



Good Manufacturing Practices in Food Processing

Introduction



Good Manufacturing Practice or GMP is a term that is recognized worldwide for the control and management of manufacturing and quality control of foods, pharmaceutical products, and medical devices.



It aimed to ensure that quality and safety are maintained throughout a process and thus prevent product rejection and financial losses. The pressures for this development came from two sources: first,

commercial pressures including:

- increasing competition between companies
- the need to access expanding national and international food markets
- product quality management systems required by major retailers.

Second, new legislation demanded systems that would both maintain quality and safety, and prove that a business is in control of these. This concept takes into account separate standards for production operations and new product development , production facilities, environmental and waste management, employment rights, health and safety , laboratory management as well as food quality and safety

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Milestones Of GMP

- 1902 - Development of the Biologic Control Act
- 1906 - Development of the Pure Food and Drug Act
- 1938 - Federal Food, Drug and Cosmetic Act
- 1941 - Initiation of GMP
- 1944 - Development of Public Health Services Act
- 1962 - Kefauver-Harris Drug Amendments released
- 1963 - Establishment of GMPs for Drugs
- 1975 - cGMPs for Blood and Components Final Rule
- 1976 - Medical Device Amendments
- 1978 - cGMPs for Drugs and Devices
- 1979 - GLPs Final Rule
- 1980 - Infant Formula Act is passed



QA, QC & GMP inter-relationship

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QUALITY RELATIONSHIP

Quality Management



Quality Assurance



G.M.P.



Quality Control

Quality assurance : All the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence a product or service will fulfill requirements for quality.

Quality control :The operational techniques and activities used to fulfill requirements for quality.



GMP covers following areas

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- raw materials, purchasing and control (including agreed specifications, supplier auditing, raw material storage, stock control, traceability, inspection, investigation of non-conformity to specification)
- process control (including identification, verification and monitoring of critical control points in a HACCP scheme, hygienic design of plant and layout to minimize cross contamination, cleaning schedules, recording of critical production data, sampling procedures and contingency plans to cover safety issues)
- premises (including methods of construction to minimize contamination, maintenance, waste disposal)
- quality control (including product specifications and quality standards for non-safety quality issues, monitoring and verification of quality before distribution)
- personnel (including training, personal hygiene, clothing and medical screening)
- final product (including types and levels of inspection to determine conformity with quality specifications, isolating non-conforming products, packaging checks, inspection records, complaints monitoring systems)
- distribution (to maintain the product integrity throughout the chain, batch traceability and product recall systems)



Principles Of GMP

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1. Design & construct the facilities & equipment's properly.
 2. Follow written procedures & instructions.
 3. Document work
 4. Validate work.
 5. Monitor facilities & equipment.
 6. Write step by step operating procedures & work on instructions.
 7. Design, develop & demonstrate job competence.
 8. Protect against contamination.
 9. Control components & product related process,
 10. Conduct plan & periodic audits.
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The benefits of a properly implemented GMP system

- ✓ economic (more cost-effective production by ‘getting it right first time’, reduction in wasted materials, fewer customer complaints, improved machine efficiency and increased manufacturing capacity)
- ✓ marketing (consistently meeting customer needs, increased customer confidence and sales)
- ✓ internal (improved staff morale, increased levels of communication, better trained staff and awareness/commitment to quality, improved management control and confidence in the operation)
- ✓ legislative (demonstrating due diligence, providing evidence of commitment to quality and ability to improve)

Good Manufacturing Practices

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DEAL WITH CONTAMINATION:-

- BY PEOPLE
- BY FOOD MATERIALS
- BY PACKAGING MATERIALS
- BY HAZARDOUS MATERIALS
- BY MISCELLANEOUS MATERIALS



GMPs in Food Processing



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BUILDINGS AND FACILITIES

10 GROUNDS

- Proper methods of storing equipments.
- Removing litter and waste.
- Cutting weeds or grass that may constitute attractant, breeding place, or harborage for pests.
- Maintaining roads , yards and parking lots.
- Maintaining draining areas.
- Operating systems for waste treatment and disposal.

PLANT CONSTRUCTION AND DESIGN

– Plant buildings and structures should be suitable in,

Size

Construction

Design

– Should be constructed in a way that,

1. Provide sufficient space for placement of equipments and storage of materials.
2. Taking proper precautions to reduce contamination of food, food contact surfaces of food packaging materials with microorganisms, chemicals and filth.



3. Taking proper precautions to protect food in outer bulk fermentation vessels by,
- Using protective coverings.
 - Controlling areas over and around the vessels to eliminate harborages of pests.
 - Checking in a regular basis for pests and pest infestation.
 - Skimming the fermentation vessels.



4. Floors, walls, ceilings, ducts, pipes must be kept clean and kept in good repair.

5. Provide adequate lighting in hand washing areas, dressing, locker rooms, toilet rooms, all areas where food is examined, processed or stored and where equipments and utensils are cleaned.

6. Provide adequate ventilation by operating fans and air blowing equipments to minimize odors and vapors.

7. Adequate screening or other protection against pests.

SANITARY OPERATIONS

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- Toxic materials used in a plant are,
 - Sanitizing agents required to maintain clean and sanitary conditions.
 - Chemicals necessary for use in laboratory testing procedures.
 - Chemicals necessary for plant and equipment maintenance and operation. (Pesticide chemicals)
- These materials should be,
 - Free from undesirable microorganisms.
 - Purchase under a supplier's guarantee or certification.

- Identified, held and stored in a manner that protect against contamination of food, food contact surfaces or packaging materials.
- Use of insecticides or rodenticides under precautions and restrictions for pest controlling.



SANITATION OF FOOD CONTACT SURFACES

- Low moisture food holdings - Should be sanitized thoroughly dried before use.
- In wet processing all the surfaces and utensils should be cleaned and sanitized before use.
- Non food contact surfaces , equipments should be cleaned properly.
- Single service articles should be stored in appropriate containers and should be handled , used and disposed in a manner that protects against contamination.
- Check whether any machine , equipment or utensils are acceptable to clean using sanitizing agents and provide adequate cleaning and sanitizing treatment.
- Cleaned equipments should be stored and handled carefully.

SANITARY FACILITIES AND CONTROLS

– Water supply

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Running water at a suitable temperature and pressure.

Should be provided to all areas where required for,

- Processing of food
- Cleaning of equipments , utensils and food packaging materials
- Employee sanitary facilities
- Plumbing

Shall be of adequate size and design and adequately installed and maintained to,

- Carry sufficient quantities of water to required locations.
- Properly convey sewage and liquid disposable waste from the plant.
- Avoid constituting a source of contamination to food, water supplies, equipments or utensils or creating an unsanitary conditions.
- Provide adequate floor drainage systems in all areas.
- Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

– Adequate sewage disposal system

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– Toilet facilities,

-Maintaining the facilities in a sanitary condition.

-Keeping the facilities in good repair at all times.

-Providing self-closing doors.

- Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

- *Hand-washing facilities*

- appropriate, hand-sanitizing facilities at necessary locations in the plant
- Effective hand-cleaning and sanitizing preparations.
- Sanitary towel service or suitable drying devices.
- Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
- Readily understandable signs directing employees handling unprotected food, packaging materials, food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated.



– *Rubbish and offal disposal.*

should be conveyed, stored, and disposed of as to,

-minimize the development of odor.

-minimize the potential for the waste becoming an attractant and harborage or breeding place for pests

-protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.



- This section presents a review of preventive controls for microbiological, chemical, and physical food safety problems in the food processing industry.
- Microbiological safety hazards cause most of the food borne illnesses and include pathogenic bacteria, viruses, and parasites.
- Chemical food safety hazards vary widely, but the most common problems cited in the literature include contamination with pesticides, allergens, and natural toxins, including scrombotoxins found in fish and mycotoxins found in crops.
- Foreign objects, or physical safety hazards, are the least likely to affect large numbers of people and usually are easily recognized.



Microbiological Safety

1. Inefficient hygienic practices among employees.

e.g.) sensor-equipped towel that prevents the cross-contamination that can occur with hand cranks.

A signal dispenser that beeps when users have washed their hands sufficiently is also available to ensure adequate hand-washing time

2. Language barriers.

Some industry experts recommend a picture-and-symbol approach to training to overcome language barriers (Higgins, 2002)

3. Ineffective training of employees.

For example, external consultants may not be familiar enough with a plant's operations and requirements to give effective advice. Other impediments to effective training might include training the wrong people, not training enough people, or not providing enough training (Blackburn and McClure, 2002).



4. Biofilms.

Adequate cleaning prior to sanitizing is therefore paramount to controlling this problem. Further, coating drains and equipment parts with antimicrobial material can counteract biofilms although it does not eliminate the need for proper cleaning and sanitizing (Higgins, 2003).

5. Niche environments.

Niche environments are sites within the manufacturing environment where bacteria can get established, multiply, and contaminate the food processed. These sites may be impossible to reach and clean with normal cleaning and sanitizing procedures. Microbiological sampling of the environment and equipment can detect a niche.

6. Plant renovations.

Following standard operating procedures (SOPs) to prevent contamination due to changes in processes.



7. Ineffective use of cleaning agents and disinfectants.

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Different cleaning agents vary in their ability to remove different microbes. (Blackburn and McClure, 2002). Thus, the correct choice of cleaning agent is essential to ensure effective cleaning in a food processing facility.



The efficiency of disinfectants is dependent on microbial species, pH, presence of bio films, temperature, concentration, and contact time

8. Lack of sanitary equipment design.

For cleaning and sanitation to be effective, all parts of the equipment should be readily accessible. Another way to improve equipment hygiene is to use antimicrobial coatings on equipment parts (Higgins, 2003).

9. Reactive rather than routine/predictive maintenance.

Reactive maintenance can result in food contamination before a failure is identified. Niches can develop or controls can become defective in processing equipment that is not routinely maintained.



11. Internalization of pathogens in fruit

While employing best control practices--such as not using dropped fruit, removing damaged fruit, and washing/brushing fruit prior to processing--minimizes these risks, the problem can only be controlled with some certainty by a kill step, such as pasteurization.

12. Contamination of raw materials.

There are numerous preventive controls available to address the hazard. Some controls minimize the risks of raw material contamination (i.e., ensuring that raw material suppliers comply with good agricultural practices) and others (i.e., irradiation, pasteurization) involve a kill-step to eliminate any pathogens.

13. Post-processing contamination.

Effective controls against post-process contamination include eliminating the pathogen from the post-processing environment by using environmental sampling to eliminate niches, effective sanitation, and various in-package pasteurization methods. Use of preservatives, such as nisin, to slow down the growth of *Listeria monocytogene* are also becoming more common.



Chemical Safety

Chemical safety hazards include

1. intentionally added chemicals (e.g., allergens)
2. unintentionally added chemicals (e.g., cleaners and solvents)
3. and natural toxins (e.g., mycotoxins)

1.Raw material contamination with pesticides.

Aside from washing and testing the produce, manufacturers can select produce from organic suppliers to avoid raw material contaminated with pesticides. Other alternative farming systems, such as low-input sustainable agriculture (LISA) and integrated pest management, are also control options at the farm level (Moulton, 1992). Other preventive control options may include genetic engineering with resistance against pests or developing safer chemicals (Moulton, 1992).

2.Indiscriminate spraying of facilities against pests.

Chemicals can contaminate food if pesticides against insects and rodents are used indiscriminately in a processing facility. Therefore, food experts generally recommend that pest control be performed only by professionals to avoid residues in food (Folks, 2001).

3.Mistaken identity of pesticides.

The best way to control the risk of mistaken identity is to store pesticides away from food ingredients, keep an inventory of pesticides, and store the products in their original containers

4.Spillage of pesticides or other chemicals.

Pesticides should be handled like poisons to avoid potential spillage. Storing chemicals away from food and packaging materials will minimize accidental spillage of pesticides and other chemicals (Tybor, 1990). Further, processors should only use food-grade lubricants and greases in manufacturing.

**MISTAKEN
IDENTITY**

5. Corrosion of metal containers/equipment/utensils.

Use appropriate, non-corrosive materials in food processing.



6. Residue from cleaning and sanitizing.

This problem can best be controlled by properly training personnel about cleaning and sanitizing (Folks, 2001; Tybor, 1990).

7. Accidentally adding too much of an approved ingredient.

There are many examples of nutritional food safety issues arising when too much of a nutrient gets added to a product unintentionally. For example, some vitamins that are added to fortified foods (such as Vitamin A) are known to be toxic at high doses. And iron, a necessary dietary component, can cause severe illness and death if too much is ingested. Controlling chemicals by keeping an inventory of additives minimizes the occurrence of this type of contamination (Folks, 2001).

8. Natural toxins.

Manufacturers should require suppliers to certify that the products they purchase are free from natural toxins.

9. Cross-contamination with allergens on production lines.

A product can become cross-contaminated with allergens on the production line. To minimize the risk of cross-contamination,

- equipment must be cleaned and sanitized to remove all traces of allergens when the next run includes product that should not contain allergens
- Enzyme-linked immunosorbent assay (ELISA) tests can also help verify cleaning procedures (Deibel et al., 1997; Morris, 2002).
- Maintenance tools should be colour-coded to prevent cross-contamination (FDA/CFSAN, 2001b; Morris, 2002).
- Allergenic materials should be stored separately from non-allergenic materials, with dedicated utensils and containers.
- Putting all of the ingredients for a specific batch on a pallet before taking them to the processing area, or "staging," will also minimize the risk of cross-contamination.
- Finally, allergens should be evaluated as part of a hazard analysis, and a HACCP plan or similar approach can be taken to identify process areas that are at high risk for contamination with allergens (Morris, 2002).

10. Raw material contamination with allergens.

When controlling a production process for allergens, manufacturers must maintain a close working relationship with suppliers of raw materials. The ingredient specification should provide assurance that the product is allergen free

11. Infestation of mycotoxins due to drought.

Thermal and chemical treatments are also available for use on crop that is already affected by mycotoxins (Park et al., 1999). Thermal inactivation, however, is not effective on certain types of mycotoxins, such as aflatoxin. Chemical treatments, such as ammoniation and activated carbons and clays, are other possible.

12. Patulin production in apples.

Patulin is a mycotoxin that is produced by a number of molds associated with fruit spoilage.

Control methods often used in the production of apple juice include using tree-picked apples, culling apples, washing apples, charcoal treatment, chemical preservation using sulphur dioxide, gamma radiation, fermentation, trimming of fungus-infected apples, and clarification methods (Bisessur et al., 2001; Jackson, et al., 2003).



Physical Safety

Materials that do not belong in food, like glass or metal, cause physical safety hazards. A physical safety hazard is any extraneous object or foreign matter in food that can cause injury or illness in the person consuming the product (Folks, 2001). Rocks, metal, wood, and other objects are sometimes found in raw ingredients. Further, contamination can occur during transport, processing, and distribution of foods due to equipment failure, accidents, or negligence (Institute of Medicine/National Research Council, 1998). Separation equipment should be used to separate the foreign bodies from the product. Detection methods include metal detectors, x-ray machines, and optical systems (Wallin and Haycock, 1998).

1. Foreign matter in raw materials.

Processors can include separation equipment, such as destoners, air cleaners, magnets, screens, sieves, traps, scalpels, and washers as part of their production lines. For example, grain processors use four screens to remove foreign materials (Stier, 2001). Foreign matter in raw materials can be controlled with raw material inspections and vendor certifications or guarantees from suppliers. X-ray technology is also available to examine incoming material (Folks, 2001).

2. Poorly maintained equipment and lines.

Routine or preventive maintenance and other periodic checks of equipment can minimize the risk from this safety issue. Risk is further minimized with the use of metal detectors and x-ray machinery. Proper calibration of equipment and minimizing contact between pieces of machinery is also.

3. Lighting fixture/other glass breakage.

Glass can be controlled by having a glass breakage policy, such as throwing away all food and containers within 10 feet of the incident (Stier, 2001). Light fixtures can be protected so that if they break, the glass does not spill out (Folks, 2001).

4. Human factors.

Production line workers can be a major source of contamination. For example, jewellery can fall off or break, fingernails can break, and pens can fall into food. Jewellery removal is required under GMPs. If pens are metallic, a metal detector can detect them. Production workers' fingernails should be cut short and gloves should be worn under certain processing conditions.

5. Introduction of foreign matter during storage.

Pests can enter products during storage, leaving remnants behind. Effective pest control is the solution. It can include preventive measures such as filling in all non-functional openings in a building; fully sealing doors, windows, and vents; protecting intake points with filters or grills; and protecting drains and other facility intakes and exits. Professional extermination is needed once pests have established. UV light traps can also be used, although they need to be designed to prevent further contamination from the tray that collects the insect remains (Wallin and Haycock, 1998).



Q & A

References

<http://www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110911.htm>



THANK YOU
