Good Manufacturing Practices (GMP) And Good Laboratory Practices (GLP)

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1. Introduction

Good Manufacturing Practices (GMP) forms an important part of the overall HACCP food safety system in a food industries. GMPs can be defined as the operational requirements necessary to enable a food industries to produce food safely. There is a heavy emphasis on compliance with GMP in all relevant food legislation and customer certification standards.

GMPs are important in order to produce safe food. The food industry has a legal and moral responsibility to produce and prepare food that will not harm the consumer. There can be a high cost to the food industries if it does not implement adequate Good manufacturing practices. All staff should be trained in the food industries GMP procedures.

The Good manufacturing practices for Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Food Hygiene, Safety Management and Other Systems Sectional Committee had been approved by the Food and Agriculture Division Council. Food processing sector includes the food processors, suppliers of equipment, raw materials, ingredients, packing materials, processing aids, pesticides, fertilizers and cleaning chemicals. However, it does not include primary production, transportation, storage and retail.

However, nothing in this GMP Indian Standard shall affect the operation of the Food Safety and Standards Act, 2006 and regulations framed thereunder; Standards of Weights and Measures Act, 1977 or any other law for the time being in force and shall be subject to the restrictions imposed thereunder, wherever applicable.

2. Basic operational conditions and procedures for GMPs

Good manufacturing practice includes many basic operational conditions and procedures that are required to be met by the food industries. These can include the following:

- The correct construction and layout of the food premises.
- The condition of the external environment of the food premises.
- The adequate maintenance of equipment and utensils used within the food industries.
- The use of suitable chemicals within and around the food premises including cleaning chemicals, pest control chemicals and machine lubricants.
- The identification and storage of waste within and by the food industries.
- The cleanliness of the food premises, equipment, utensils, floors, walls and ceilings.
- An effective pest control program implemented within the food premises and surrounds.
- The avoidance of foreign matter within the finished product. Sources of foreign matter can include wood, glass, metal, plastic, pests, paper, string, tape.

3. Elements of GMPs

Personnel Practices: Personnel and their practices can affect the safety of the foods they handle. Through training and monitoring employee practices, the potential for the contamination of foods can be controlled. Managers of food operations have the responsibility for assuring that all personnel comply with this part of the GMPs. To accomplish this, management has been given the responsibility of training personnel in food protection principles and food handling techniques. A written training program should be established, routinely evaluated, and updated as necessary. Training must be applied as stringently to temporary personnel as with permanent employees. Contract service personnel must be trained in quality and food safety.

There are several personnel practices with which food industries should be concerned:

Disease Control - Personnel with contagious illnesses, open lesions, boils, sores, infected wounds, or any other abnormal source of microbial contamination that could contaminate foods or food contact surfaces with microorganisms should be excluded from areas where contamination may occur. This includes areas where they would contact food, food contact surfaces, or packaging materials In some instances, e.g. norovirus infection, workers should be excluded from the entire facility. Personnel should be instructed to report such conditions to their supervisor until the condition is corrected. Personnel should also be instructed to report any exposure outside of the workplace that would pose a risk to the work environment. A comprehensive health policy outlining employee restrictions should be developed by each organization.

Cleanliness –

- Employees need to wear clean garments that are suitable for their activities.
- Clean footwear should be appropriate for the work environment and available for use in production areas
- Uniforms where provided should be maintained and cleaned on a regular schedule
- It should be assured that any outside clothing be clean and sanitary if allowed in production areas
- Personal cleanliness needs to be maintained by washing hands prior to work, when hands are soiled, after eating, and after using restrooms.

Jewelry or other objects that are insecure (such as objects in shirt pockets, necklaces, earrings, etc.) need to be removed. Hand jewelry can be a source of microorganisms or a source of foreign material and should not be worn where foods are processed.

Effective hair covering and beard covering should be worn where products, food contact surfaces, and packaging materials are exposed. Mustaches may also be required to be covered.

Foods, chewing gum, beverages, tobacco products, medicine, coins, and like products need to be confined to areas such as break rooms, offices, or other designated areas of the facility so as to prevent product contamination. Lockers or other isolated storage areas should be provided for workers to store personal items.

Precautions should be taken to prevent contamination from foreign substances including, but not limited to, perspiration, cosmetics, chemicals, fingernail polish, and medicines applied to the skin.

Education and training - Personnel responsible for identifying sanitary failures or food contamination should have training, education, experience, or a combination thereof, to

provide the level of competency necessary for production of clean, safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices. Special training should take place on food allergy and for the need for special care to prevent cross contamination/mislabeling. This training should apply to temporary and contract workers as well as permanent employees.

- Each worker's responsibility and accountability should be documented in a clearly understandable manner as to job expectations.
- Personnel practices should be monitored through internal audits.
- Visitors should follow the same rules as employees and be so instructed when entering a facility.
- No glass should be allowed inside a production area.
- Only impermeable gloves should be used and be kept clean and sanitary during use.
- Cross contamination between 'dirty' and clean areas should be strictly controlled through segregation of equipment and personnel.

Educate workers on the importance of proper hand washing techniques: Thorough hand washing before commencing work and after using the restroom is very important. Employees must wash and dry their hands before working with foods. Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Contaminated hands can also transmit infectious diseases. Do not assume that workers know how to wash their hands properly. Proper hand washing before and after the workday, using the bathroom, and eating, drinking, or smoking is a simple eight-step process:

- Wet hands with clean warm or hot water
- Apply soap
- Scrub hands and fingernails (for 20 seconds)
- Rinse off soap thoroughly with clean water
- Dry hands with single-use towels
- Discard used towels in trash
- Sanitize hands with an appropriate sanitizer.
- Dry hands

Building and Facilities

Plants and Grounds - To comply with the GMPs, all food processing and storage operations should be designed to facilitate maintenance and sanitation operations. This includes the exterior of the operation, the structure of the building, and the interior facilities. Plant and grounds schematics should be available and up to date. Process flow charts are also helpful to have available.

Exterior Grounds - The exterior grounds around a food operation need to be maintained so as not to be a pest harborage or a source of contamination, such as dust, dirt, or water. Pests around the exterior of buildings may be controlled by frequently cutting weeds and grasses, maintaining waste disposal areas, eliminating standing water, using shrubs and trees that do not attract insects and birds, and properly storing idle equipment and parts that are left outside away from manufacturing buildings.

- Roads, parking lots, and yard areas need to be maintained so as not to be a source of airborne dirt or other contamination that could enter the operation, nor a source of mud that could be tracked into the facility.

- Provide for "no vegetation" strips around the exterior building walls and cover the strip with crushed stone or similar material.

Facility Construction - Buildings that house food operations should be of suitable size, design, and construction to allow the operations to be conducted in such a manner that food safety will not be compromised. To fulfill this, the facility needs to:

- Be of sufficient size to adequately move equipment in the course of production, maintenance and sanitation activities. Storage areas need to be of suitable size to facilitate good housekeeping practices.
- Be designed to reduce the potential contamination of foods, food-contact surfaces, and food packaging materials. Examples of ways to accomplish these are: Enclosing systems, physical separation (walls or space), logical traffic flow patterns, appropriate air flow such as positive pressure in finished product area, line covers, adequate interior and exterior lighting, etc.
- Be designed to control condensate, leaks or drippage from walls, ceilings, pipes, ducts, and roofs especially over product zones. Be designed to control water from any source in production areas in order to prevent the risk of Salmonella growth and potential product contamination.
- Eliminate or protect (enclose) glass in lighting fixtures, skylights, insect light traps, etc. while providing adequate lighting to maintain an acceptable level of sanitation.
- Be constructed with materials and in a manner that will allow walls, ceilings, and floors to be adequately cleaned and kept in good repair.
- Provide adequate ventilation to control fumes such as from roasters and odors such as in trash disposal rooms.

Sanitary Operations

General Maintenance – Buildings, fixtures, and other physical facilities of the plant should be maintained in a sanitary condition and kept in repair sufficient to prevent food from becoming adulterated.

- Storage of substances used in cleaning and sanitizing toxic materials – The only toxic materials allowed in a food plant are those necessary for use in the plant (e.g., for cleaning, pest control, and equipment maintenance, or for use in lab testing procedures or the plant’s operations).

Sanitation of food contact surfaces – All food contact surfaces should be cleaned as frequently as necessary to protect against contamination of food. Chemicals used on food contact surfaces must be food grade. When choosing sanitizing agents appropriate experts should be consulted to identify the most effective sanitizers for each purpose and to learn how they are applied.

- Special attention should be applied to portable equipment such as step ladders and fans that they are properly cleaned and sanitized before use.
- Workers should be properly trained in the use of sanitizing agents.
- Proper disposal of containers should be documented.
- Material Safety Data Sheets (MSDS) should be available for all chemicals used.

Pest Control

Pests should be prevented from entering any area of a food plant. The term, pests, can be interpreted to mean rodents, insects, birds, or other types of animals. Many of these pests are capable of movement and it is essential that an effective pest control program be developed and implemented to prevent pest problems from developing.

To accomplish this, an effective documented program to prevent pest entry into a building is needed. Within the building, prevention programs such a trapping, elimination of harborage locations, using pesticides in accordance with labeling directions, and monitoring the pest control devices will help to insure compliance.

Recommended elements of an effective pest control program are as follows:

- Ensure all exterior doors are weather stripped and maintained on a continuing program.
- Keep exterior doors closed when not in use.
- Install automatic closures on exterior doors.
- Maintain adequate surface drainage.
- Windows should be properly screened.
- Exhaust fans should be installed and maintained.

Equipments

All food contact surfaces should be made of non-toxic materials, appropriate to their use, resistant to deterioration by cleaning and sanitizing agents and materials that can be easily cleaned and maintained.

- Equipment and utensils should be designed so as to provide access for cleaning and be cleanable.
- Equipment should be well maintained, with no rust, excess lubrication, flaking paint, etc. Plastic (such as baskets, conveyors) should be well maintained without chips, cracks or breaks in the material.
- All cold storage facilities in the plant should be equipped with a temperature measuring or recording device that can be accurately read to confirm temperature. This device should be calibrated at least annually to ensure accuracy. Cold storage facilities should have an alarm system or an automatic temperature control device.
- If compressed gases are used in the facility, a certificate of purity should be obtained from the vendor and kept on file.

Production Controls

Raw Materials

- All arriving vehicles carrying raw materials (including ingredients and packaging) should be inspected:
- Ensure all transporting vehicles used for foods are not used for chemicals, livestock, waste products, or other contaminants.
- Examine all incoming vehicles carefully to determine if doors, hatches, and seals are intact and no evidence of tampering exists.
- Record the seal numbers of the doors and hatches prior to their removal. Note any broken or damaged seals and report such findings to the carrier and shipper.
- Upon opening and prior to unloading of the product, examine the exposed interior of the container for evidence of any potential contaminants and adulterants

including but not limited to non-food allergens, insects, rodent, mold or undesirable odors. Continue this examination during the entire unloading operation.

- Check for rodent activity evidenced by droppings and urine stains. Use of "black light" is recommended to find urine stains on containers, in vehicles or on contents.
- Ensure materials from cold storage are inspected for evidence of improper "tempering" (mold, mildew, dampness). If evidence of moisture is noted, perform microbiological assays to assure safety, as needed.
- Ensure each shipment of foods or other raw products arrive with a grade certificate or certificate of analysis, if required.

4. Documenting GMP and its inspection

To assist in the effective implementation of GMPs within the food industries it is advisable to document procedures on how the food industry is going to implement relevant GMP. Equally important is to maintain records to support that any GMP have been implemented.

To ensure the effective implementation of GMPs, it is beneficial for the food industries to undertake its own internal GMP inspection. This generally involves reviewing the site visually to see if it is complying to customer expectations and regulatory requirements. This inspection should not merely be a “tick and flick” activity but a comprehensive assessment of the site to determine the level of GMP compliance. A record of any GMP inspection undertaken is required to be kept as evidence in a third-party certification audit. Any issues identified during the GMP inspection should be quickly rectified and a root cause analysis performed to avoid reoccurrence.

5. Good laboratory practices (GLP)

GLP embodies a set of principles that provides a framework. It is a quality system concerned with the organizational process and the conditions under which non-clinical health, and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

The raw materials, packaging materials, intermediates and finished products are ultimately released based on the analytical results generated in the quality control laboratory. Accuracy, precision and reliability of these results are of paramount importance.

- GLP makes sure that the data submitted are a true reflection of the results that are obtained during the study.
- GLP also makes sure that data is traceable.
- Promotes international acceptance of tests.

Tests and Control Articles:

- Samples should be tested in accordance with the written methods & referred to in relevant specifications.
- In- process checks done by QC personnel on the batches in production should also be attached to the analytical reports for the batch.
- Test methods should be validated.
- Where the results of testing appear doubtful, repeat the test but do not fabricate the results to cover up mistakes or to avoid work.

How to avoid general hazards?

1. If any flammable substances:

- Use minimum quantity
- Store in special storage cabinet
- Use temperature-controlled heating sources

2. If any spillages:

- Evacuate area, alert personnel and cordon off so that aerosols may settle
- Clear up spillage promptly

3. Gas cylinders:

- Cylinders are heavy and can do serious damage to you if they fall
    - Ensure that they are chained when in use
    - Move only with a cylinder trolley
- Use regulators & control equipment suitable for the gas concerned
- Consider the consequences if your cylinder leaks

4. Cryogenics:

- Liquid gasses are extremely cold and can cause burns
- Liquid gases evaporate and many can cause asphyxiation

5. Electrical Equipment:

- Always do a visual check on electrical equipment before use, looking for obvious wear or defects
- All portable electrical equipment must have a current “PAT test” sticker

Safety in food microbiology lab:

- Every specimen must be regarded as dangerously infective and treated as such.
- All accidents-must be reported immediately to the lab instructor.
- All discarded cultures must be placed in a bucket provided, ready for sterilization.
- Used material should be disinfected.
- Do not discard any fluid to the sinks or drains.
- Hands must be washed thoroughly before leaving the laboratory.

Conclusion: The good manufacturing practices are essential requirements for organization in the food processing sector, has been developed to assist organizations to implement and operate effective manufacturing practices, to produce and process products as per specifications and reduce the risk of contamination. The design, documentation and implementation of an organization’s GMP system is influenced by the specific needs of the products provided and the processes employed. And GLPs provide guidelines and better control for maintenance of instruments, environmental control, and preservation of test records. Over all in the food industries/laboratories there is no margin for error and one must follow good practices.