and Corrective Action Request (GMP Audit Program)

The auditor will provide the site with an Audit Summary and/or a Corrective Action Request Form at the close of the audit. The Audit Summary is not an official report but will provide a preliminary indication of whether a follow up will be needed as required by the program. The outcome indicated on the audit summary may be subject to change after a UL independent technical review of the audit results. Technical review occurs immediately following the audit, and if there are any changes to results, these will be communicated by UL Client Services.

Overview of the CAPA Process (GMP audit Program)

As the GMP audit program is a certification program, the CAPA plans must be submitted and approved before a certification decision can be rendered and final Audit Results released. As such, facilities receive Corrective Action Request at the end of the audit and adhere to the following process:

1. The facility will be left with a Corrective Action Request, detailing all issued nonconformances, at the end of the audit.
2. The facility will then have 30 days from receipt of this request to complete root cause and plans. Form is submitted to LST.ENF.CAPA@ul.com, as per the instructions on the CAR form.
3. UL will review CAPA plans and root cause for approval. Rejections for insufficient plan or Cause Analysis will be resubmitted to the facility for revision.
4. The site will have 15 calendar days for possible rejection cycle. If sufficient CAPA plans are not able to be obtained after a maximum of 45 calendar days, certification will be denied and a re-audit may be required.



Note: Plans not submitted within the required timeframe may be subjected to a late fee of $1000 per late submission. If any extension is needed on CAPA plan submission, permission must be requested of UL, using the LST.ENF.CAPA@ul.com email address. If a facility wishes to dispute, this may be done within 14 calendar days of the audit, through the same CAPA email. UL will escalate to CVS delays or issues arising out of the CAPA process.

Follow up Audit (GMP Audit Program)

The type and/or number of nonconformances issued on an audit will determine whether a follow up activity will be required of a GMP site. This will be indicated preliminarily on the Audit Summary left at the close of the audit. The intent of the follow up audit is to verify closure of nonconformances through review of evidence. The type of follow up activity is determined by the UL certification committee, dependent on the type of nonconformances and CAPA that must be verified. The following table explains how different audit results impact outcome and next steps under the GMP Program:

Type of Nonconformance Received	Program required 'next steps'
One or more Critical	CAPA plan submission w/in 30 calendar days. Follow up audit within 90 days* of plan approval
One or more Major	CAPA plan submission w/in 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	CAPA plan submission w/in 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 w/in 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 is in agreement.

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 CAP submission process. Where a follow up is deemed required by CVS, this will be scheduled with the site by UL for completion based upon facility target completion dates. Follow ups will not impact the timing of the scheduling of annual audits.

Where a follow up audit is failed, or the supplier is unable to demonstrate closure of the CAPA, a re-audit may be required. CVS will be made aware of the failure of the follow up audit and indicate 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 this 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 take into account 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. 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*

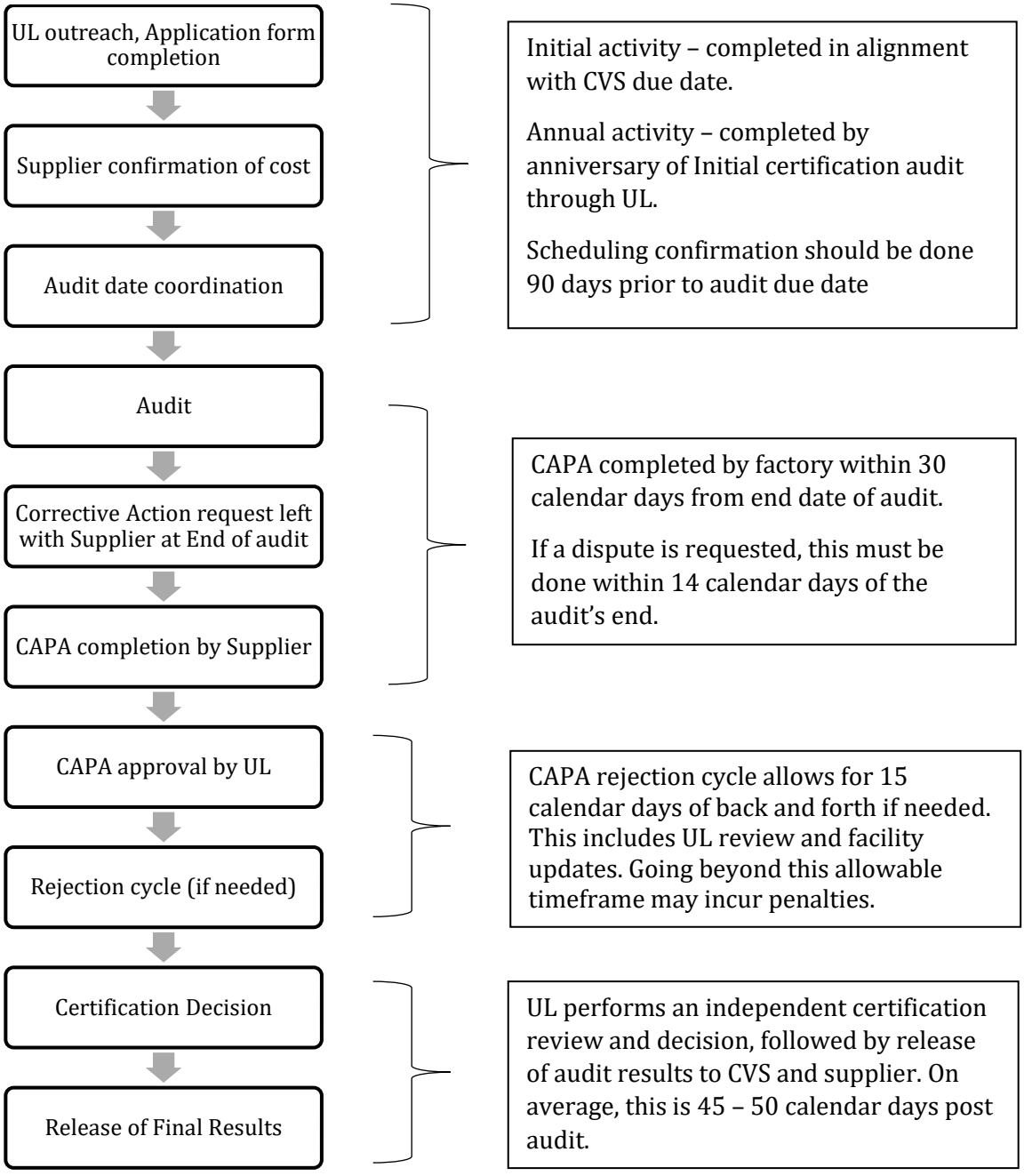
UL CAPA Fee No additional charge	**UL CAPA Fee** No additional charge
CVS Administrative Fee $1000 or $1500 Dependent on audit scope $500 for Food Addendum audits (all follow up audits - $500 administrative fee) Covers activities done by the CVS Quality Vendor Audit Team, who verifies supplier adherence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

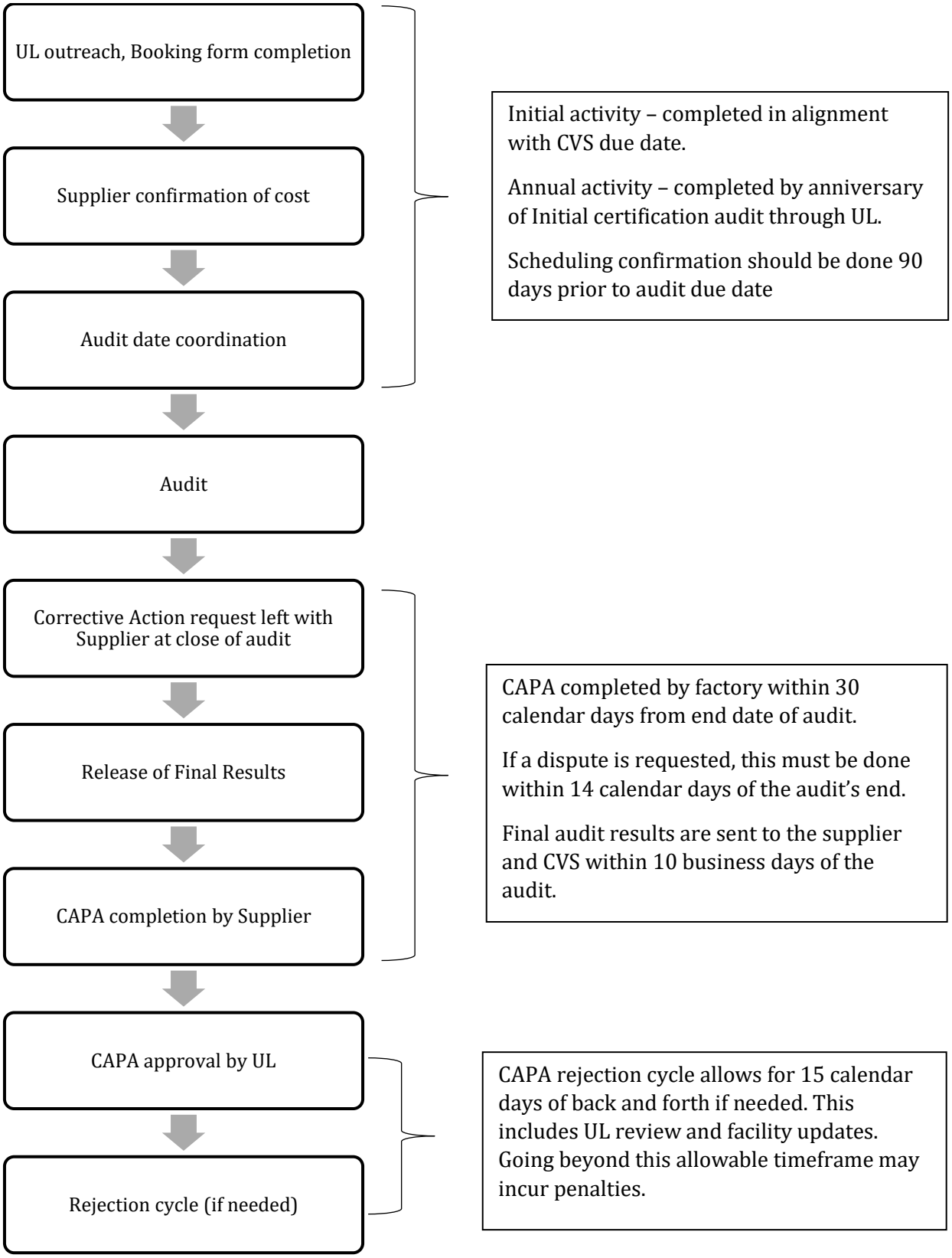
Audit Fees
Audit Per Day Fee $850 – $2050 *This is a range, and is dependent on region in which audit will occur
Auditor Expenses are charged at Cost Estimated range from $300 – $500 per day *Average daily expense varies based on region
UL CAPA Fee $200 *Only charged if nonconformances are issued
CVS 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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