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Referenced Documents

[A1 SOP 003 Change Control Procedure](#)

[A1 SOP 024 Finding Grading Procedure](#)

[A1 SOP 001 Audit Planning Procedure](#)

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1. SECTION 1 - Program Description

The AuditOne Initiative (AuditOne) is designed to reduce redundant quality audits for supplier's quality system audits conducted by fast moving consumer goods (FMCG) companies. AuditOne applies a standard audit meeting the expectations of multiple brand owners.

The audits required for this program will be in-depth audits, verifying effectiveness of quality systems, documented via objective evidence. AuditOne is designed to be an annual thorough and comprehensive verification of quality systems and the system's effectiveness reducing risk while providing assurance the required quality systems are fully implemented.

2. SECTION 2 - AuditOne Scope

Beginning in 2016, non-food brand owners and non-food raw material and packaging suppliers have been eligible to participate in the AuditOne Initiative. AuditOne provides a list of approved auditors, harmonized audit standards, specific audit addendums where appropriate, auditor guidance policies 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 the quality systems are operating as prescribed.

3. SECTION 3 - Audit Scheduling Process

- 3.1. Brand owners invite suppliers to set up their profiles on the AuditOne platform. From this point forward, all process activities will be conducted on the AuditOne platform.
- 3.2. During the onboarding process, suppliers agree to the program terms of service and select the standard appropriate for their facility from the menu of those approved by brand owners. If a supplier's products fit multiple categories, the highest ranked standard will apply. The standards chart can be found both on the AuditOneGlobal.com website and on the AuditOne Platform.
- 3.3. The supplier will submit an RFP (request for proposal) for the appropriate standard on the AuditOne platform to auditors qualified to audit to this standard. Those qualified will return proposals to the supplier.
- 3.4. AuditOne will provide, at a minimum, one proposal for every "request for proposal" (RFP) issued over the AuditOne platform except in geographies which are deemed a high travel risk (e.g., Pakistan).
- 3.5. The supplier will select an auditor to conduct the audit by uploading the signed proposal. Once signed, the proposal acts as a contract between the supplier and qualified auditor. The supplier provides contact information for the person responsible for scheduling the audit.
- 3.6. The supplier and auditor jointly schedule the audit date, sharing details with the brand owner(s) via the AuditOne platform.
- 3.7. The designated qualified auditor will provide the contact information of the auditor to the supplier and brand owner.
- 3.8. Should they wish, brand owners may contact the auditor in advance of the audit to discuss audit focus, prior findings, items to be reviewed or other concerns. This enables the auditor prior to the audit, to validate the supplier is meeting brand owner's expectations and incorporate brand owner guidance in the final audit plan.

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- 3.9. The auditor uploads the audit plan 4-6 weeks in advance of the audit, at which point the supplier pays for the audit (if they have not done so already). The funds are held in escrow until the audit report is uploaded and the audit completed.
- 3.10. The auditor will schedule a [pre-audit conference](#), develop an audit plan, for the supplier detailing:
 - Audit deliverables (reports, follow ups, scores)
 - Audit purpose
 - Audit history
 - Audit focus areas
 - Tools
 - Audit standard and any addendums
 - Audit report and executive summary format
 - Benchmarking the audit report against the applicable standard and minimum acceptable requirements
 - Audit guidance – the audit will focus on systems, system implementation, system effectiveness, and objective evidence to provide the system is meeting its intended purpose.
 - Brand owner input regarding specific focus areas
 - Audit preparation expectations
- 3.11. Once the audit is completed, and a certification decision made, the audit report will undergo technical review, if applicable. When the technical review is complete, AuditOne or the auditor uploads the audit report, approved CAPA plan and certificate to the AuditOne platform at which point it is shared with brand owners who issued the audit requirement(s).
- 3.12. The supplier may choose to make their certificate public or private. Likewise, they can share the audit report with other brand owners if they wish.

4. SECTION 4 - Audit Timeline

- 4.1. In general, the process takes approximately 20 weeks from platform invite to audit completion.
- 4.2. The audit timeline starts once the supplier selects the auditor and notifies participating brand owners.
- 4.3. The Supplier must schedule the audit with sufficient time to accommodate the auditors stated lead-times
- 4.4. The auditor must ensure the audit date is provided to the supplier within 7 working days of contract signing.
- 4.5. Once the audit is scheduled, the details will be shared with brand owners participating in the AuditOne program via the AuditOne platform.
- 4.6. The auditor will escalate to AuditOne any supplier that resists an audit, and any planned or requested audit date that is does not enable re-certification prior to the expiration of the current certification. 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.
- 4.7. A cancellation policy will apply to any audit cancelled or delayed.

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5. SECTION 5 - Audit Report: Certifiable and Non-Certifiable Audit Scheme

- 5.1. Auditors are to complete and issue the audit reports and certificates in accordance with the audit Scheme/Standard’s requirements.
- 5.2. AuditOne defaults to the scheme/standard specifications, when there is no specification provided. AuditOne will adhere to AuditOne policy
- 5.3. Where the scope of the audit process includes the verification and close out of non-conformances, in order to obtain certification, the supplier must complete these activities in accordance with their approved CAPA plan.
- 5.4. The supplier will provide brand corrective actions within the time-frame prescribed by the AuditOne brand owners – 28 working days from the formal audit report.
- 5.5. If a supplier misses a date for critical or major corrective action implementation the certification may be invalidated. The supplier must immediately escalate notification to brand owners 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.

6. SECTION 6 - Audit Costs, Rescheduling/Cancellations

Audit costs, scheduling and cancellation fees are considered part of each contract between the auditor and the supplier. The supplier is responsible to schedule, reschedule or cancel an audit based upon program requirements and expectations. Any associated cancellation costs are the sole responsibility of the supplier.

7. SECTION 7 - Audit Posting

The completed audit report will be posted to the AuditOne platform by the auditor, corrective actions (CAPAs), and any additional audit responses must be posted when due (if applicable).

When a supplier engages in an audit to the accepted AuditOne standard, with an AuditOne approved auditor, the completed audit must be posted on the AuditOne portal by the auditor. The auditor must post any completed AuditOne audits to the platform and the results must be shared with all brand owners who have issued requirement(s).

The AuditOne program is strictly an audit program, and as such, once an audit is undertaken it must be executed as an audit. The AuditOne governance does not allow a scheduled assessment or certification audit to be converted into a gap assessment, or a consulting opportunity. AuditOne recommends that suppliers prepare for the AuditOne audit by conducting an internal gap assessment or scheduling a gap assessment prior to the audit execution to prepare.

The supplier will authorize brand owners access to the completed audit using the AuditOne Platform. The platform will notify brand owners who have issued requirement(s) 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 confer to develop a mitigation plan.

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8. SECTION 8 - Confidentiality and Rights

AuditOne, the supplier, the brand owner and the auditor enters into a confidentiality agreement when registering with AuditOne. The results of the audit will be maintained by the auditor and posted in PDF format to the secure AuditOne Platform. Brand owners who issue requirements will automatically be notified of audit availability. The supplier will grant brand owners who have not issued an accepted requirement, 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 authorized brand owners.

9. SECTION 9 - Maintenance of Audit Schemes/Standards

Harmonized audit standards will be reviewed at least every 2 years by the AuditOne Scheme Advisory Team. The team will be comprised of a cross section of an AuditOne brand owner representatives whose responsibility it is to ensure that the standards are meeting the needs of the participating brand owners and Health Authorities (HAs). The committee will work with the standards bodies to ensure that the standards utilized in the program are current.

10. SECTION 10 - Change Control Process

Any changes or modification to the AuditOne harmonized standards or AuditOne Terms of Service will be reflected on the platform and users notified within 30 days. All changes will be approved by AuditOne Strategy 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.

[A1 SOP 003 Change Control Procedure](#)

11. SECTION 11 - Audit Hosting Program

The completed audits will be posted on the AuditOne platform by the auditor/AuditOne in a PDF format, the supplier will allow access to participating brand owners by providing access via the AuditOne Platform. Brand owners who issued an audit requirement that is accepted by the supplier will be granted access to the completed audit.

Brand owners will be limited to observing audits that pertain to the audit standard agreed upon. If 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 platform.

12. SECTION 12 - Detail Fee Structure for Program Participants

The total quoted audit cost for the program will be based upon the auditor’s fee for conducting the audit to the standard selected, possible follow up audits for verification of corrective action implementation, cost for report writing, scheme certification costs, the AuditOne Platform Referral fee of 25% of the total cost will be added to all proposals to maintain the AuditOne system and provide secure access to selected brand owners. The travel expense for the auditor is exempt from the referral fee.

13. SECTION 13 - Audit Access System Security

Access to audits once posted by the auditors, will be controlled solely by the supplier to the participating brand owners in the AuditOne program, except for brand owners issuing audit

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requirements, who will be granted access automatically once the supplier accepts the requirement on the platform. The platform will provide security, preventing unauthorized access to any data posted on the platform, follow up CAPA information or issue resolution postings. The greenfence platform is responsible for security and meets the applicable GDPR requirements.

14. SECTION 14 - Audit Firm/Auditor Selection

AuditOne will provide platform access to approved auditors, 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 contacts the Certifying Body and qualified auditors via the platform RFP process.

Only approved auditors that are authenticated to a particular scheme/standard will receive RFPs over the AuditOne platform. The supplier must ensure the audit results are posted on the AuditOne platform when the technical review has been completed and the audit is finalized.

15. SECTION 15 - Anti-bribery, Conflict of Interest Policy

AuditOne and its brand owners maintain strict policies with regard to bribery and conflict of interest. Except during start up (2018) where an approved audit can be uploaded off platform, under no circumstances can a supplier post an audit directly to the AuditOne Platform, the audit must be posted by the auditor/AuditOne in PDF format. The supplier must use only AuditOne qualified auditors. Brand owners have the right to contact the auditor to validate audit information posted on the platform is accurate. Responses to audit findings including non-conformances will be posted by the auditor to maintain consistency. Audits and Certificates are authenticated by AuditOne and referenced on the AuditOne platform to insure validity of all posted information.

16. SECTION 16 - Audit Firm, Auditor Selection and Approval

Auditor selection and approval criteria will include evaluation of the auditor qualifications by the AuditOne Steering Team. For auditor acceptance, the steering team will review the standards and geographic coverage of the auditor, auditor qualification process, auditor training, frequency of company led witnessed audits, auditor rating process among other established criteria.

AuditOne is open to all auditors that meet the established auditor selection criteria agreed to by the AuditOne Steering Team.

Audit reports and auditor feedback can 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 via a survey following each audit engagement as part of the evaluation process.

Auditors can be removed from the AuditOne program for failure to meet the auditor approval criteria established, integrity requirements, adherence to AuditOne policies and standard operating procedures, by a majority vote of the participating brand owners present at time of the vote.

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Reinstatement 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 reinstatement will be taken, if a majority of members present vote for reinstatement the auditor will be admitted back into the AuditOne program.

17. SECTION 17 - Audit Consistency/Witnessed Audits

To maintain consistency between the auditors and the standards selected, the brand owners participating in AuditOne will shadow audits annually. This ensures 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 non-disclosures executed between the supplier, auditor and brand owner witness.

The brand owners registered for AuditOne will conduct at a minimum, one witnessed audit per calendar year.

There is no restriction on the number of witnessed audits a brand owner can execute. The results of the witnessed audits will be shared with AuditOne and the other participating brand owners as a means of evaluation of the overall integrity of the audit.

18. SECTION 18 - Governance Review - Continuous Improvement Process

Each calendar year beginning in 2019, on or before April 15th of the following year, the Strategy Team will meet and review the AuditOne initiative.

The annual review will include but not be limited to:

- Auditor evaluation will be based upon supplier feedback, technical review and thoroughness of audit reports, results of shadow audits, results of surveys, and data collected from the participating audit firms.
- Results of shadow audits conducted for Certifying Bodies to validate auditor consistency
- The schemes/standards being utilized will be reviewed as well as any updates will be addressed.
- The governance process will be reviewed and updated as needed ensuring compliance with the change control program.
- Brand owner, Supplier, and auditor feedback, complaints, and opportunities for continuous improvement will be presented to the AuditOne Strategy Team with recommended corrective actions.
- Status of harmonizing the audit planning and reporting templates, automating auditor tools, and providing greater program consistency will be reviewed.
- Updates to the program guidance and opportunities for process simplification will be discussed.
- Review to ensure that audits are capturing and documenting the effectiveness of the quality systems being audited through objective evidence in the uploaded audit reports.
- Changes in the regulatory landscape will be shared with AuditOne.
- Input from this internal review will be documented and addressed using the program’s CAPA procedure

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- Status of corrective actions arising from internal audits, will be reviewed as part of the annual brand owner continuous improvement process.
- Brand owner review will include review of compliance with standard operating procedures including impartiality, change control, appeals and complaints.

Internal Audit

An internal audit of the AuditOne program will be conducted by a brand owner at a minimum of every two years beginning in 2018 using ISO 17021 as the guideline to ensure the program is meeting its governance principles. Following an audit report will be issued to AuditOne member companies and the AuditOne Strategy Team for review and continuous improvement opportunities.

AuditOne will address all findings utilizing the corrective action preventive action policy. Brand Owners will review the CAPA process at Steering Committee Meetings and provide input and guidance.

19. SECTION 19 - Continuous Improvement

As part of the AuditOne, auditor guidance may include a section on Continuous Improvement (CI). The brand owners and AuditOne will require continuous improvement efforts from qualified suppliers. The auditor 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.

20. SECTION 20 - Audit Findings - Dispute resolution – Appeals Process

In the event a certification body/auditor and supplier cannot find common ground regarding an "audit observation/finding" AuditOne will collect the required information and insure that the following appeals process is followed to resolve the dispute.

1. AuditOne will document the appeal and support the parties with the process outlined.
2. The auditor will document the observation as the auditor believes it represents the condition observed at the supplier's site as part of the audit report, the observation/finding will be provided to the technical reviewer as part of the audit report process.
3. The supplier will document their rebuttal to the observation/finding, including supporting documentation, required to refute the auditors finding/s to the observation/s, and submit their rebuttal report with the completed audit report to the technical reviewer.
4. The technical reviewer will evaluate the auditors documented observation, and the suppliers documented rebuttal and make an assessment.
5. If the technical reviewer determines that the auditor's observation/s was inaccurate or made in error and did not capture the actual condition at the supplier's site, the audit report will be returned to the auditor for correction with the feedback from the technical reviewer.
6. If the technical reviewer determines that the auditor's observation/s were accurate and reflect the condition observed by the auditor, the report will be approved and uploaded to the AuditOne platform as a final report.
7. In all cases, AuditOne will provide formal notice at the conclusion of the dispute resolution process to all stakeholders involved.

Appeal Process:

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8. If the supplier disputes the auditor and technical reviewer’s findings, the supplier has the right to appeal to the brand owners issuing an audit requirement through the AuditOne program.
9. The brand owners issuing an audit requirement to the supplier will review and evaluate the final audit report, and the supplier’s rebuttal and make a decision to either accept the final audit report or the supplier rebuttal.
10. The brand owners issuing an audit requirement have the right to contact the auditor and supplier over the AuditOne platform for additional information to make their evaluation.
11. The brand owners have the right to visit the supplier’s site to further investigate the disputed findings if desired.
12. Following the brand owners completed evaluation, if the brand owners issuing a requirement, are satisfied with the supplier’s rebuttal no further action is required.
13. If the brand owners issuing a requirement, agree with the auditor, and technical reviewer, then further corrective actions will be required by the supplier to address the audit finding. The supplier will have to accept the findings and develop a CAPA (corrective action/preventive action plan to address)
14. If the supplier refuses to accept the brand owner requirement for the required corrective action to address the auditor finding/s, then, it will be up to the brand owner to determine what, if any, implications there may be from such refusal.
15. The appeal process will be documented on the AuditOne platform by including the process findings in the final audit report.

21. SECTION 21 - AuditOne Program Dispute Resolution

- 21.1. In the event of a claim of any kind, dispute, complaint, question, inappropriate behavior, or disagreement arising from or relating to this the AuditOne Governance Document, AuditOne Terms of Service, AuditOne Auditor Guidance Document, including all AuditOne requirements, or the breach thereof, the parties hereto shall use their best efforts to settle the dispute, claim, question, or disagreement.
- 21.2. To this effect, they shall consult and negotiate with each other in good faith and, recognizing their mutual interests, attempt to reach a just and equitable solution satisfactory to both parties.
- 21.3. If they do not reach such solution within a period of 60 days, then, upon notice by either party to the other, all claims of any kind, disputes, questions, or differences shall be finally settled by arbitration administered by the American Arbitration Association in accordance with the provisions of its Commercial Arbitration Rules.
- 21.4. Any controversy, dispute, disagreement or claim of any kind, relating to AuditOne, including a breach of confidentiality, inappropriate behavior, failure to follow rules and processes as developed in the AuditOne Governance Document, Auditor Guidance Document, Terms of Service, including any and all AuditOne requirements, that cannot be settled through the parties best efforts as described, shall be settled by arbitration administered by the American Arbitration Association in accordance with its Commercial [or other] Arbitration Rules, and judgment on the award rendered by the arbitrator(s) may be entered in a Delaware, USA court, having jurisdiction thereof.

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22. SECTION 22 - Critical Findings

In the event of a critical finding (as defined in the governance), during the audit being conducted by the auditor, a notification to each participating brand owner issuing a requirement to the supplier, will occur within 24 hours of the discovery of the finding.

An observation is defined as “critical” when any one or more of the following conditions are identified:

- Product that may result in an immediate or latent consumer or patient safety risk, or result in a failure to meet therapeutic efficacy claims
- Fraud, misrepresentation or falsification of processes, products or data
- Any non-conformance or non-compliance that, if allowed to continue, might result in marketplace recall or field action, or serious regulatory action (e.g. Warning Letter or similar)
- Repeat “critical” or “major” observation from a previous audit or a failure to meet a commitment made to a regulatory authority
- The complete absence of one or more quality system elements or system components necessary to meet regulatory requirements

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

[A1 SOP 024 Finding Grading Guidance](#)

23. SECTION 23 - AuditOne Governance Teams

The AuditOne program will be governed by four teams:

1. Strategy Team - Overall strategy and guidance of AuditOne.
2. Scheme Advisory Team - Responsible for standards selection and prioritization as part of our harmonization effort.
3. Platform Experience Team - Provides feedback about the platform: user experience, enhancements and suggestions for the product roadmap.
4. Auditor Guidance Teams - Responsible for the auditor management process: selection, approval and certification, including program updates.

The teams will meet as needed to provide the oversight and guidance for the program.

24. SECTION 24 - Material Distributors

The Brand Owner will issue a requirement to the Material Distributor for an audit of their Tier 2 supplier, to the appropriate standard, for the supplier product category.

The Material Distributor will join the AuditOne platform and issue the requirement from the brand owner to the material supplier.

The resulting audit will be shared with the Brand Owner issuing the requirement to the Material Distributor

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25. SECTION 25 - Certification Cycle

AuditOne follows the scheme/standard certification requirements. In some cases, the scheme adopted by AuditOne requires an initial audit, followed by two annual surveillance audits, AuditOne adheres to the scheme requirements. In the event the standard does not provide certification cycle requirements, the AuditOne program defaults to an annual initial audit for the standard required.

26. SECTION 26 - Authentication

Where AuditOne is utilizing certifications based upon non-AuditOne audits already granted to the supplier, AuditOne engages in a thorough Authentication process. AuditOne collects verifiable information to accept certificates or transfer certification cycles to AuditOne. All AuditOne criteria must be met to transfer a certificate. Only following authentication of the transferred certificate, the certificate can be posted to the AuditOne platform.

27. SECTION 27 - Technical Review

The AuditOne program requires an independent Technical Review for each audit report issued by an auditor. AuditOne Technical Reviewers are independent and are not involved in conducting audits. CB's participating in the AuditOne program are accredited to ISO 17021 and follow the prescribed guidance involving certification decisions. Technical Reviewer's contracted to AuditOne are required to follow the same requirements as AuditOne employees.

28. SECTION 28 - CEO Oversight

AuditOne CEO approves and oversees the development and implementation of objectives/policies/procedures governing AuditOne activities.

AuditOne CEO ensures impartiality, supervises finances, and all other related activities related to the management of AuditOne.

Further, the CEO delegates responsibility to competent and qualified personnel where appropriate.