
GOOD MANUFACTURING PRACTICE
GMP

The Regulations

- GMP stands for Good Manufacturing Practices
- You will also see cGMP, the "c" represents "current"; that is, it reflect the notion that manufacturing processes are always improving.
- Regulations are a minimum requirement.

Basics of GMP

- Quality is the responsibility of everyone
- Don’t leave it to someone else to fix your problems
- Quality Control is not there to fix your work, just to confirm your work meets the standards required.

Personal Hygiene and Sanitation Practices

- Wash hands with soap and water:
  - before starting work
  - after using the toilet
  - after blowing your nose
  - after handling dirty things
  - after touching body surfaces
  - after eating

What is Poor Personal Hygiene?

- Dirty Hands
- Dirty Fingernails
- Dirty Uniforms
- Smoking in food areas
- Being sick at work
- Open cuts and/or sores

Organization and Personnel

- The company shall have a Quality Department responsible for approving or rejecting materials, processes, procedures and specifications
- Everyone is required have sufficient training, knowledge and experience to perform the work.

Organization and Personnel

- Wear clean cloths
- Wear protective apparel
- Prevent contamination
- Practice good sanitation
- If you are sick or have lesions that would impact the product, then you will be excluded from direct contact with the product

Food Handlers

- Hair should be clean and covered
- Uniform and aprons to be clean
- Hands are clean and sanitary
- Gloves are required when handling foods that are not to be cooked again
- Worker to be in good health
- No Jewelry

Buildings and Facilities

- Building will be adequately sized for proper storage of equipment and materials.
- Operations will be performed in specific areas.

Buildings and Facilities

- Raw materials will be placed in quarantine until tested.
- Rejected material must be segregated.
- There must be adequate lighting
- There will be adequate environmental controls.
- Air controls to flow through HEPA filter to ensure clean air is introduced into the facility.

Buildings and Facilities

- Sewage and trash will be stored and disposed in a safe and sanitary manner.
- Adequate washing and toilet facilities will be available.
  - Hot and cold water
  - Soap
  - Single service towels

Buildings and Facilities

- Building will be maintained in a clean and sanitary manner.
- There will be cleaning schedules with approved cleaning products
  - Standard operating procedures in place for cleaning
- Building is in a good state of repair

Buildings and Facilities

- Buildings are maintained and are pest and rodent free.
- Policies and procedures in place using approved rodentcides, insecticides and fungicides
  - These chemicals cannot affect products.

Equipment

- Equipment is to be in a good state of repair
  - Cleaning and preventative maintenance schedule must be available
  - A cleaning schedule should be in place and a log to show that cleaning is completed after each batch
  - A repair log is to be maintained.
- Approved cleaning agencies that do not affect the product.
- Each piece of equipment requires an ID number

Control of Raw Materials

- Received in quarantine and not used until it has been released.
- Written procedures in place for receiving, handling and sampling product.
- Containers stored off the floor.
- Each container should include:
  - Product name/number/code/lot number
    - Status (Quarantined, released, rejected)

Control of Raw Material

- Sampling shall:
  - be representative
  - maintain cleanliness where sampling is conducted
  - be administered in an approved area
  - prevent any cross-contamination
  - containers marked from which sampling occurred.

Production and Process Control

- Requires written procedures
- Activities to be documented
  - Batch records
  - Log books
- Contamination controls
- Cleanliness:
  - tanks, paddles, piping, probes etc.
- Being organized

Warehouse

- Shall be clean
- Sections are clearly defined
  - Quarantined – **yellow**
  - Released – **green**
  - Rejected – **red**
- First in –First out (FIFO)
- Tracking system for inventory, sold lots, (quantities to where)

Laboratory

- Will have specifications, standards, sampling plans, test procedures
- Shall have a calibration and maintenance program (written with a time period for performance)
- All testing is documented in a log book.

Laboratory

- Inform the supervisor if something is wrong
  - Don’t continue with improper testing
  - Check results **prior** to discarding samples
    - Have a second person check the results
    - Check the acceptance value
- Conduct stability testing
- Keep reserve samples of final products past the expiry date

Documentation

- Records to be maintained for the following:
  - batch records
  - testing
  - investigations
  - maintenance
  - training
  - cleaning
  - pretty much anything else one can think of
    - Remember, if it wasn't documented, it didn't happen
  - Documentation needs to be in ink or other non-erasable medium

Documentation

- Cross out with a single line, initial and date when making an error
  - do not use whiteout
  - don’t use scrap paper
- Have a change control number for all documents
  - have a review mechanism in place for changes
- Sign only what you have performed or verified.

Documentation

- Record the date
  - do not backdate
  - if you forgot to record something, write the following:
    - Performed on May 17, 2016 and written on May 19. 2016.