

# GMP Audit Checklist for Food Production



Use this GMP audit checklist to help your team conduct internal audits and ensure you're maintaining Good Manufacturing Practices compliance.

## Regulatory requirements

- The facility possesses an FDA registration number.
- A food traceability system is implemented to track products from their entry to exit, whether in their original state or as a part of another product.
- Initial and annual mock recall exercises are conducted, thoroughly documented, and proven effective.

## Food safety plan

- The facility maintains a comprehensive and documented food safety plan.
- One or more qualified individuals are designated to oversee and administer the food safety plan.
- Records of food safety plan compliance, including daily, weekly, or monthly inspections, are maintained on site.

## Personnel qualifications and trainings

- Documentation of personnel qualifications and training records is kept current and well-maintained.
- Every employee is either a qualified individual or is under the supervision of one.
- All personnel receive documented annual training in food hygiene and safety relevant to their specific roles.
- Supervisory staff are specifically tasked with overseeing the GMP practices of their subordinates.

## Personal Hygiene

- A Personnel Hygiene Policy (PHP) is established, enforced, and documented, applicable to all staff and visitors.
- The PHP covers essential personal hygiene practices, including clothing and footwear requirements.
- The PHP specifies the types of uniforms and personal protective equipment (PPE) required for different roles, along with their maintenance and usage conditions.



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- The PHP details guidelines on handwashing, the use of nail polish, and hair containment.
- The PHP outlines rules for storing personal items and clothing, as well as restrictions on wearing jewelry.
- The PHP contains regulations on eating, drinking, smoking, vaping, and similar activities on premises.
- The PHP addresses the prevention of allergen cross-contamination in relation to personnel hygiene.
- The PHP includes procedures for reporting, managing, and cleaning contamination incidents involving blood or bodily fluids in food or production areas.
- The PHP establishes protocols for employees to report illnesses.
- The PHP stipulates conditions under which sick employees are restricted from production areas until it is safe for them to resume specific duties.
- The PHP sets forth guidelines for first aid, including the management of open lesions, infected wounds, boils, and similar injuries.

## Supply chain

- A procedure is documented and maintained for the appropriate receiving and storage of raw materials and ingredients.

## Processes and Controls

- All operations adhere to comprehensive sanitation principles and practices.
- Quality control protocols are established, executed, and upheld to ensure the safety and suitability of food and packaging materials.
- One or more qualified individuals are tasked with overseeing facility sanitation.
- A system, such as color-coded equipment, is in place and maintained to prevent allergen cross-contamination.
- Procedures for testing to detect sanitation, allergen, or other food contamination issues are documented and followed as needed.



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- Documented controls are in place to ensure that contaminated food is rejected, treated, or processed to eliminate contaminants.
- A documented system for inspecting, handling, segregating, and storing raw materials is maintained.
- Procedures are documented for washing or cleaning raw materials used in food production to remove contaminants.
- Water used in food contact processes, such as washing or rinsing, is safe and, if treated, is regularly monitored to ensure quality.
- Procedures are documented for identifying raw materials that require treatments such as pasteurization, along with the treatment processes themselves.
- Control measures and identification protocols are documented for raw materials susceptible to aflatoxins or other natural toxins.
- Control measures and identification protocols are in place for raw materials at risk of contamination with pests, undesirable microorganisms, or extraneous materials.
- Raw materials, ingredients, and rework are stored in suitable containers under appropriate temperature and humidity conditions.
- All food-related activities, including storage, processing, and packaging, are conducted to minimize risks of contamination, spoilage, or deterioration.
- Measures such as sterilization, irradiation, and pasteurization are documented and implemented to destroy or inhibit microorganisms.
- Procedures are in place to protect against contamination from the use of equipment, containers, utensils, or tools.
- Protocols are established to prevent contamination from metal or other extraneous materials.
- Procedures for disposing of or reconditioning adulterated food or materials are documented to prevent further contamination.
- All food and ingredient preparation must comply with best practices to prevent contamination.
- Food is safeguarded against contaminants that might drip, drain, or be drawn into it.
- Heat blanching processes are properly documented, and records of routine equipment sterilization are maintained.
- Food preparations such as batters and gravies are managed to prevent contamination and microbial proliferation.
- Food preparation procedures are designed to avoid contamination and prevent microbial spread.



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Controls to prevent contamination and manage microorganisms in dry mixes, nuts, and other ingredients dependent on water activity control are in place and documented.

Measures to maintain the pH of acid and acidified foods at 4.6 or below are implemented and monitored.

Ice used in food production is sourced from water that meets safety standards.

## Defect Action

Documentation is maintained for defect action controls as necessary.

Quality control operations are carried out to minimize potential defects, with thorough documentation and record-keeping of their implementation.

Protocols are in place to prevent defective food from contaminating uncontaminated food.

## Equipment and Utensils

All equipment and utensils should be made from materials that can withstand repeated and thorough sanitation, cleaning, and maintenance.

Equipment and utensils must be utilized in a manner that prevents the adulteration or contamination of food.

All personnel receive documented annual training in food hygiene and safety relevant to their specific roles.

Food-contact surfaces must be constructed from non-toxic, corrosion-resistant materials suitable for repeated use, cleaning, and maintenance.

Food-contact surfaces should be maintained with appropriate construction details like sanitary welds.

Non-food contact equipment within production areas must be kept in a clean and good condition.

Equipment and systems for holding, conveying, and manufacturing must be designed and built to enable repeated use, maintenance, cleaning, and sanitation.

Refrigeration and freezing compartments should be equipped with devices that indicate temperature.

Instruments and controls used for measuring, regulating, or recording temperatures, pH, and similar parameters must be accurately calibrated and maintained.

Any compressed air or gases used in food production should be filtered and free of oil.



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## Maintenance and Sanitation

- Buildings, fixtures, and other facilities are meticulously maintained in a sanitary and clean state.
- A documented policy for the maintenance of equipment, including its cleaning, sanitation, and post-repair inspection, is actively implemented.
- Procedures for cleaning and sanitizing are documented, ensuring methods do not lead to food contamination or adulteration.
- Cleaning and sanitizing agents are free from undesirable microorganisms and are suitable for their intended purposes.
- Chemicals are securely stored in a controlled, locked area and are clearly labeled.
- An effective pest control program is documented, implemented, and maintained.
- A map of pest control stations is maintained and readily accessible.
- Documentation for routine maintenance and inspection of pest control equipment is available and accessible.
- Pest control device types, numbers, and placements are deemed appropriate.
- The facility maintains a pest-free environment.
- The use of pesticides is rigorously controlled to prevent food contamination.
- All food-contact surfaces and utensils are regularly cleaned, sanitized, and the process is documented under the supervision of a competent employee.
- Sanitizing and drying procedures for tools and equipment used in processing low-moisture foods are established, implemented, and documented.
- Cleaning and sanitizing procedures for tools and equipment used in wet processing are established, implemented, and documented.
- Procedures for cleaning and sanitizing food-contact surfaces are established, implemented, and documented.
- Single-service items are managed in a manner that prevents food contamination during handling, storage, and disposal.
- Non-food contact surfaces of equipment are cleaned and maintained properly.
- Portable equipment that contacts food is kept and stored in conditions that prevent contamination.
- All chemicals used within the facility are safe and appropriate for use in food production environments, including food-grade lubricants.



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## Warehousing and Distribution

- Practices for storing and transporting food are designed to prevent contamination or adulteration and ensure suitable conditions.
- Control measures are in place to inspect and document the condition of incoming goods.
- Wash certificates, detailing the previous loads of tanker trucks, are available when required.
- Control measures ensure that outgoing shipments of food meet appropriate conditions and quality standards.
- Packaging materials are managed in a way that prevents contamination during storage and handling.
- Retained, returned, or damaged products are segregated in a designated area and are clearly marked.
- Documented procedures are in place and followed for the correct sequence and use of materials within their designated shelf life.

## Food By-Products for Animal Food

- Human food by-products for use as animal food are maintained in conditions and equipment that avoid contamination and are regularly cleaned and maintained.
- Every Human food by-products are held in a way that avoids contamination. is either a qualified individual or is under the supervision of one.
- Proper labelling of human food by-products exist and are implemented.
- Shipping containers and bulk transport vehicles are inspected and maintained appropriately to avoid contamination.

## Facility and Grounds

- Facility design and construction is suitable for the intended use and should exhibit properties to prevent contamination of products.
- The facility grounds are maintained to avoid pest harborage including the removal of garbage and debris.
- Facility grounds are surfaced to avoid standing water, prevent dust and offensive odors.
- Facility waste containers are adequate and regularly emptied, maintained, and documented.



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- The facility grounds are not affected by uncontrolled contamination risks from adjacent properties. If a risk is identified, controls are established, implemented, and documented.
- The facility has the necessary space for adequate operations, maintenance, sanitation, and production activities.
- Bulk storage vessels are constructed to avoid contamination and allow for cleaning, sanitation, and maintenance.
- Facility components including floors, doors, ceilings, walls, etc are designed to facilitate sanitation and maintenance as required.
- Adequate procedures and controls are in place to avoid overhead condensation.
- Catwalks and stiles are constructed and located in a way that avoids contamination.
- All areas have sufficient lighting to maintain adequate sanitary conditions and operations.
- All glass and fixtures are sufficiently protected to avoid glass contamination in case of breakage.
- Fans and air-moving equipment shall be located and adjusted to minimize contamination.
- Buildings are reasonably free of excessive dust, heat, steam, condensation, vapors, smoke, or fumes.
- Doors, windows, or openings are properly closed, sealed, or screened to avoid contamination and pests.



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