MODULE 5

Current Good Manufacturing Practices (cGMPs)
Learning Objectives

- To gain general knowledge about cGMPs and what is required in the regulation.
- Become familiar with how cGMPs requirements sets the foundation for food safety in a food processing facility.
- Identify cGMPs rules that can be improved in your facility.
Regulatory Qualifications/Training

■ The management of an establishment must ensure:
■ That all individuals who manufacture, process, pack, or hold food are qualified to perform their assigned duties, (including temporary and seasonal personnel).
■ Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.
Regulatory Qualifications/Training

The management of an establishment must ensure:

- Supervisory personnel responsibility for ensuring compliance by individuals must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.
Good Manufacturing Practices (GMPs)

- Current Good Manufacturing Practice rules and regulations are found in Subpart B of the regulation for Preventive Controls for Human Food 21CFR Part 117.

- The regulation establishes the conditions and practices a food processing facility must follow for processing safe food under sanitary conditions.

- There are nine main sections for Current Good Manufacturing Practices (cGMPs).
Main Sections of Current Good Manufacturing Practices (cGMPs)

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and controls
- Equipment and utensils
- Processes and controls
- Warehousing and distribution
- Holding and distribution of human food by-products for use as animal food
- Defect action levels
Main Sections of Current Good Manufacturing Practices (cGMPs)

A closer look at the 9 main sections for Current Good Manufacturing Practices

A General Overview
Personnel

The management of the establishment must take reasonable measures and precautions to ensure the following:

- Disease control - Any person that have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination must be excluded from any operations which may be expected to result in contamination of food, food-contact surfaces, or food-packaging material.

- Personnel must be instructed to report such health conditions to their supervisors.
Personnel

The management of the establishment must take reasonable measures and precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging material.

1. Wear suitable outer garments.

2. Maintaining adequate personal cleanliness.

3. Washing hands thoroughly.

4. Removing all unsecured jewelry and other objects.

5. Maintaining gloves, if used, in an intact, clean, and sanitary condition.
Personnel

6. Wearing effective hair restraints.

7. Appropriate storage of clothing and other personal belongings.

8. Designated area for eating food, chewing gum, drinking beverages, or using tobacco.

9. Protect against microorganisms or foreign substances (including perspiration, cosmetics, chemicals, and medicines applied to the skin).
Personnel Exercise

Review the list for Personnel.

- Are there any areas that you need to consider or provide additional training in your processing operation?
- You might want to circle the number/s on the list.
Plant and Grounds

The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food.

The methods for adequate maintenance of grounds must include:

- Properly storing equipment and maintain immediate vicinity by removing litter/waste, cutting weeds/grass to discourage harborage for pests.
- Maintaining roads, yards, parking lots, adequately draining areas.
- Adequately maintaining waste treatment and disposal.
- Bordering grounds not under the operator's. Care must be exercised to exclude sources of food contamination.
Plant and Grounds

The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food production purposes. The plant must include:

- Proper spacing/placement of equipment and storage of materials.
- Separation of operations in which allergen cross-contact and contamination are likely to occur.
- Precautions to protect food in installed outdoor bulk vessels.
- Constructed so floors, walls, and ceilings can be adequately cleaned.
Plant and Grounds

- Drip or condensate from fixtures, ducts and pipes
- Provide adequate lighting in hand-washing and processing areas.
- Shatter-resistant light bulbs when suspended over exposed food.
- Operate fans and air-blowing equipment to minimizes allergen cross-contact, contaminating food, food-packaging materials, and food-contact surfaces.
- Adequate screening to protect against pests.
Plant and Grounds Exercise

Review the list for Plant and Grounds.

- Are there any areas that you need to consider or improve in your processing operation?
- Consider writing down items that might need to be reviewed.
Sanitary Operations

General Maintenance

Buildings, fixtures, and other physical facilities of the plant

- Must be maintained in a clean and sanitary condition.
- Must be kept in repair adequate to prevent food from becoming adulterated.
- Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.
Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be:

- Identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- Be free from undesirable microorganisms.
- Safe and adequate under the conditions of use.
- Obtain letter of compliance for chemicals.
Sanitary Operations

General Maintenance

- Have pest control.
- Sanitation of food-contact surfaces.
- Food-contact surfaces for low-moisture food must be in a clean, dry, sanitary condition before use.
- In wet processing equipment must be cleaned and sanitized as necessary to protect against allergen cross-contact or the introduction of microorganisms.
Sanitary Operations

General Maintenance

- Single-service articles properly stored, handled, and disposed to protect against cross-contact and contamination.
- Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned.
- Proper storage and handling of cleaned portable equipment and utensils to protect food-contact surfaces from cross-contact and contamination.
Sanitary Operations Exercise

Review the list for Sanitary Operations.

- Are there any items that you need to improve upon in your processing operation?
- You might want to ‘star’ that list item.
Sanitary Facilities and Controls

Each plant must be equipped with adequate sanitary facilities and accommodations including:

- Water supply derived from an adequate source and at a suitable temperature.
- Plumbed for adequate water supply throughout plant.
- Properly convey sewage and liquid disposable waste.
- Provide adequate floor drainage.
Proper sewage disposal.

Provide readily accessible and clean toilet facilities.

Adequate and convenient hand-washing facilities to ensure that an employee's hands are not a source of cross-contact and contamination.

Rubbish and offal disposal.
Sanitary Facilities and Controls Exercise

Review the list for Sanitary Facilities and Controls.

■ Are there any items that you need to improve?
■ Do you know where the handwashing stations are in your facility?
Equipment and Utensils

All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be:

■ Designed and of such material and workmanship as to be adequately cleanable.

■ Adequately maintained to protect against allergen cross-contact and contamination.
Equipment and Utensils

Significant details are written into the rule to assure that equipment, utensils, and food-contact surfaces are not a source of food contamination and allergen cross-contact.

Such as:

- Designed and constructed to avoid the adulteration of food with lubricants, fuel, metal fragments.
- Equipment must be installed to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.
- Food-contact surfaces must be corrosion-resistant when in contact with food.
Equipment and Utensils

- Seams on food-contact surfaces must be smoothly bonded.
- Equipment in the processing area that does not come into contact with food must be constructed so it can be kept in a clean and sanitary condition.
- Holding, conveying - so constructed to be maintained in an appropriate clean and sanitary condition.
- Freezer/cold storage compartments must have a temperature recording devise.
Equipment and Utensils

■ Instruments and controls used for measuring safety parameters must be accurate and precise and adequately maintained.

■ Compressed air or other gases mechanically introduced into food are not a contaminant to food.
Equipment and Utensils Exercise

Review the list for Equipment and Utensils.

■ Are there any items that you should improve, underline in the list?
■ In your facility how do you control allergen cross-contact?
■ Share a method with the group.
Processes and Controls

All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.
General Requirements

- Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe.

- Sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

- Appropriate testing where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.
Processes and Controls

Raw Ingredients

■ Frozen raw materials and other ingredients must be kept frozen and thawing must be done in a manner that prevents adulteration.

■ Raw materials/ingredients held in a manner that protects against allergen cross-contact and against contamination.

■ Raw materials/ingredients/rework that are food allergens or that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.
Processes and Controls

Manufacturing operations

- Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing.

- All food manufacturing, processing, packing, and holding must minimize the potential for the growth of microorganisms, allergen cross-contact, contamination, and deterioration of food.

- Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated.
Processes and Controls

- Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling $A_w$ that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

- Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse.
Processes and Controls

- Means used to convey must protects against allergen cross-contact and against contamination.
- Protect against the inclusion of metal.
- Methods of manufacturing must be performed to protect food against allergen cross-contact, against contamination, contaminants that may drip, drain, or be drawn into the food, and minimizing the potential for the growth of undesirable microorganisms.
- When ice is used in contact with food, it must be made from a safe water source.
Exercise Processes and Controls

Review the list for Processes and Controls.

- Are there any items that are new to you?
- Circle items in the list that need additional consideration in your facility.
cGMPs for By-Products Sent to Animal Food

Holding and distribution of human food by-products for use as animal food.

**Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, must be held under conditions that will protect against:**

- **Contamination**
- Containers and equipment used to convey or hold human food by-products must be constructed of appropriate material and cleaned as necessary to protect against contamination.
- Protect against contamination from sources such as trash.
- Must be accurately identified. Must be affixed to or accompany human food by-products for use as animal food when distributed.
- Shipping containers must be examined prior to use to protect against contamination of the human food by-products.
Defect Action Levels

- The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

- The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food.

See the Defect Levels Handbook, which is accessible at

https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm056174.htm
Other Preventive Control Elements

- Hygienic zoning in ready-to-eat facilities
- Preventive maintenance
- Signage or color coded equipment
- Standard Operating Procedures (SOPs)
- Pathogen Environmental Monitoring
- Others specific to a facility
cGMPs and Preventive Control Elements

Summary

- cGMPs and other preventive controls elements provide the foundation necessary for production of safe and wholesome food.
- cGMPs support the Food Safety Plan.
- cGMPs are required.
- The cGMPs regulation is found in Part 117 Subpart B.
- Education and Training is needed to understand and effectively implement cGMPs.