NonFoods Quality Assurance

Audit Expectations

Version XVIII

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Contents

Audit Purpose

The Factory Good Manufacturing Practices (GMP) Audit is a requirement for all factories and packaging facilities producing product for Costco Wholesale worldwide. The audit looks at the factory's capabilities, capacities, processes, procedures and compliance for producing products. The audit assesses the risks associated with manufacturing and packaging, while determines which processes and procedures the factory does and does not have.

The GMP Audit allows Costco to map its supply chain. It also provides transparency and validation to Costco about the factory producing goods to be sold to Costco's members. The audit is not connected to an item, but instead it is connected directly to the factory. If a factory is producing multiple items for Costco within the same product category, only one audit process is potentially needed.

The GMP Audit looks solely at the factory no matter whether Costco product or another retailer's product is being produced at the time of the audit. Costco prefers a Factory GMP Audit be conducted prior to production of Costco goods; however it is not a requirement.

If a factory has a valid Factory GMP Audit that was done for another retailer, please forward the entire audit and all supporting documents to the Factory Audit Staff, and it will be reviewed to see if it meets Costco's requirements for Factory GMP Audits. Not all outside audits are accepted, as not all audits meet Costco's equivalency standards.

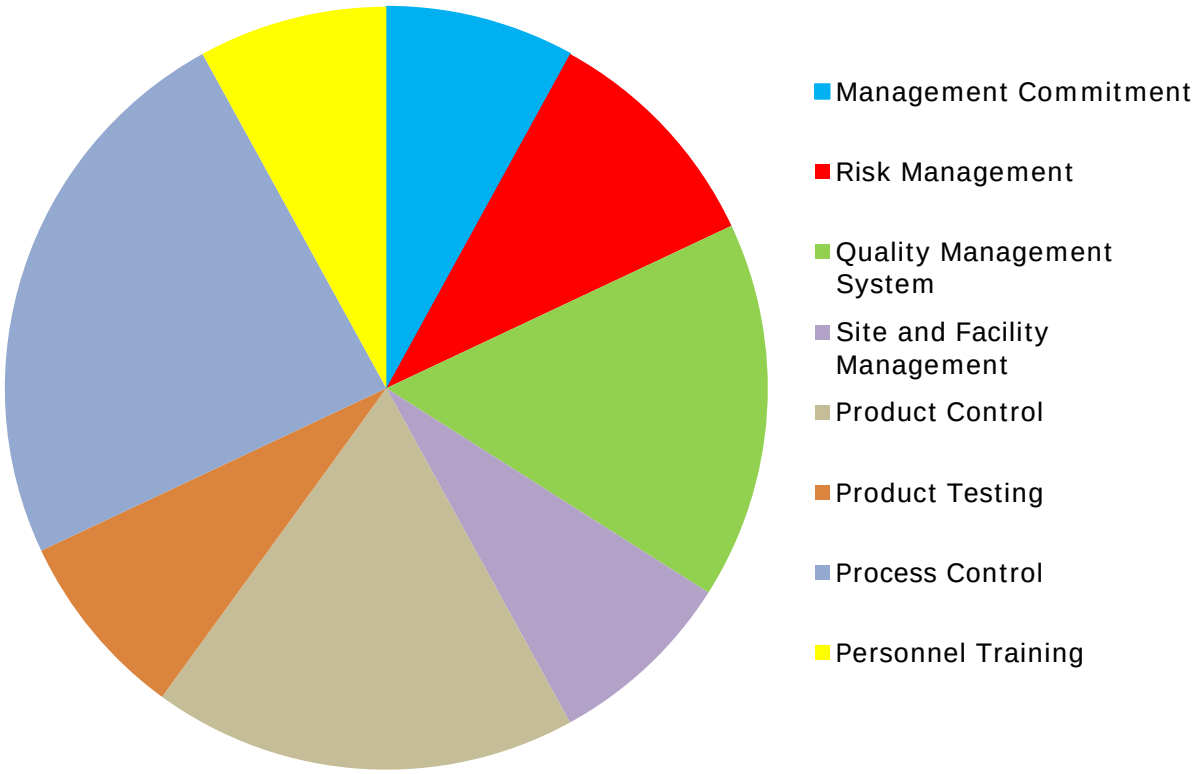
Business Process Management Systems (BPMS)

The Factory Audit Team uses the Enterprise Facility Audit (EFA). EFA is a system within the Business Process Management Systems (BPMS) tool that allows Costco to automate, document and track the flow of audits. It will provide global visibility for groups involved in the audit process to ensure that suppliers have the capability to keep up with demand, manufacture products ethically, and ship them safely.

EFA will provide Costco with the following:

- Consistent process for conducting audits
- Audit results stored in a central location
- Automated workflows throughout audit process
- Single source of information for all audit parties
- Visibility and metrics over supply chain quality

Audit Scope



Audit Criteria

1. Management Commitment & Continual Improvement
   - Is Senior Management of the facility involved in the continual improvement of the facility?
2. Risk Management System
   - Does the facility know and understand the compliance and safety requirements for the product category that they are producing and the countries where they are shipping to?
   - Does the facility have a product risk analysis system for each product category produced and consistently reviews it?

   2.1 Legislative and Safety Requirements

   2.2 Risk Assessment

   2.3 Verification of Risk Assessment

3. Quality Management System
   - Document and record control for quality management in the facility.
   - Identification and traceability

   3.1 Documented Quality System

3.2 Organizational Structure, Responsibility and Authority

3.3 Customer Focus

3.4 Specifications

3.5 Purchasing, Supplier and Sub-Contractor Approval and Performance Monitoring

3.6 Identification & Traceability

3.7 Incident Management and Product Recall

3.8 Complaint Handling

3.9 Corrective and Preventive Action

3.10 Document Control

3.11 Internal Audit

4. Sites and Facilities Management
   - Review of the factory site and facility workings; both internal and external.

   4.1 Factory layout

   4.2 Production flow

   4.3 Segregation of products

   4.4 Staff facilities

   4.5 Cleaning and hygiene practices (Where applicable based on nature of the products)

   4.6 Pest control

   4.7 Lighting and ventilation

   4.8 Contamination

5. Product Control
   - Traceability of all materials from raw materials to finished goods, as well as reference samples, packaging, chemicals used in production, etc.

   5.1 Reference Samples (Preproduction and Production Sample)

   5.2 Chemical Control

   5.3 Product Packaging Materials

   5.4 Control of Non-conforming Materials

   5.5 Product Transport, Storage and Distribution

   5.6 Stock Control and Product Release

6. Product Testing and Product Claims

- Internal product quality control system within the facility.

  6.1 Product Testing

  6.2 Product Claims

  6.3 Labeling & Packing

7. Process Control
   - Operational quality control system within the facility.

     7.1 Control of operations

     7.2 Control of incoming components and raw materials

     7.3 Calibration and control of measuring and monitoring devices

     7.4 Equipment and tooling maintenance

     7.5 Final product packing and control

     7.6 Packaging materials

     7.7 Industry Module

8. Personnel Training and Competency
   - Continued and updated training of the staff within the facility, as well as record keeping of that training.

Audit Templates

There are multiple audit templates which can be used, depending on the type of product being produced. These audit templates help to assess the risks associated with manufacturing and packaging.

- Textiles / Apparel
- Integrated Textiles / Apparel (with Weaving or Yarn Facility)
- Footwear
- Electronic and Electrical
- Toys
- Furniture
- General Hardgoods
- Packaging / Re-Packaging

The audit company assigned to conduct the audit, will determine which template is to be used, based on the answers from the factory or supplier on the Pre-Audit Questionnaire (PAQ). The PAQ will be sent from the audit company and must be completed in full and returned within 2 working days from receiving it. The audit cannot be scheduled without the PAQ.

Audit Details

A Factory GMP Audit is to be scheduled within 10 to 20 working days from receipt of the audit request. All audit requests are sent by Costco Wholesale through the EFA system and will have the audit company conducting the audit, on copy. Communication between the audit company and the factory/supplier can be established quickly, and the audit can be scheduled, prepaid, and conducted in a timely manner. Please always respond to emails concerning an audit either from Costco or the audit company assigned.

GMP audits are typically 2 man days and the cost varies by factory location and 3rd party audit companies around the world. All audit costs are the responsibility of the Supplier or the Factory. Audit procedures may vary slightly by country and by 3rd party audit company.

Corrective Action Plan (CAP)

The purpose of the Corrective Action Plan (CAP) is to allow the factory/supplier to know and understand the non-conforming findings found during the audit. The CAP provides the factory/supplier the ability to show how each finding is being addressed and corrected. This process shows that the factory/supplier is working toward the required goal of continuous improvement.

A Corrective Action Plan response must be included for each deficiency found in the audit. The responses are to be submitted via BPM/EFA to the audit company that conducted the audit, on the supplied audit template within 10 working days of the audit. The CAP must be completed within 30 days from the date of the audit. If a factory/supplier feels that more time is needed in order to record how the non-conforming points will be addressed, a maximum of 90 days from the date of the audit is acceptable. However this is on a case by case basis. The Audit Company that conducted the audit will be following up within the 30 day time limit.

Facilities with a total GMP Audit score of 98% and above will not be required to complete a CAP, as long as no major/red non-conforming points are found. In this case, the audit is valid for 1 year from the date of the audit.

If any major/red non-conforming points are found, a CAP and re-audit are required.

If no major/red non-conforming points found, Costco still encourages those points to be addressed immediately, so as to have them corrected by the next required audit.

CAPs will be reviewed by the audit company of record and will be closed out upon satisfactory assessment by the audit company. The CAP review is done at the audit company facility, not at the factory. The CAP review is sometimes referred to as a desk review. Communication is done through EFA, email or via phone.

The cost of the CAP is included in the cost of the audit. For CAPs where no re-audit is required, evidence will be collected by the audit company, in support of the CAP. If a re-audit is required, no evidence is required, as the re-audit will review any evidence that may have been needed to substantiate the CAP. For those facilities that require a re-audit, if

the CAP is not complete by the time of the re-audit, the CAP process will stop and those non-conforming points not yet addressed will be noted as non-conforming on the new audit.

The factory/supplier will work directly with the audit company for submission and questions regarding the CAP. If after three CAP submissions, the CAP is not approved, the audit company will escalate the CAP to the Costco Wholesale NonFoods Factory GMP Audit Staff through EFA. If the CAP cannot be completed, the non-conforming finding will be listed again on the next audit as non-conforming.

Costco urges all factories and suppliers to work with the audit company to show continuous improvement. If the factory/supplier is unable or unwilling to improve upon the previous audit, Costco's buying staff will be notified of the findings the factory/supplier is unable or unwilling to correct.

Costco reserves the right to suspend current or future business with a factory/supplier due to the lack of continuous improvement within the GMP Audit. This includes but is not limited to continuous improvement on re-audits, as well as annual audits.

Audit Format

All Factory GMP Audits can be announced or unannounced.

Audit companies typically conduct the GMP Audit in the following manner:

- Opening Meeting
  - 1 hour
    - To familiarize the Factory Staff with Audit Staff
- Factory Tour
  - 6 to 12 hours
    - Receiving to shipping and all processes in between
    - Pictures are taken
- Employee and Management interviews
  - 1 to 2 hours
    - To gather knowledge about the factory
    - To assess the competency of the workers conducting selected tasks/processes
- Documentation and Records Review
  - 2 to 4 hours
    - To review documented processes, and procedures and their corresponding records
- Closing Meeting
  - 1 to 2 hours
    - Corrective Action Plan (CAP) is presented to Factory Staff
- Report Generation
  - 3rd party audit company sends out final report within five working days of audit

Note: Time frames noted are a general estimate. The audits conducted by each auditor/audit company may vary slightly.

Audit Scoring

A comparative score is attached to the completed audit. This score alone does not depict the ability of the factory as the GMP Audit is not a pass/fail process. Instead the findings associated within each of the modules previously mentioned directly affect the score and the frequency of audits for the facility.

The purpose of the audit is to map Costco's supply chain. The audit also provides feedback to our suppliers and their factories of how they can improve their processes, which will in turn provide better products to Costco. The goal is continuous improvement. The initial audit is the benchmark for the factory and determines what future actions are needed.

Below is how the score attached to an audit depicts the next steps of the Factory GMP Audit process:

100% - 98%

- If no major/red non-conforming points are found, the audit is valid for 1 year from the date of the audit. If any non-conforming points are found at all, Costco encourages those points to be addressed immediately, so as to have them corrected by the next required audit.
- If major/red non-conforming points are found, a Corrective Action Plan (CAP) is required within 10 working days of receipt of the audit from Costco. Once that CAP is approved, a partial re-audit is required within 3 months from the date of the audit.

97% - 85%

- If no major/red non-conforming points are found, a Corrective Action Plan (CAP) is required within 10 working days of receipt of the audit from Costco. Once that CAP is approved, the audit is valid for 1 year from the date of the audit.
- If major/red non-conforming points are found, a Corrective Action Plan (CAP) is required within 10 working days of receipt of the audit from Costco. Once that CAP is approved, a partial re-audit is required within 3 months from the date of the audit.

84% - 70%

- If no major/red non-conforming points are found, a Corrective Action Plan (CAP) is required within 10 working days of receipt of the audit from Costco. Once that CAP is approved, the audit is valid for 6 months.
- If major/red non-conforming points are found, a Corrective Action Plan (CAP) is required within 10 working days of receipt of the audit from Costco. Once that CAP is approved, a partial re-audit is required within 1 to 3 months from the date of the audit.

69% - 60%

- A Corrective Action Plan (CAP) is required within 10 working days of receipt of the audit from Costco. Once that CAP is approved, a partial re-audit is required within 1 to 3 months from the date of the initial audit.

59% or less

- A Corrective Action Plan (CAP) is required within 10 working days of receipt of the audit from Costco. Once that CAP is approved, a complete re-audit is required within 1 to 3 months from the date of the audit.

Reasonable Testing Program (RTP) Audit

Reasonable Testing Program (RTP) Audits are defined as an audit for a factory that is producing a juvenile product for Costco that will ship to the United States (U.S.) and where Costco is the Importer of Record or if the juvenile product for Costco that will ship to the U.S., is a Kirkland Signature branded product.

The basis of the RTP Audit is the Consumer Product Safety Commission (CPSC) and the Consumer Production Safety Improvement Act (CPSIA) of 2008, specifically 16 CFR 1107.

The RTP Audit is item triggered and is conducted based on a supplier/factory relationship. This means if multiple suppliers are using the same facility, each supplier will be required to complete an RTP Audit.

The RTP Audit can be conducted at the same time as a GMP Audit, if scheduling permits. It will be coordinated, if possible, by the Costco Audit Staff.

The RTP Audit may require its own CAP and its own re-audit, at a different time frame than that of the GMP Audit. The RTP Audit also will have its own expiration date.

Packaging / Re-Packaging Audit

As stated earlier, which audit template is to be used, is determined by the Audit Company. Their determination is based on the information provided by the supplier and/or factory, when filling out the Pre-Audit Questionnaire. If a factory within the supply chain for Costco, is only packaging or re-packaging an item, using product manufactured at a different facility, it is possible that that factory may only require a Packaging / Re-Packaging Audit.

This audit template focuses on risks associated with packaging. It is a one-day audit, compared to the typical two-day full GMP audit.

Small Order GMP (SO-GMP) Audit

Small order GMP audits (SO-GMP) are defined as an audit that is for a factory that is producing product for **one** Costco region, where the supplier **is** the Importer of Record, and the product will only be in **one-fourth or less** of the locations in that region.

Example – 400 buildings in the region and the product will only be in 100 buildings or less.

The use of a SO-GMP Audit, will be determined by the Costco Audit Staff.

SO-GMP Audits are to be used only for factories that qualify and are to be used on a one time basis. The audit **will** be considered a pass/fail and will only be valid for 6 months. A passing score for a SO-GMP Audit is greater than or equal to 90%. After completion of a successful SO-GMP Audit, the factory will be expected to conduct the standard Factory GMP audit on their following anniversary audit.

If the factory does not pass the SO-GMP Audit, a complete Factory GMP Audit will be immediately ordered and is required to be completed.

The SO-GMP Audit is registered to the factory itself, not to any supplier. If a factory has gone through a SO-GMP Audit, that factory no longer has the option of the SO-GMP audit.

Cause for an Immediate Re-audit

There are multiple reasons that an immediate complete re-audit may be needed at any time, no matter the most recent audit score, or expiration date. The following are some examples:

- A poor score (less than 60%) on any Factory GMP Audit.
- A product recall, quality withdrawal or serious risk incident with a product produced at the factory in question. This can be determined by the Senior Management, Buying Staff, Product Safety Committee or Audit staff.
- If a member of Costco's staff visits a facility and what they see does not coincide with the recent Factory GMP Audit findings.
- A Small Order GMP Audit score below 90%.
- Costco Wholesale staff deems it necessary based on supplied evidence.

Audit Term Definitions

Initial Audit: The first complete audit that is conducted on a factory. This is the benchmark for the factory and starts the continuous improvement process.

Anniversary Audit: Once the initial audit is complete and deemed valid, an expiration date is assigned. The next audit that is conducted is referred to as the anniversary audit.

Partial Re-audit: The review of the Corrective Action Plan non-conforming findings at the factory from the previous GMP Audit.

Full Re-audit: A completely new GMP Audit is conducted due to the previous audit found a large amount of non-conforming findings that lowered the comparative score to below 60%.

RTP Re-audit: The review of the Corrective Action Plan non-conforming findings at the factory from the previous RTP Audit.

Continuous Improvement: The overall goal of the Factory GMP Audit is for the factory to show that they have the processes and practices in place to produce high quality, safe products. Continuous improvement is defined as showing an increase in the score of the audit or maintaining a high level of score at the factory, i.e., 75% to 87%, or 99% to 99%.

Approved 3rd Party Audit Companies

Costco works with multiple 3rd party audit companies that are qualified and certified to conduct NonFoods Factory GMP Audits and NonFoods Factory RTP Audits around the world.

All audits are to be requested through the Factory Audit Staff, and Costco requires that all audit companies rotate auditors, to eliminate the chance that an auditor is in the same facility for more than 3 consecutive years. This does not include re-audit visits, and only pertains to anniversary audits.

As previously noted, Costco does accept outside, non-Costco requested audits; however this is a case-by-case basis and all audits must be complete with all supporting documents and reviewed by Costco GMP management for approval and acceptance. There are no exceptions.

NonFoods Factory Audit Contacts

Matt Gonyea	Technician	(425) 416 1283	mgonyea@costco.com
Faith Matthews	Coordinator	(425) 427 3270	fmatthews@costco.com
Mark Burbrink	Coordinator	(425) 313 2529	mburbrink@costco.com
Sam Haugen	Global Manager	(425) 416 8803	shaugen@costco.com
Carla Kopet	Assistant General Manager	(425) 427 7639	ckopet@costco.com
Craig Wilson	Vice President	(425) 313 2880	cwilson@costco.com

General Inbox	NFGMP@costco.com