

Good Manufacturing Practices in Manufacturing, Packing or Holding of Human Foods (cGMPs)

Food Processing for Entrepreneurs Series

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Good Manufacturing Practices regulations require a quality approach to manufacturing that enables companies to minimize or eliminate instances of contamination, mix-ups and errors. This in turn protects the consumer from purchasing a product that is impure, misrepresented in labeling or even dangerous.

What you will learn:

Good manufacturing practice is a term that describes regulations and procedures designed to ensure the maintenance of sanitation in food manufacture. Federal laws require that food manufacturers, processors and packagers ensure that their products are safe, pure and correctly labeled. These regulations are often difficult for the entrepreneur to implement; however they involve quality assurance procedures for everyone. Consumer product manufacturers want to test products to maintain consistent high quality, and to train employees to practice good hygiene and sanitation. The regulations simply encourage the establishment of procedures that eliminate the possibility of poor sanitation or food safety accidents.

Find out what you already know about Good Manufacturing Practices in Manufacturing, Packing or Holding of Human Foods by taking this short quiz.

Introduction Quiz

The following questions are multiple-choice with three or more possible answers given. Select only the most completely correct answer by placing an X in the box.

1. Good Manufacturing Practices (GMPs) are:

- a. Optional
- b. Applicable only to meats
- c. Mandated to ensure the safety and wholesomeness of the processed food supply.

2. Failure of firms to comply with GMP regulations:

- a. Can result in very serious consequences including recall, seizure, fines and criminal charges.
- b. Has no effect on cleanliness or disease control.
- c. Has little impact on a company's success.

3. Education and training of employees is important because:

- a. Food plant personnel are vital to a company's success.
- b. The regulations state that necessary measures must be taken to ensure proper education, training and supervision to enforce compliance.
- c. Human error is the most frequent cause of product failure and noncompliance.
- d. Training should emphasize the importance of personal hygiene, proper food handling procedures, proper sanitation, record keeping, product testing and process procedures.
- e. All of the above.

4. Sanitation is vital to disease control and cleanliness. Which of the following statements regarding sanitation programs is true?

- a. The most important aspect in sanitation is the commitment to producing safe, wholesome products in a clean plant environment.
- b. The commitment to sanitation must be communicated to all employees.
- c. The sanitation program's top priority should be to communicate to all employees the necessity and importance of proper cleaning and sanitation practices.
- d. All of the above.

5. Which of the following equipment guidelines are required under current GMPs?

- a. Food contact surfaces should be inert, smooth and non-porous.
- b. Contact surfaces should be easily cleaned and sanitized.
- c. Motors, pulleys and drums should be fully enclosed and sealed, and not mounted directly above food contact surfaces.
- d. Conveyers and conveyor parts need to be fully accessible for easy cleaning.
- e. All of the above.

See Page 4 for the answers.

You have been able to assess the depth of your knowledge by taking the preliminary quiz. Please read the information that follows. Our goal is to teach basic principals that will encourage sanitary handling and manufacture of foods.

Good Manufacturing Practices in Manufacturing Packing or Holding of Human Foods (cGMPs)

GMP refers to the Good Manufacturing Practice Regulations promulgated by the US Food and Drug Administration (FDA) under authority of the Federal Food, Drug and Cosmetic Act, Chapter IV. These regulations, which have the force of law, require that manufacturers, processors and packagers of food take proactive steps to ensure that their products are safe, pure and correctly labeled. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups and errors. This in turn protects the consumer from purchasing a product that is impure, misrepresented in labeling or even dangerous. **Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure, fines and criminal charges.**

Good Manufacturing Practices regulations address issues including record keeping, sanitation, cleanliness, personnel qualifications, complaint handling, and in some cases equipment verification and process validation. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide how to best implement the necessary controls. This process provides flexibility, but also requires that the manufacturer interpret the requirements in a manner that makes sense for that particular business.

GMP is also referred to as “cGMP.” The “c” stands for “current” reminding manufactures that they must employ technologies and systems that are up-to-date in order to comply with the regulation. The Current Good Manufacturing Practice Regulations for foods can be found in 21 Code of Federal Regulations (CFR), Part 110. These regulations were mandated to ensure the safety and wholesomeness of the processed food supply. Several basic areas of food processing are discussed in the following summary of the regulations.

Personnel

Food plant personnel are vital to company success. It is the responsibility of management to provide education to employees on the fundamental principles of food plant sanitation and the importance of personal hygiene. The regulations

state that necessary measures must be taken to ensure proper education, training and supervision to enforce compliance. This education must include training to ensure disease control and sanitation.

Education and training

Employees lacking necessary training have proven to be detrimental to a quality assurance program. Human error is the most frequent cause of product failure and noncompliance. Each person has a unique set of skills necessary to complete the job effectively. The level of competency necessary to perform job tasks depends upon the education and training the individual has received.

Sanitation training is especially important for personnel handling food. This training should emphasize the importance of personal hygiene, proper food handling procedures, proper sanitation, record keeping, testing and process procedures. Training should be done when employees are hired and should continue throughout the length of their employment. The education level and prior training of the employee should be considered so the appropriate level and variety of methods are used (visual signs, videos, lectures, demonstrations, role-playing, hands-on-training). Forms of training should allow the employee to visualize the problem in a manner that will prevent it. Forms of training could include:

Petri plate testing

Petri plate testing is a demonstration tool for teaching the importance of proper personal hygiene and plant sanitation involving the use of petri plates. Plates are inoculated with various bacterial sources, such as dirty fingers, hair, coins, saliva and samples collected from floors and counters. Incubate the petri dishes and discover what grows.

Demonstrations of bacterial transmission — A visual demonstration using a product called Glow Germ is a very effective tool in teaching the necessity of hand washing and personal hygiene. This product uses invisible oil and ultraviolet lights to mimic the transmission of microbes through personal contact and illustrates that thorough hand washing greatly reduces the transfer of microorganisms to foods.

Signs — Signs are very useful if placed where readily visible. Signs provide the proper procedures for certain tasks and can be easily referenced using visual signs and reminders. It is beneficial if signs and training materials are presented in a multilingual format if English is a second language for some personnel. There are many sign ideas available for free through the USDA Center for Food Safety and Applied Nutrition.

Supervision — Proper supervision is necessary to ensure that personnel are using GMPs. Management must make regular, routine inspections of processing areas as well as personnel areas, such as restrooms and locker rooms to check for violations. An inspection checklist appropriate for your particular plant or processing operation should be developed. It is also the responsibility of management to inform employees about good manufacturing practices and to make sure that the regulations are understood. A copy of the Good Manufacturing Practices found in the Code of Federal Regulations, Part 110, should be given to each employee. The employee should be asked to read the regulations and sign a statement indicating that they have read them and will comply.

Disease Control and Cleanliness

Personal cleanliness

- Daily bathing is required before work.
- Hair must be washed at least once a week.
- Nails should be kept clean and properly trimmed.
- Jewelry is not permitted on the production floor.
- Disposable gloves must be worn if bandages or cuts are present on hands.
- Communicable illnesses must be reported. Personnel affected or suffering from open lesions or infected wounds should not be allowed to work with edible food products.

Uniforms and underclothing

- Uniforms/frocks must be kept clean and neat.
- All frocks and equipment will be removed before using restrooms.
- Frocks will not be worn outside of the plant.
- Frocks worn in raw product area must be removed, and clean frocks worn in cooked product areas.
- Pockets are not permitted above the waistline.
- Protective shoes and eyewear should be worn if appropriate.
- Sweaters (or like clothing) should be avoided or covered by a uniform.
- Uniforms should be changed if soiled.
- Pants must be tucked into boots.
- Boots need to be cleaned before entering processing area.

Hair restraints

- Hair must be covered; hair bonnets are preferred.
- Hair bonnets should be new and unused. Each time a bonnet is removed it should be discarded.
- Males must be clean-shaven or facial snoods are necessary. Moustaches are permitted if trimmed and they are above the corners of the mouth.
- Sideburns must be covered above ear lobes.

Hand washing

- Hands must be washed following proper hand washing procedure.
- Hands must be washed after:
 - coughing or sneezing
 - using the restroom
 - smoking
 - breaks
 - handling soiled containers, waste materials or animal products
 - using the telephone
- Hand washing must be made convenient. Sinks with hot water are necessary for proper washing habits.
- All personnel equipment should be cleaned at the end of each shift, or more often if necessary.
- Wall-mounted dispensers of anti-bacterial soap and sanitizing solution should be placed beside sinks, and rolls of clean disposable towels made available.
- To minimize contact with germs on faucet handles by dirty hands, workers should be trained to shut off the water with the towel after drying their hands.

- If there is a door in the hand washing area, employees should open the door with the towel, then dispose of the towel as they exit the room.

Conduct

- Spitting, smoking and chewing tobacco are not allowed.
- Urinals and toilets must be flushed after each use.
- Maintenance tools or parts are not permitted on food contact surfaces.
- Eating or drinking must be done in specified areas, separate from food processing area.
- Lockers should be kept clean and orderly.
- Running, horseplay and riding on equipment are not allowed.

Building and Facilities

Plant and plant grounds

The regulations for maintenance of buildings and facilities refer to the structures under the company's control. The immediate vicinity of a facility must be kept clean from trash and refuse. The roads and parking lots associated with the facility should be paved to avoid unintentional contamination. Grass or weeds around the facility should be mowed or kept short to eliminate breeding or harboring of pests. This is especially important as rodents, birds and insects carry numerous types of disease that can be transmitted to or hazardous to humans. Adequate drainage of facility grounds is essential to eliminate seepage, tracking of dirt and pest breeding grounds. If problems are present in areas not under the company's control, appropriate measures need be taken to ensure that those areas will not present any type of contamination (i.e. extermination of pests).

Plant construction and design

The plant needs to be easily cleaned and sanitized. The placement of equipment has a direct impact on ease of cleaning and accessibility. Providing sufficient room for proper cleaning and sanitizing makes the process much easier. The floors, walls and ceilings should be easily cleaned and kept in a sanitary condition. Floors should be slightly sloped to allow for proper drainage and to avoid water accumulation. Fixtures, ducts and pipes should be suspended away from working areas and aisles, and working areas must be kept unobstructed. Ventilation and lights should be adequate; and lights enclosed in safety fixtures to avoid contamination due to breakage. Separating the food processing area from the rest of the facility is necessary to reduce the potential for contamination. Minimize pests by keeping door and window sills tight. Protect windows and other openings with screens to prevent entry of unwanted pests. Drains need traps and proper covers or grills.

Sanitation

The most important aspect in sanitation is the commitment to produce safe, wholesome products in a clean plant environment. This commitment must come from management and be communicated to all employees. It is important to assign at least one employee to be responsible for sanitation practices in the manufacturing facility. Support of this employee's needs is

essential, and management should require daily reports from this employee. This employee should have training in the areas of microbiology, chemistry and entomology, whether from a degree or short course on these subjects. Once a sanitation program is established, it is important that improvements be made as new developments continually arise. The sanitation program's top priority should be to communicate to all employees the necessity and importance of proper cleaning and sanitation practices. The Code of Federal Regulations, Part 110, Subpart B, gives specific guidelines concerning sanitary operations, facilities and controls. These should be read and fully understood by management and sanitation personnel.

Equipment

While each processing facility has different pieces of equipment that is specific for the food it is producing, certain factors are universal when designing and installing equipment. Since this equipment must produce sanitary food products, it is important to plan and operate following specific guidelines. General guidelines are listed below and further reference should be made to the Code of Federal Regulations, Part 110, Subpart C.

General guidelines

- Food contact surfaces should be inert under conditions of use, smooth and non-porous. Stainless steel is preferred. Wood is not permitted. All surface seams should be smooth, continuous, and flush with surface.
- Equipment contact surfaces should be easily cleaned and sanitized by using access doors, removable covers or disassembly.
- Equipment assembly parts such as bolts, nuts, washers and gaskets should be kept away from food during equipment operation. Moving parts should have sealed or self-lubricating bearings.
- Installation of equipment should allow for 3 feet of clearance around, and 6 inches off of the floor for the working area and proper cleaning. Equipment should be installed considering convenience, serviceability and maintenance.
- Clean in-place systems are preferred over cleaning out-of-place systems.
- Motors, pulleys and drums should be fully enclosed and sealed, not mounted directly above food contact surfaces.
- Conveyors and conveyor parts need to be fully accessible for easy cleaning.
- Valves for water and steam should not allow for leakage; and valves for food should be easily disassembled for cleaning and inspection.
- Pipes, irons and beams should be installed following very specific guidelines. These are referenced in the CFR, Part 110, Subpart C.
- Kettles or cookers require lids and a self-draining design.

Production and Process Controls

Each processing facility will have a unique process specifically designed for the product it produces. The CFR guidelines should be used to reference specific needs but some general guidelines follow.

- All operations in receiving, transporting, packaging, preparing, processing and storing of food must follow sanitary principles.
- Raw materials must be inspected and separated from processed products.
- Raw material containers need to be inspected.
- Ice, if used, must be sanitary if used for food production.
- Food processing equipment should be inspected and cleaned on a regular basis.
- Processing factors such as time, temperature, humidity, pressure, and other relevant variables must be properly controlled and documented.
- Testing procedures must be in place to check finished product for quality and safety.
- Packaging materials must be approved and provide appropriate protection.
- Finished products must be coded to provide information such as place and date of production.
- Production records need to be correctly maintained and retained for an appropriate amount of time specified in the CFR.
- Products must be warehoused and shipped under sanitary conditions and away from harmful substances.

There are special regulations for low-acid foods (Part 113), acidified foods (Part 114), bottled water (Part 129), and infant formula (Part 107).

A company following these guidelines and those mandated in the Code of Federal Regulations can manufacture a product that meets the needs of their consumers and operate the processing facility in a safe and efficient way. By doing this, employees will be more productive and have fewer accidents. Consumers will have fewer complaints, and both the consumer and producer will benefit.

References

Code of Federal Regulations (CFR) Part 110, Subpart A-G. *cGMPs/Food Plant Sanitation*, Wilbur A. Gould, PhD., CIT Publications, 1994.

| Answers to the Quiz | | |
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| 1. c | 2. a | 3. e |
| 4. d | 5. e | |