cGMP Audit Guideline

June 1, 2023

ASI

We Audit That™

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Introduction

ASI's cGMP Audits are HACCP based audits that underlines the criteria expected for a modern food processing, food packaging or food storage and distribution facility to meet the basic food safety and food defense requirements of retailers, applicable regulatory agencies, and the general public.

These audits evaluate the competence of the facility's food safety management system, compliance to the food safety management systems documented procedures, and the effectiveness of the food safety management systems procedures to control and mitigate food safety and defense risks.

During the audit the site will also need to complete an effective mock recall within a reasonable time frame for which the amount of product is being recalled.

All facilities located inside of the United States or facilities outside of the United States that export to the United States shall meet all applicable FDA and USDA regulatory requirements. All facilities that are outside of the United States that do not anticipate to export to the United States shall meet all applicable regulatory requirements for that specific country.

Documentation

Documents Reviewed During the Audit

This list is to provide guidance to what documents the auditor will ask for during the audit. There may be additional documents requested that are not included in this list. Some of these documents may not be applicable to every facility. Facilities may also name documents differently from what the documents are listed as below. When documents are held at a corporate location, it is the facility's responsibility to prove to the auditor that they readily know how to access applicable documents.

- Food Safety Systems
    - Company policy and mission statement
    - Organizational chart identifying key food safety personnel
    - Job descriptions identifying key personnel's responsibilities
    - Record keeping procedure
    - Annual review of food safety management system
    - GMP program
    - Internal audit procedure
    - Supplier approval program
    - Traceability program
    - Non-Conforming product procedure
    - Glass, hard plastic and ceramic control procedure
    - Water safety program
    - Customer complaint program
    - Training program
- HACCP
    - HACCP team outlined
    - Process flow diagram
    - Hazard analysis
    - Critical limits worksheet
    - Product specifications and food safety characteristics
    - Verification and monitoring of any CCPs
    - Corrective action procedures
    - Annual review of HACCP Plan
    - Validation of CCPs
- Pest Control
    - Integrated pest management program
    - Pest sighting log
    - Pesticide usage log
    - Current certificate of insurance and business license for pest control company
    - SDS for all pesticides used onsite
    - Pest control map
- Allergens
    - Allergen management program
    - List of any legally-defined allergens stored on-site
    - List of major recognized allergens appropriate to site's geographical location

- Food Defense
    - Food defense program
    - Food defense team outlined
    - Visitor policy
    - Incoming and outgoing trailer policy
- Operational Methods
    - Monitoring procedures
    - Corrective action procedures
    - Verification procedures
    - Rework/Reprocess procedures
    - Incoming and Outgoing trailer inspection procedure
    - Billing/shipping records
    - Pre-Operational inspection procedures
    - Labeling and product rotation procedure
- Maintenance
    - Preventative maintenance program
    - Calibration procedure
- Cleaning Programs
    - Environmental monitoring program
    - Master cleaning schedule
    - Chemical control program

Non-Conformities

Minor

A minor non-conformity is a deficiency in the food safety management system that may lead to a risk to food safety.

Major

A major non-conformity is a deficiency in the food safety management system that carry a food safety risk or likely lead to a risk to food safety.

Critical

A critical non-conformity is a clear deficiency that will potentially cause serious illness or death or any falsification of food safety records are found.

Examples of Critical Non-Conformities

- An imminent condition to building or equipment exists that could contaminate the product in storage or direct product contamination is observed
- Exposed product directly under unprotected glass
- Product or product contact surfaces are found to be unsatisfactory conditions and contamination is imminent
- Live pest activity such as, rodents or decomposed rodents, cockroach activity, bird activity including nesting or droppings, gnawing evidence or insect infestations
- Roof leaks or condensation that could contaminate stored product or product in production
- GMP violation that results in product contamination
- Chemicals used inconsistent with label directions that could result in product or equipment contamination
- Chemicals not segregated from processing and not under lock and key
- Receiving ingredients or product on the same container with toxic chemicals and accepted by receiving employees
- Allergens not properly stored and leaking onto non-allergen products
- Improper storage of ingredients or finished product that will likely result in temperature abuse
- Site has no control over traceability of ingredients or packaging material
- Intentional record falsification
- Failure to effectively take corrective action for a critical limit deviation
- Use of non-potable water as part of production or use on product contact surfaces
- Equipment found out of calibration leading to potential for unsafe food
- Evidence of cross-contamination of allergens
- Mislabeling of product contain allergens

Scoring Guidelines

The overall audit score is based on the total number and level of non-conformances. The overall audit is allocated 100% and deductions based on auditor findings are made as follows:

Minor = -1%

Major = -5%

Critical = -25%

Audit Rating	Audit Score	Certificate
Excellent	**90 – 100%**	**Certificate Issued**
Good	**80 – 89%**	**Certificate Issued**
Complies	**70 – 79%**	**Certificate Issued**
Fails	**0 – 69%**	**No Certificate Issued**

Certificate

All sites that receive a 70% or higher on the audit will be granted a certificate of compliance. Sites that receive an excellent rating two (2) audits in a row will receive a superior rating on their certificate.

Although certificates are issued to sites who receive 70% and above on an audit, retailer and/or supplier requirements might require the site to maintain a higher percentage audit score. This is to be agreed upon by the site and the retailer and/or supplier.

Certificate expires 30 days beyond the anniversary of the audit date. See example Certificate below.

Corrective Actions

Although not required to attain a certificate, ASI strongly recommends identifying the root cause of non-conformities and implementing corrective and preventative actions, so as to drive continuous improvements in food safety.

Repeat Deficiencies

Auditors shall use previous audit reports to monitor the sites effective implementation of their corrective action procedures. Where a site does not take corrective action to a previously cited non-conformance in the most recent ASI Food Safety audit, it shall be noted by the auditor in the report.

Recall

In the event of a recall, in addition to the appropriate regulatory agency, ASI shall be notified by the site within 24 hours. The site shall submit the following information:

i. Summary of the event including date of notification and products involved.
ii. Ongoing communication regarding the activities conducted by the site to determine the scope of the food safety event.
iii. Follow up activities conducted by the site that addresses the reason behind the food safety event, implemented corrective action, and/or other follow up activities as appropriate.

ASI shall be notified at Recalls@asifood.com.

Appeals, Complaints & Disputes

Appeals & Complaints

Any site or outside entity can initiate the formal complaint process by submitting the *Appeals, Complaints and Disputes Form* to any ASI office staff member or ASI contract auditor. This process can also be initiated online via the ASI website (www.asifood.com). Once the appeal, complaint or dispute is received, it will be investigated and resolved appropriately.

Any informal appeal, complaint or dispute made through email, letter or phone conversations to an ASI employee or contract auditor will be recorded on the *Appeals, Complaints and Disputes Form* by the receiving employee. Once the appeal, complaint or dispute is documented on the form, it will be investigated and resolved appropriately.

ASI shall give a formal written notice of the outcome with reasons for the decision to the complainant and all interested parties within 30 calendar days of initiated complaint. Regardless of the appeal or complaint, a certificate decision will not be delayed.

Disputes

A customer can file a dispute with the *Appeals, Complaints and Disputes Form* within 30 calendar days after the appeal or complaint decision has been submitted to the complainant. The dispute will be escalated to ASI's Independent Committee. The Independent Committees' decision is final, and the written decision will be released to the customer within the allotted 30 calendar days.

Customers can email appeals, complaints or disputes to info@asifood.com or call 1-800-477-0778.

FAQs

What is the difference between a HACCP Plan and Food Safety Plan?
Hazard Analysis and Critical Control Points (HACCP) is a preventive food safety strategy that is a systematic approach to the identification and assessment of the risk of hazards from a particular food or food production process or practice and the control of those hazards that are reasonably likely to occur. HACCP systems have been mandated by U.S. Federal regulations issued by the Food and Drug Administration (FDA) for seafood and juice and by the Food Safety and Inspection Service (FSIS) for meat and poultry.

The preventive controls approach to controlling hazards used in a Food Safety Plan incorporates the use of risk-based HACCP principles in its development. Although a Food Safety Plan and a HACCP plan are similar, they are not identical.

See the Comparison table in Appendix 2.

Do I still need HACCP Training if I attend PCQI Training?
Yes.

What's the difference between verification and validation?
Verification – The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Are we doing what we say we're doing?

Validation – Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented is capable of effectively controlling the identified hazards.

Is what we are doing going to work?

What are the "big 8" allergens?
Eggs, Peanuts, Tree Nuts, Milk, Fish, Shellfish, Soybean, and Wheat.

How can I change my audit date?
You can cancel or change your audit date at any time by contacting the scheduling department. Cancelling or moving the audit date within 14 business days will result in a $400 fee, plus any travel fees that have already been arranged. If the audit is aborted the day of the audit, you will be charged full price.

When will I receive my invoice?
An invoice will be sent after the review and billing process is complete. This process typically takes between 3-5 business days.

How can I pay my invoice?
There are multiple ways to pay your invoice.

- Online through via e-check or credit card
- Mailing a check to *PO BOX 419161 St. Louis, MO 63141*
- Calling into the accounting department (e-check, credit card, or wire transfer)

Does ASI offer food safety training and consulting?
ASI offers various different types of training and consulting. Including our completely FREE, monthly learning lunch webinars.

Training

- Principles of HACCP - CODEX
- Internal Auditor
- FSPCA Preventive Controls for Human Food (PCQI)
- Foreign Supplier Verification Program (FSVP)
- FREE learning lunch webinars

Consulting

- Mock Audits and Pre-Assessments
- FSMA ad Industry Compliance
- GAP Analysis
- Food Fraud Vulnerability Assessments and Mitigation Plans
- Food Defense Assessments
- HACCP Development and Implementation
- Food Safety Plan Development and Implementation
- GFSI – Food Safety Management System Development and Implementation
- SOP Development and Implementation

What are the requirements of a cGMP audit?
Contact ASI at 1-800-477-0778 or info@asifood.com to receive a copy of the cGMP audit requirements.

How long is a cGMP audit?
The length of the audit is determined by the size of the facility and how many processing lines there are. Typically all cGMP audits are between 6-8 hours long.

When can I expect to get my final cGMP audit report and certificate?
You will receive your audit report and certificate once the audit is reviewed by the technical director and the invoice has been paid in full.

How long is my cGMP certificate valid?
The cGMP audit certificate is valid for 1 year after the audit date, plus 30 days.

Terms & Definitions

Adenosine Triphosphate Testing (ATP) – ATP is found in all animal, plant, bacterial, yeast, and mold cells. It occurs in food and in microbial contamination. The ATP test uses bioluminescence to detect the presence of ATP left on a surface after cleaning to verify the removal of product that could contribute to microbiological contamination on product contact surfaces.

Adulteration – To make imperfect by adding extraneous, improper, or inferior ingredients.

American National Standards Institute (ANSI) - ANSI facilitates the development of American National Standards (ANS) by accrediting the procedures of standards developing organizations (SDOs).

Audit – A systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an entity's food safety processes and procedures.

Auditor – A person who conducts an audit.

Back Siphonage – The flowing back of used, contaminated, or polluted water from plumbing fixture or vessel into the pipe which feeds it; caused by reduced pressure in the pipe.

Certificate of Analysis (COA) – A document containing test results that are provided to the customer by the supplier to demonstrate that product meets the defined test.

Control Point – Any step in the process at which biological, chemical or physical hazards can be controlled, reduced or eliminated.

Corrective Action – Documented procedures followed when a process or product deviation occurs.

Critical Control Points (CCP) – A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such a hazard to an acceptable level.

Critical Limit – A maximum and/or minimum value, or combination of values, to which a biological, chemical or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process preventive control or at a CCP.

Current Good Manufacturing Practices (cGMP) – See Good Manufacturing Practices (GMP).

Environmental Protection Agency (EPA) – The US government agency tasked with developing and enforcing regulations that implement environmental laws enacted by Congress. This includes, but is not limited to, regulations such as: pesticide laws and registration, the Clean Water Act, and drinking water requirements.

Food and Drug Administration (FDA) – The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

Food Safety Modernization Act (FSMA) – The act signed into law on January 4, 2011 that aims to ensure the safety of the US food supply by shifting the focus from responding to contamination to preventing it.

Food Safety Plan – A plan which identifies, evaluates, and proactively controls hazards which are significant for food safety.

Foreign Supplier Approval program (FSVP) – The import requirements of FSMA that deals with verification of the safety of food offered for import into the United States. Importers that fail to comply with this program are prohibited from importing food into the United States.

Good Agricultural Practices (GAP) – are the basic environmental and operational conditions necessary for the production of safe, wholesome fruits and vegetables.

Good aquaculture Practices (GAqP) – are a series of considerations, procedures, and protocols designed to foster efficient and responsible aquaculture production and expansion and to help ensure final product quality, safety, and environmental sustainability.

Good Distribution Practices (GDP) – are the basic operational conditions and practices necessary for the storage and distribution of safe food.

Global Food Safety Initiative (GFSI) – GFSI is the organization/technical committee that has established the criteria against which benchmark certification standards. The criteria are also used to benchmark food safety management schemes.

Good Manufacturing Practice (GMP) – The regulation (117 Subpart B) that outlines the conditions and practices the regulated food industry must follow for processing safe food under sanitary conditions, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels considerations.

Hazard Analysis Critical Control Point (HACCP) – A systematic approach that identifies, evaluates and controls hazards significant to food safety.

Integrated pest Management (IPM) – An effective and environmentally sensitive approach to pest management that relies on a combination of common sense practices. The information in combination with available pest control methods is used to manage pest damage by the most economical means and with the least possible hazard to the people, property, and environment.

International Organization for Standardization (ISO) – an international standard-setting body composed of representatives from various national standards organizations. Founded on 23 February 1947, the organization promotes worldwide proprietary, industrial and commercial standards.

Less Than Load (LTL) – A shipment that contains materials that will be delivered to multiple sites.

Pathogen – a bacterium, virus, or other microorganism that can cause disease.

Pest Harborage – Any condition or structural defect that provides a place for pests to live and reproduce.

Prerequisite Program (PRP) – All procedures used in the site, which address operational conditions providing the foundation for the HACCP plan. Examples include; Cleaning & Sanitation Programs, Good Manufacturing Practices Program, Pest Management Programs, etc.

Preventive Action – Action taken to eliminate the causes of a potential non-conformity, defect or other undesirable situation in order to prevent occurrence.

Preventive Control – Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packaging, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of analysis.

Preventive Controls Qualified Individual (PCQI) – A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Rework – Clean, unadulterated product that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and is suitable for use as packaging material.

Ready-to-Eat (RTE) – Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Standard Operating Procedure (SOP) – A set of step-by-step instructions compiled by a site to help employees carry out operations.

Safe Quality Food Institute (SQFI) – a division of the Food Marketing Institute (FMI) and the SQF scheme owner.

Traceability – The identification of any suspect ingredient of finished product and its initial shipment location.

United States Department of Agriculture (USDA) – The USDA provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management.

Validation – Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification – The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Appendix 1: Food Allergens - International Regulatory Chart

https://farrp.unl.edu/IRChart

FOOD ALLERGENS	USA	CANADA	EU	AUSTRALIA/NZ	HONG KONG	CHINA	KOREA	TAIWAN*	ARGENTINA	THAILAND	BOLIVIA	BRAZIL	CHILE	COLOMBIA	COSTA RICA	CUBA	MEXICO	NICARAGUA	SOUTH AFRICA	VENEZUELA	MALAWI	SINGAPORE	JAPAN**	GSO***	ISRAEL (PENDING)	INDIA (IN DEVELOPMENT)
CRUSTACEAN SHELLFISH	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
EGG	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
FISH	x	x	x	x	x	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x		x			
MILK	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
PEANUT	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
SOY	x	x	x	x	x	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x		x			
TREE NUTS	x	x	x	x	x	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x		x			
WHEAT	x	x	x	x		x	x				x	x		x	x	x		x	x	x		x				
CEREALS W/ GLUTEN		x	x	x	x	x			x	x	x	x	x	x	x	x	x	x		x	x	x				
BUCKWHEAT							x																x			
CELERY			x																				x			
LUPIN			x	x																			x			
MOLLUSCAN SHELLFISH		x	x	x			x											x			x		x			
MUSTARD		x	x																				x			
SESAME		x	x	x																			x			
SULFITES	x	x	x	x	x				x	x	x	x	x	x	x	x	x	x		x	x	x		x			
BEE POLLEN/ PROPOLIS				x																						
ROYAL JELLY				x																						
MANGO							x																			
PEACH						x																				
PORK						x																				
TOMATO						x																				
LATEX (NATURAL RUBBER)											x															

KEY:

*Taiwan FDA released a new draft version of regulations on 12-11-2017 to include 11 proposed food allergens but they have not been finalized.

**Voluntary labeling recommended for Abalone, Mackerel, Squid, Salmon, Salmon Roe, Cashew, Walnut, Matsutake Mushroom, Sesame, Soybean, Yam, Apple, Banana, Kiwifruit, Orange, Peach, Beef, Chicken, Gelatin, Pork.

***GSO includes the countries of Saudi Arabia, UAE, Kuwait, Bahrain, Oman, Qatar, and Yemen

Crab, shrimp, prawn	Crab, shrimp	Crab, shrimp, Mantis shrimp, lobster	Mackerel	Squid, clam, oyster, abalone, mussel	Clams
Lacteal secretion from cows	From mammary gland of farmed animals	Walnuts	≥10 mg/kg	Directly added or ≥10 mg/kg	

Appendix 2: HACCP Plan vs. Food Safety Plan

https://www.fda.gov/downloads/food/guidanceregulation/fsma/ucm517391.pdf

Element	HACCP Plan	Different in Food Safety Plan
Hazard Analysis	Biological, chemical, physical hazards	Chemical hazards include radiological hazards, consideration of economically motivated adulteration (21 CFR 117.130(b)(1)(ii))
Preventive Controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs (21 CFR 117.135(a)(2))
Parameters and values	Critical limits at CCPs	Parameters and minimum/maximum values (equivalent to critical limits for process controls) (21 CFR 117.135(c)(1))
Monitoring	Required for CCPs	Required as appropriate for preventive controls (21 CFR 117.145)
Corrective actions and Corrections	Corrective actions	Corrective actions or corrections as appropriate (21 CFR 117.150(a))
Verification (including validation)	For process controls	Verification as appropriate for all preventive controls; validation for process controls; supplier verification required when supplier controls a hazard (21 CFR 117.155, 117.160)
Records	For process controls	As appropriate for all preventive controls (21 CFR 117.190)
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified (21 CFR 117.139)