Perennia

Nova Scotia's Food Development Agency

Production Good Manufacturing Practices and Quality Considerations

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Introduction

Good manufacturing practices (GMPs) are important in all manufacturing facilities. By maintaining GMPs, you can help ensure your product remains consistent, within quality targets and have confidence in its' safety for consumers.

Standard GMPs cover many aspects of the entire production. This includes the building/grounds, equipment, ingredients, sanitation, personnel traceability, and final product. No matter the size of your operation, it is important to have standard operating procedures (SOPs) and guidelines in place to ensure GMPs are being followed.

In addition to GMPs, it is important to set up a Quality Manual. This is the "holy grail" of documents that will lay out all the quality parameters and procedures that are required to achieve the product you want to make. This includes:

- Defining the products being produced in sufficient detail to know what you are aiming to make and ensuring it can be done consistently.
- Defining every single material used in the facility, anything that will help create the product and anything that forms a key part of the process, which includes processing aids to cleaning agents.
- Defining exactly how all the processes are to be carried out (SOPs). This includes the intake of ingredients, creating the product, heat treatment (if necessary), packaging and downstream processes, but also the surrounding processes such as cleaning and sanitization of the equipment and facility.

This document summarizes some general considerations for good manufacturing practices. Please note this report summarizes the major considerations but is not inclusive of all considerations. It is important to be aware of and stay up to date on constantly changing regulations to ensure compliance and be mindful that certain quality matters are specific to your facility and products.

GMPs – Facility and Grounds

Grounds

The area around the production facility must be well maintained to help control pests that could lead to infestation and food safety risks. This includes the following:

- Vegetation must be kept away from the building.
- Water must drain properly.
- Outside storage areas should be kept tidy and secure.
- If there is outside storage of ingredients in containers or silos make sure the area is kept protected and clean.
- Areas of waste, trash, liquid by-product, and any by-product must be kept covered, cleaned and maintained.
- Pooling of stagnant water close to the facility should be removed to prevent it from being tracked into the facility.
- All drainage should flow away from the facility.

Facility Design

Equipment and storage

There should be adequate spacing for all equipment and storage. It is important to keep a perimeter around equipment and materials to allow pest control personnel and employees to move around for inspection and to keep clean.

Ingredients and food storage

- All ingredients should be kept at their recommended storage conditions to maintain their quality and safety over time.
- All ingredients should be kept in clean conditions, protected from contaminants, in closed containers or packages, and never stored on the floor.
- If kept in vessels, those should remain sealed and ensure vessels are clean.
- Regular inspection of the ingredients should occur to check for pest infestations, quality, damage, and tampering.

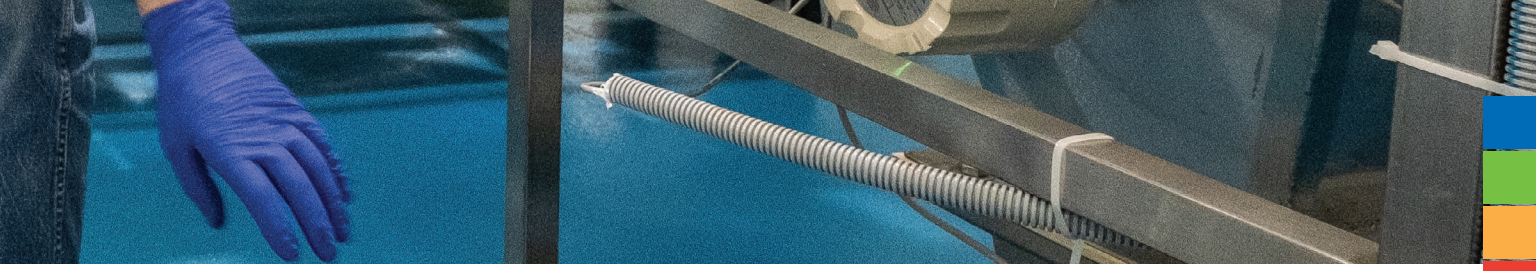
Allergens

Allergen control must be considered in the design of a facility, especially if allergen-containing products and ingredients and non-allergen products are being produced in the same facility. The main point to consider is, at any point, can there be cross-contamination of an allergen into a product where it is not wanted.

- Is a separate packaging line required if obtainable?
- Is the area cleanable to help prevent cross-contamination?
- Are there certain cleaning procedures required between doing an allergen run and an allergen-free run?
- Consider using dedicated hoses, gas lines and tanks.
- Consider keeping allergenic products and ingredients stored separately from others.
- If possible, design the production schedule to help prevent cross-contamination (i.e. running the allergen-free product first before allergen-containing products).

Sanitation

The facility should be constructed so that overheads, piping and all floors and walls can be cleaned. There should be no exposed dry wall or types of insulation. Any wet or dirty/ dusty areas around the production equipment should be cleaned at a frequency that prevents



any contamination issues. This can be ensured by making sure there is a proper cleaning schedule in place for the facility.

Lighting

All lighting in a manufacturing facility must have shatterproof bulbs and/or protective coverings to prevent glass contamination anywhere food handling occurs.

Areas where ingredients and product are being examined must have proper lighting to ensure proper cleaning and handling occurs.

Handwash areas, locker rooms and washroom facilities must have proper lighting to ensure employees are washing their hands properly.

Ventilation

Proper ventilation is essential to ensure that air quality in the facility is clean and does not contaminate the product. In areas that create steam, it is also important that ventilation occurs to prevent high humidity and the forming of condensation that can promote mold growth, which has the potential to contaminate open product, ingredients, or packaging.

Doors and Windows

If doors and windows are open in the facility, sufficient screening must be in place to prevent any pests from entering the facility. Receiving or overhead doors must be closed when not in immediate use, and all doors, windows, and overheads must be properly sealed and secured.

Product Flow and Segregation

It is important to look at the big picture of all the movement and flow of personnel, products, ingredients, tools, etc., in the facility to ensure there are no points of risk or contamination. Some points to consider are:

- Use designated tools for higher-risk equipment, such as the packaging lines.
- Use designated tools for food-use and non-food use (food contact and non-food contact) (i.e. tools to clean tanks should not be the same as tools to clean the floors).
- Consider the location of the ingredient storage to a blending room or product preparation room and the flow of the process to packaging ensuring ingredients and product are not travelling through areas of potential cross-contamination.
- Do trash bins have to be moved through any areas that have open product?
- Are there enough storage and workspaces?
- Keep chemicals, raw materials, packaging, and finished goods all segregated.
- All food should be stored above non-food products if stored together.
- Be mindful that the route that materials take to get to the production area does not pose a safety risk to the products.
- Raw ingredients/products should not be able to cross paths with the finished goods or packaging area to reduce the risk of contamination.
- If there are any elevated perforated walkways make sure there is no risk of any materials falling into processing below.

Utilities

Ensure that there is sufficient potable water at the point of use. If there is any stored water, have it tested for microorganisms regularly, make sure water tanks are cleaned regularly and checked for chemical residue. Water line dead ends should be removed to prevent any biological buildup and growth.

Make sure that gases do not pose a contamination risk to the product. Use food grade gases, be mindful of backflow/dirty gas hoses allergen risks if there are not dedicated lines and that the lines are in good condition so there is no risk of pieces getting into the product.

GMPs – Personnel

The key concepts surrounding GMPs for the personnel in a facility are very simple:

- Control the spread of disease.
- Maintain personal cleanliness to protect against contamination of food.
- Personal hygiene is a top concern, and all personnel entering the establishment must wash their hands before entering and have designated work shoes and/or boot mat dip.

Policies should be set in place to ensure these points are always met.

GMPs – Sanitation and Maintenance

The facility and all equipment must be properly maintained to ensure safety. Preventative maintenance programs should be set in place for all equipment in the facility, and regular inspections of the building should occur to make sure no repairs are necessary.

Proper cleaning and sanitation procedures must be in place to ensure the safety of the product being produced. When cleaning equipment, utensils, or anything else that will be in contact with the product, either use food grade cleaners or set procedures in place to ensure all chemicals are removed before using. When working with chemicals, ensure personnel are properly trained and have any required personal protective equipment (PPE), such as goggles and gloves so that injury does not occur.

Quality Considerations – Ingredients

To help ensure quality and consistency, it is important to have procedures and specifications set in place for the ingredients being used in the production process. The first important consideration is to have at least two suppliers of each ingredient in the case of potential availability or supplier issues.

Upon ingredient arrival, ensure each ingredient comes with a specification document and/or a certification of analysis (CoA) for the lot received and that they are within the expected specifications that you have set for your product needs.

Log all incoming ingredients using lot code and/or assigned internal codes on your quality/traceability paperwork.

It is up to the facility to decide what attributes, specifications and testing they would consider important and are also mandatory for their quality procedures. Ensure these requirements are clearly laid out in SOPs.

Quality Consideration – Processing and Packaging

Again, it is important to have all of the important steps and control checks documented in SOPs for each product that is being produced. This ensures the same steps are being followed, checks are being completed and paperwork filled out. This will give confidence in consistency and also allow for proper troubleshooting if something does not meet final specifications.

Processing Control Parameters

During production, quality control checks and critical control points are essential to ensure that products are being made safely and of acceptable quality. Well-documented paperwork needs to be in place at every step of the production process

For example:

- Batch records to ensure ingredients are being weighed properly and incorporated in proper orders.
- Mixing times or speeds, when applicable, need to be stated and records completed.
- Temperature targets should have paperwork stating what they are and that they are met and checked on a frequent basis (including indicating how often temperature should be checked).
- Any analytical testing (i.e. pH, brix) that occurs in the process had to be indicated when testing is required and what the specifications are. If there is a QC department that does this testing, then checks need to be in place so that testing occurs before moving to the next step in the process.

A critical control point is a step at which control (testing or a parameter) can be applied and is essential to prevent or eliminate a food safety concern. When you are producing a product, it is important that you review the process and parameters to determine what is considered a crucial test or parameter that, when not met, jeopardizes the quality and safety of the product.

For example:

- Achieving a final product target pH
  - » Testing after blending, before and during packaging
- Ensuring the product is achieving proper temperature for pasteurization
  - » Monitoring pasteurization charts during production

Packaging Control Parameters

There are many control parameters to be mindful of when it comes time for packaging, including:

- Packaging properties – ensure the package has the correct attributes and is absent of damage and foreign bodies.
- Contents – ensure the required volume is being delivered to each container (fill weights).
- Package integrity – ensure it is properly sealed and labelled, including coding.
- Product composition – various testing of the product during production run.

During a packaging run, it is important to implement testing protocols at consistent time points where product is removed directly from the line and inspected for all the above parameters and documented.

This includes:

- Checks that all equipment processing paperwork is being updated.
- Visual inspections of the packaged product.
- Can seam checks, or for bottled product, cap torque checks on product pulled from the line.
- Coding checks on the primary and final secondary packaging.
- All measurements on the product itself to ensure it is meeting specifications.

Traceability

Traceability is defined as the ability to trace a product or components of a product through all the steps in the process, from receiving through to shipping and place of sale. It is much more than putting a lot code or date code on a final product. Proper traceability ensures that when a quality or safety issue occurs with a product, you can find where the product is in the marketplace and/or source the root cause of the problem. For example, if an issue is found with one lot of an ingredient, it could then be sourced to which products it was used in.

Documentation is the key to proper traceability and keeping it simple is the best.

Key documents to have for traceability purposes

Incoming Ingredients

Ensure records are kept for all incoming ingredients, that they passed through internal inspections and are given an internal code consistently so they can be easily traced throughout the production process.

Processing

Create batch records for the product being produced that list all the ingredients, their supplier and internal codes. These batch records should also have the recipe listed and places to fill exactly what was measured and used for that product. It can also include the testing that is required and at what stage in the process. Traceability of ingredients can also help with inventory and ordering.

The product being made should also be given an internal code (batch code) so that from this point on, it can be tracked in the remainder of the production process. This code could include the name of the product and date or be a set of numbers. It is up to the facility how they choose to code, so long as it remains consistent to avoid confusion or errors.

Packaging

Traceability during packaging is a very important step. Here, you should put a code on the final packaging and secondary packaging that you are able to use to track the following points:

- When it was produced
- And from what batch of product

Additional information to document during packaging is the lot code of the materials being used. For example, what lot code of cans or bottles from the supplier and the same for cartons or tray packs.

All of this information should be tracked on paperwork that is routinely updated and verified during a packaging run by the quality control team. This paperwork can be tied into your quality control and supply chain paperwork, so everything is together and easily traced.

Traceability does not stop once the product is in its packaging. The code on the final packaging is now used to track where it goes when it leaves the facility. All shipping documents should identify the quantity and destination of each lot of product packaged.

To "test" out the traceability program that you set in place, run a mock recall or consumer complaint and work it backwards through your process. If a complaint comes to your company with a product and states, "I want you to tell me where this went, when it was packaged and when it was produced and what ingredients were used", you should be able to go back in the paperwork and answer all those questions.

Conclusion

By implementing proper Good Manufacturing Practices in your facility, it can help ensure your product remains consistent, within quality targets and have confidence in its' safety for consumers. GMPs are essential for all food and beverage production facilities and spending the time to set protocols, procedures and documentation in place will in turn help your company produce quality products.

For additional information on regulations please review **Safe Food for Canadians**

Perennia also provides additional resources for your review at the following links **Food Safety Resources** and **Regulatory Food Safety**

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