

PROGRAM GOVERNANCE



AUDITONE™
The Power of Transparency

Issue Date: 06/10/17

Issue and Revision Number: 3

Governance Elements

Section 1	AuditOne Program Description
Section 2	AuditOne Scope
Section 3	Audit Booking process
Section 4	Audit Timeline
Section 5	Certifiable Audit Scheme
Section 6	Rescheduling / Cancellations
Section 7	Audit Posting
Section 8	Confidentiality and Rights
Section 9	Maintenance of Audit Standards
Section 10	Change Control Process
Section 11	Audit Hosting Program
Section 12	Detail Fee Structure for Program Participants
Section 13	Audit Access System Security
Section 14	Audit Firm Selection
Section 15	Anti-bribery, Conflict of Interest Policy
Section 16	Audit Firm Selection and Approval
Section 17	Audit Consistency
Section 18	Annual Governance Review
Section 19	Continuous Improvement
Section 20	Dispute Resolution
Section 21	Critical Findings

SECTION 1

Program Description:

The AuditOne Initiative (AuditOne) is designed to reduce redundant quality audits for raw material and packaging supplier's quality system audits conducted by consumer products companies to one standard audit that meets the expectations of each brand owner member in the program. The audits required for this program will be in-depth audits, verifying the effectiveness of the quality systems being reviewed through objective evidence. This audit program is designed to be a thorough and comprehensive verification of quality systems and the systems effectiveness towards reducing risk while providing assurance that the required quality systems are fully implemented.

SECTION 2

QAHI Scope:

Beginning in 2016, all non-food brand owners and non-food raw material and packaging suppliers are eligible to participate in the AuditOne Initiative. AuditOne will provide a list of approved audit firms, harmonized audit standards, specific audit addendums, Certifying Body guidance documents and program instructions for use by suppliers participating in the program. The program is based upon an annual audit to the standard required, the audit must be based upon objective evidence that the quality systems are operating as prescribed.

SECTION 3

Audit Booking Process:

1. Brand owners, Audit Firms and Suppliers will register with AuditOne at www.AuditOneGlobal.com as part of the AuditOne program. The registration will involve agreement to the program structure, confidentiality provisions, and anti-trust regulations.
2. Once registered, participating brand owners will invite suppliers to the AuditOne platform, and agree in advance to the approved quality standard plus any addendums (AVM's) required to meet the category of business for the service provided. When a supplier's products fit multiple categories, the highest ranked standard will apply. AuditOne provides a standard ranking chart located on the website (AuditOneGlobal.com) in the resource section.
3. The supplier will select the Audit Company (CB -certification body) to conduct the audit from the approved list of certification bodies based upon appropriate accreditation, geographic coverage, cost, and availability to perform the audit to the agreed to standard.
4. The supplier is responsible for contacting the approved certification bodies (CB's) over the AuditOne platform to discuss their audit requirements, and align on the standard required, verify capability and establish an audit date.
5. The supplier will request a quote for the audit cost from the CBs selected, the AuditOne Platform has been designed to assist with this process.
6. The supplier, after selecting their preferred CB, and confirming the required audit standard and any addendums required, will notify participating Brand Owners of the AuditOne program the status of the audit process at this time, the contact information for the audit firm selected, assigned Certifying Body, and the scheduled date of the audit.
7. The Brand Owners participating in the AuditOne have the right to contact the Certifying Body assigned to the audit (preferably in writing) over the AuditOne platform prior to the audit, with copy to the audit firm prior to the audit date, to discuss audit focus, prior findings, specific items to be thoroughly reviewed, any concerns, to ensure the Certifying Body is prepared to validate that the supplier is meeting all participating Brand Owner's expectations.
8. The audit will then be contracted by the supplier with the selected audit company referencing the AuditOne program.

9. The audit company CB selected then manages each subsequent stage of the audit up to and including uploading the final audit report in PDF format to the AuditOne Platform along with all required follow up information and data.
10. The audit company CB will schedule a pre-audit conference with the supplier detailing the following:
 - A. Audit deliverables (reports, follow ups, scores)
 - B. Audit purpose
 - C. Audit history
 - D. Audit focus areas (some may be derived from the Brand Owner-Certifying Body pre-audit conference)
 - E. Tools
 - F. Audit standard and any addendums added by members
 - G. Audit report and executive summary format
 - H. Benchmarking the audit report against the applicable standard and minimum acceptable requirements
 - I. Audit Guidance -the audit will focus on systems, system implementation, system effectiveness, and objective evidence to prove that the system is meeting its intended purpose
 - J. Brand Owner input for specific focus areas
11. The supplier is responsible to notify the participating Brand Owners that the audit is complete, and that the audit is posted. The supplier can then invite their participating Brand Owners access the completed audit, and subsequent audit responses.
12. The audit findings will be addressed according to the Standard protocol and addendum requirements. Action plans, audit responses, CAPA's will be uploaded to the AuditOne Platform and Brand Owners notified to access according to the target dates agreed to in the standard or addendum.

SECTION 4

Audit Time-line:

1. The audit timeline starts once the supplier selects the audit company and notifies participating Brand Owners.
2. The Supplier must schedule the audit with sufficient time to accommodate the audit firms stated lead-times
3. The audit company must ensure the audit date is provided to the supplier within 5 working days of contract signing.
4. The audit must take place within 45 working days of the audit contract signature.
5. Once the audit is scheduled, the supplier will notify its Brand Owners participating in the AuditOne program.
6. The CB will escalate to AuditOne any supplier that resists an audit, and any planned or requested audit date that is outside the 45-day timeframe. If the supplier fails to notify their Brand Owners of the need for the audit delay, AuditOne will do so in an effort to maintain the integrity of the program.

SECTION 5

Audit Report: Certifiable and Non-Certifiable Audit Scheme:

1. Certifying Bodies and CBs are to complete and issue the audit reports and certificates in accordance with the Audit Standard's requirements.
2. Where the scope of the audit process includes the verification and close out of non-conformances, in order to obtain certification, the approved CB must complete these activities in conjunction with the supplier as part of the audit process.
3. This is also the case for non-certifiable audit standards where only an audit report with pass or fail recommendation is delivered.
4. The supplier must provide to their Brand Owners the status of the required corrective actions within the time-frame prescribed by the audit scheme (dependent on which audit is carried out).

5. If a supplier will miss a date for corrective action implementation that will invalidate a certification, the supplier must immediately escalate notification to each Brand Owner involved in the AuditOne program, to develop next steps up to and including cessation of manufacturing. Each Brand Owner has the right to assess risk associated with an audit finding and work with the supplier to find acceptable means to mitigate.

SECTION 6

Audit Costs, Rescheduling/Cancellations:

Costs, scheduling and cancellation costs are considered as part of each contract between the CB and the Supplier. The Supplier is responsible to schedule, re-schedule or cancel an audit based upon program requirements and expectations. Any associated cancellation costs are the responsibility of the supplier.

SECTION 7

Audit Posting:

The completed audit will be posted to the AuditOne platform by the CB, corrective actions, CAPAs, and additional audit responses must be posted when due.

When a supplier engages in an audit to the accepted AuditOne standard, with an AuditOne approved Certification Body, the completed audit once approved by the supplier, must be posted on the AuditOne portal by the CB. The suppliers participating in the AuditOne program do not have the right to decide not to post a completed audit for any reason. Participating CB's have been instructed to notify AuditOne in the event that a supplier fails to post a completed audit for any reason. In this case, all participating AuditOne Brand Owners will be notified and appropriate actions will be taken to protect consumers from undue risks.

The supplier will authorize their Brand Owners access to the completed audit in writing using the AuditOne Platform. The supplier will notify their Brand Owners when the audit and additional information has been uploaded to the AuditOne platform. Brand Owners will evaluate the information posted and may contact the supplier with input or suggestions. If a Brand Owner believes an audit finding contains significant risk, the supplier and Brand Owner will develop a mitigation plan acceptable to both.

SECTION 8

Confidentiality and Rights:

AuditOne, the supplier, the Brand Owner and the audit firm (CB) will enter into a confidentiality agreement when registering with AuditOne. The results of the audit will be maintained by the audit company and posted in PDF format to the secure AuditOne Platform. The supplier will grant Brand Owners access to the completed audit on the AuditOne platform for the audit report and corresponding information. Confidentiality will be maintained by granting secure access to only authorized Brand Owners.

SECTION 9

Maintenance of Audit Standards:

Harmonized audit standards will be reviewed at least every 2 years by the AuditOne Standards Advisory Team. The team will be comprised of a cross section of AuditOne representatives, 2 participating Brand Owners, 2 participating Suppliers and 2 Certifying Body representatives whose responsibility is to ensure that the standards used for the program are meeting the needs of the CPG/FMCG Industry and Health Authorities (HAs). The committee will work with the standards bodies to ensure that the standards utilized in the program are current.

SECTION 10

Change Control Process:

Any changes or modification to the AuditOne harmonized standards, or AuditOne Initiative will be captured and member organizations notified within 30 days. All changes will be approved by AuditOne Strategy Steering Team prior to adoption. Silence is consent, if there is no response from a member organization following notification, it will be understood that the change has been accepted.

SECTION 11

Audit Hosting Program:

The completed audits will be posted on a secure platform CB in a PDF format, the supplier will allow access to Brand Owners participating in the AuditOne by providing permission on the AuditOne Platform. Brand Owners will be limited to observing audits that pertain to the audit standard agreed upon. When a supplier has been audited to more than one audit standard, access will be granted by the supplier to participating Brand Owners for each relevant standard. The supplier will control permission for who can review their audit or any other material posted on the AuditOne portal.

SECTION 12

Detail Fee Structure For Program Participants:

The total quoted audit cost for the program will be based upon the audit company's fee for the audit standard selected, the travel expense for the Certifying Body, possible follow up audits for verification of corrective action implementation, cost for report writing, the AuditOne audit hosting service fee of 25% of the total cost to maintain the system and provide secure access to selected Brand Owners.

SECTION 13

Audit Access System Security:

Access to audits once posted by the CB, will be controlled solely by the supplier to the participating Brand Owners in the AuditOne program. The platform provider will maintain security provisions to prevent unauthorized access to the supplier's confidential audit data, follow up CAPA information or issue resolution postings. The platform hosting provider is fully responsible for security on the AuditOne platform.

SECTION 14

Audit Firm Selection:

AuditOne will provide access on the platform to approved audit companies, with their contact information, audit standard certifications, and geographical coverage. The supplier will establish the audit standard/standards required to meet their Brand Owner expectations. Where a supplier provides service or product in multiple categories the highest ranked audit standard will be used. The supplier is responsible to contact the audit company and in conjunction with their Brand Owners establish the audit criteria, the audit cost, and schedule the audit. The supplier must ensure the audit results are posted on the AuditOne platform within the time-frame required.

SECTION 15

Anti-bribery, Conflict of Interest Policy:

AuditOne and its Brand Owner base maintain strict policies with regard to bribery and conflict of interest. Under no circumstances can a supplier post an audit directly to the AuditOne Platform, the audit must be posted by the CB in PDF format. The supplier must use only AuditOne approved audit companies. Brand Owners have the right to contact their CB to validate audit information posted on the portal is accurate. Responses to audit findings, non-conformances will be posted by the audit company to maintain consistency.

SECTION 16

Audit Firm Selection and Approval:

CB selection and approval criteria will include evaluation of the audit firm's standards by the CB AuditOne Guidance Team for Certifying Body qualification, Certifying Body training, frequency of company led witnessed audits, Certifying Body rating process among other established criteria.

AuditOne is open to all CB's that meet the established audit firm selection criteria agreed to by the AuditOne Guidance Team. Audit reports and Certifying Body feedback will be compared to Brand Owner's prior assessments of the supplier to ensure balance and be used as another metric in this assessment process. Supplier feedback will be collected following each audit engagement as part of the CB evaluation process and will be reviewed by the AuditOne Guidance Team .

CB's can be removed from the AuditOne program for failure to meet the Audit Firm approval criteria established, by a majority vote of the participating Brand Owners present at time of the vote. Re-instatement to the AuditOne program can be accomplished, once the deficiencies that led to removal have been resolved to the satisfaction of the member Brand Owners. A vote for re-instatement will be taken, if a majority of member's present vote for re-instatement the CB will be admitted back into the AuditOne program.

SECTION 17

Audit Consistency:

To maintain consistency between the approved audit firms and the standards selected, standards bodies and scheme owners, the Brand Owners participating in AuditOne will shadow audits conducted at least annually to ensure the efficacy and rigor required to meet both supplier and Brand Owner expectations are maintained. All shadow audits will be conducted in strict confidence with a non-disclosure document executed between the supplier, the CB, Brand Owner witness. Each CB will have a shadow audit conducted at a minimum of every 3 years. AuditOne will engage in spot checks to ensure the integrity of the system, spot checks will be undertaken by Brand Owners to verify corrective actions posted to the AuditOne platform are fully executed. Certifying Bodies will be instructed to verify that the quality system is documented as well as effective. The effectiveness verification may lengthen the audit time-frame; the supplier should be prepared to demonstrate the effectiveness of their quality systems through objective evidence.

SECTION 18

Annual Governance Review - Continuous Improvement Process:

Each calendar year, on or before April 15th, the Strategy Steering Team will meet and review the AuditOne initiative.

The annual review will include but not be limited to:

- CB evaluation based upon supplier feedback, thoroughness of audit reports, results of shadow audits, and data collected from the participating audit firms as to their overall usage
- Results of shadow and spot check audits conducted for audit firm CB consistency
- An internal audit of the AuditOne program will be conducted by a member company at a minimum of every two years to ensure the program is meeting its governance principles -an audit report will be issued to AuditOne member companies and the AuditOne Advisory Board for review and continuous improvement opportunities.
- The standards being utilized, any updates or concerns will be addressed
- The governance process will be reviewed and updated as needed ensuring compliance with the change control program
- Brand Owner, Supplier, CB feedback, complaints, and opportunities for continuous improvement to the AuditOne Strategy Steering Team.

- Overall program assessment and future plans.
- Status of harmonizing the audit templates and automating Certifying Body tools for each standard to provide consistency across the program
- Updates to the program guide and opportunities for process simplification
- Review to ensure that audits are capturing the effectiveness of the quality systems being audited through objective evidence
- Other review as needed

SECTION 19

Continuous Improvement:

As part of the AuditOne, Certifying Body guidance, may include a section on Continuous Improvement (CI)- the Brand Owners and AuditOne program will require continuous improvement efforts from qualified suppliers -the Certifying Body will work with suppliers based upon their technological ability to point out opportunities for CI. Under no circumstances do these CI opportunities need to be included in the final audit report.

SECTION 20

Dispute resolution:

In the event a CB Certifying Body and supplier cannot find common ground regarding an "audit observation/finding" the following process will be followed to resolve the dispute.

1. The audit firm will write the observation as they believe it represents the finding and post as part of the audit on the interactive web portal
2. The supplier will write their rebuttal including supporting documentation required to refute the Certifying Bodies finding to the observation and submit with the completed audit report to the interactive web portal
3. The Brand Owners participating in the AuditOne program will review both points of view and if required contact the Certifying Body and supplier to make their evaluation. If Brand Owners are satisfied with the supplier's response no further action is required - if Brand Owners perceive too much risk then further corrective actions will be required.

SECTION 21

Critical Findings:

In the event of a critical finding during the audit being conducted by the CB a notification to participating Brand Owners in the AuditOne program will occur within 24 hours of the discovery of the finding.

A critical finding is defined as: An observation is defined as "Critical" when any one or more of the following four conditions apply:

- Any nonconformance or non-compliance that will or already has adversely affected product performance meeting specification, safety, therapeutic efficacy, or regulatory requirements.
- Any nonconformance or non-compliance that if allowed to continue, might result in product rejection, Field Action, or serious regulatory action (e.g., Warning Letter or similar).
- Repeat "Critical" or "Major" observation from a previous AuditOne audit or a failure to meet a commitment made to a regulatory authority.
- The observation represents the complete absence of one or more quality system elements or system components necessary to meet regulatory requirements as defined in the AuditOne applicable standard or addendum.

In the event of a critical finding the following process will be followed within 24 hours of the finding:

1. The supplier must notify all participating AuditOne Brand Owners of the critical findings within 24 hours. The notification by the supplier should also contain a primary quality contact for each AuditOne participating Brand Owner.
2. The Certification Body Certifying Body must notify AuditOne of the finding. AuditOne will insure all involved Brand Owners have been notified within the 24 hour time-frame required. Failure to do so will result in all AuditOne participating companies being notified of the audit's critical finding(s).
3. The supplier must post the critical finding(s) on the AuditOne portal. Participating Brand Owners will evaluate the criticality of the finding. The Brand Owner assumes all responsibility to respond/act in accordance to the requirements of their internal procedures/processes and any applicable Health Authority regulations.
4. The supplier will immediately develop a plan of correction to address the critical finding, the plan will be provided to each participating Brand Owner through the AuditOne platform. Each Brand Owner will evaluate the plan and either accept or reject.
5. In the case the CAPA is rejected, the supplier will repeat the process until the risk is mitigated acceptably by all participating Brand Owners.

SECTION 22

Governance Teams

The AuditOne program will be governed by four teams:

1. Strategy Steering Team - Overall strategy and guidance of AuditOne. – Jean Pierre, Tessa
2. Standards Advisory Team - Responsible for standards selection and prioritization as part of our harmonization effort. – Tessa, Christine C, Jean-Pierre
3. Platform Experience Team - Provides feedback about the platform: user experience, enhancements and suggestions for the product roadmap. – Christine C, Tessa,
4. CB AuditOne Guidance Team - Responsible for the CB management process: selection, approval and certification. – Jean-Pierre, Christine C