


# EFFECTIVE GOOD MANUFACTURING PRACTICES

Northwest Food Processors Association  
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## 21 CFR PART 110.5 CURRENT GMP

- Good Manufacturing Practice:
  - Clarification of the FD&C Act
  - Criteria to determine if a food is adulterated
- 402(a)(4) - Food, Drug, & Cosmetic Act
  - A food is deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated




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## GMP'S - 21 CFR PART 110

- 110.10 - Personnel
- 110.20 - Plant and grounds
- 110.35 - Sanitary operations
- 110.37 - Sanitary facilities and controls
- 110.40 - Equipment and utensils
- 110.80 - Processes and controls
- 110.93 - Warehousing and distribution




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## EFFECTIVE GMP'S

- ◉ GMP's - Mandatory
- ◉ "Effective GMP's"
  - Best Practices
  - Recommended approaches
  - The practices behind the practices
  - Make it easy to succeed/ comply



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## 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Disease Control

Any person who, by medical examination or supervisory observation, is shown to have or appears to have, an **illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination** by which there is a reasonable possibility of food, food-contact surfaces, or food packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination.



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## 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Disease Control

- ◉ Effective GMP:

- Paid sick leave
- Materials to cover cuts/ sores
  - Bandages, sleeves, gloves
- Predetermined activities for people with exposed cuts/ sores
- Internal sanitation program includes routine sanitizing of common surfaces - door knobs, phones, etc.



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### 21 CFR PART 110.10 PERSONNEL

◉ GMP: Garments

- ◉ Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging material.



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### 21 CFR PART 110.10 PERSONNEL

◉ GMP: Garments

◉ Effective GMP:

- Don't rely on street clothes
- Use company issued garments
- Use company laundered garments
- Provide designated storage areas for uniforms away from personal items
- If aprons are used, ensure separate hooks for varied operations:
  - ◉ Raw material/ finished product
  - ◉ Allergen / non-allergen
  - ◉ Facility garments/street clothes



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### 21 CFR PART 110.10 PERSONNEL

◉ GMP: Hand Washing

- ◉ Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.



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### 21 CFR PART 110.10 PERSONNEL

- ⦿ GMP: Hand Washing
- ⦿ Effective GMP:
  - Provide hand wash stations where needed
    - At all entrances to processing areas, not just main entrance
    - Ensure enough sinks for # of people at shift change
    - Create foot traffic lanes that force persons to pass by hand wash stations
    - Make hand wash stations highly visible



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### 21 CFR PART 110.10 PERSONNEL

- ⦿ GMP: Jewelry and Loose Objects
- ⦿ Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand.



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### 21 CFR PART 110.10 PERSONNEL

- ⦿ GMP: Jewelry and Loose Objects
- ⦿ Effective GMP:
  - Provide secure storage (lockers) for jewelry storage
  - Provide tool boxes or pouches for storage of pens, stopwatches, thermometers, calculators, and other small tools
  - Eliminate pockets on shirts
  - Provide plenty of clocks, so watches are not needed
  - Provide tethers for eyewear
  - No pens or markers with caps



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Gloves
- ◉ Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Gloves
- ◉ Effective GMP
  - Easy access to replacements
  - Multiple sizes available
  - Designated storage for reusable gloves
    - Separate by area of use: Raw/ Finished



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Hair Restraint
- ◉ Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Hair Restraint
- ◉ Effective GMP:
  - Multiple size hairnets
  - Easy access to replacements
  - Non-glass mirror at hand wash stations to check for stray hairs



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Personal Belongings
- ◉ Storing of clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Personal Belongings
- ◉ Effective GMP
  - Provide designated, secured storage areas
  - If personal clothing is needed for some tasks, such as jackets for going outside during bulk receiving, provide hooks or closet designated for this purpose
  - Provide secure storage for food



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### 21 CFR PART 110.10 PERSONNEL

◉ GMP: Eating, Drinking, Tobacco

◉ **Confining** the following to areas other than where food may be exposed or where equipment or utensils are washed: **eating** food, **chewing gum**, **drinking** beverages, or using **tobacco**



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### 21 CFR PART 110.10 PERSONNEL

◉ GMP: Eating, Drinking, Tobacco

◉ **Effective GMP:**

- Defined areas - not just "outside"
- Close enough to various workstations to promote use
- Determine if more than 1 area needs to be designated for these activities
- Determine how the employees are to get their personal item (food, drink, tobacco) to this area
- Provide drinking fountains
- Provide adequate breaks



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### 21 CFR PART 110.10 PERSONNEL

◉ GMP: Education and Training

◉ Personnel responsible for identifying **sanitation** failures or **food contamination** should have a background of **education and experience**, or a combination thereof, to provide a level of **competency** necessary for production of clean and safe food. **Food handlers** and **supervisors** should receive **appropriate training** in proper food handling techniques and food-protection.



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Education and Training
- ◉ Effective GMP
  - Include responsibility for identifying failures in job description and competency evaluations
  - Provide adequate training
    - ◉ Training by professional trainers
    - ◉ Training by food safety experts
  - Ongoing training
    - ◉ Weekly activities
  - Training in the employees' preferred language



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Supervision
  
- ◉ Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel



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### 21 CFR PART 110.10 PERSONNEL

- ◉ GMP: Supervision
  
- ◉ Effective GMP:
  - List the responsibility in job description
  - Include in performance evaluation/ competency review



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### 21 CFR PART 110.20 PLANT & GROUNDS

- GMP: Grounds
- The grounds around a food plant...shall be kept in a condition that will protect against the contamination of food
  - Properly storing equipment
  - Removing litter and waste
  - Cutting weeds or grass
  - Structures that constitute a pest attractant, breeding place, or harborage for pests
  - Maintaining roads, yards and parking lots
  - Adequate draining areas that may contaminate food by seepage, foot-borne filth, or provide a breeding place for pests



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### 21 CFR PART 110.20 PLANT & GROUNDS

- GMP: Grounds
- Effective GMPs
  - Designated equipment storage area - away from building
  - Pave premises
  - Include grounds and waste collection equipment on Cleaning Schedule



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### 21 CFR PART 110.20 PLANT & GROUNDS

- GMP: Plant Construction and Design
- Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations
  - Sufficient space
  - Separate of operations in which contamination is likely to occur
  - Floors, walls, and ceilings may be adequately cleaned
  - Adequate lighting / safety-type glass
  - Adequate ventilation
  - Locate fans in a manner that minimizes potential for contamination



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## 21 CFR PART 110.20 PLANT & GROUNDS

- ◉ GMP: Plant Construction and Design
- ◉ Effective GMP:
  - Don't purchase any light bulbs that aren't coated
    - End caps get left off
    - Sleeves get burned
    - "Office use only" lights get used in production
  - Install physical barriers and define traffic routes
    - Raw Product / Finished Product
    - Allergens / Non-Allergens
  - Establish ventilation so that portable fans and open (screened) doors don't need to be used



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## 21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: General Maintenance
- ◉ Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from being adulterated. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food.



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## 21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: General Maintenance
- ◉ Effective GMP:
  - All areas of the plant, including walls/floors/ceilings are on the cleaning schedule
  - Designated areas/ rooms for cleaning of utensils and portable equipment
  - No cleaning of a line while an adjacent line is running/ Or use of curtains between a line in operation and a line being cleaned



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21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: Cleaning/ Sanitizing Substances
- ◉ Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.



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21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: Cleaning/ Sanitizing Substances
- ◉ Effective GMP:
  - Dedicated chemical supplier
  - No store-bought chemicals
  - Segregation of janitorial vs. plant sanitation chemicals
  - If pesticides are stored on-site, have designated out-building
  - Lock chemicals so that only trained personnel have access



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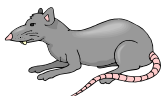
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21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: Pest Control
- ◉ Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by the pests.



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21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: Pest Control
- ◉ Effective GMP:
  - Understand that the majority of Pest Control is not the responsibility of the Pest Control Technician
  - Pest Control is
    - Barriers to prevent entrance to plant
      - Keep doors closed or screened
      - Air curtains/ fly fans
    - Sanitation on the interior and exterior
    - Eliminate harborage and pest attraction
      - Do not place insect lights where they can be seen from outside
      - Minimize vegetation and standing water on the grounds
    - Inspect items (pallets, equipment) stored outside before bringing them into the plant



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21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: Sanitation of Food Contact Surfaces
- ◉ All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.



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21 CFR PART 110.35 SANITARY OPERATIONS

- ◉ GMP: Sanitation of Food Contact Surfaces
- ◉ Effective GMP:
  - Master Cleaning Schedule
    - All equipment
    - Disassembly instructions
    - Specialized procedures
      - Allergen changeover
      - Flavor changeover
      - Highly viscous product



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**21 CFR PART 110.37 SANITARY FACILITIES & CONTROLS**

- GMP: Hand-washing Facilities
- Hand-washing facilities shall be adequate and convenient and furnished with running water at a suitable temperature.
  - Effective hand-cleaning and sanitizing preparations
  - Sanitary towel or suitable drying device
  - Fixtures designed to protect against recontamination of clean, sanitized hands



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**21 CFR PART 110.37 SANITARY FACILITIES & CONTROLS**

- GMP: Hand-washing Facilities
- Effective GMP:
  - Avoid depletion
    - More than one towel dispenser
    - More than one soap dispenser
  - Confirm that water temperatures can be maintained at heavy use times (shift change)
  - Hands-free operation



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**21 CFR PART 110.37 SANITARY FACILITIES & CONTROLS**

- GMP: Rubbish and Offal
- Rubbish and any offal shall be so 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, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.



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### 21 CFR PART 110.37 SANITARY FACILITIES & CONTROLS

- GMP: Rubbish and Offal
- Effective GMP:
  - Ensure trash cans are on Cleaning Schedule
  - Identify traffic routes from removal of waste
    - Avoid taking waste from support areas (restrooms, break areas) through production areas
    - Avoid taking raw waste through finished goods areas



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### 21 CFR PART 110.40 EQUIPMENT & UTENSILS

- GMP: Equipment and Utensil Design
- All plant equipment and utensils shall be so designed and of such material and workmanship as to adequately cleanable, and shall be properly maintained.
- The design, construction, and use shall preclude the adulteration of food.



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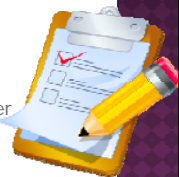
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### 21 CFR PART 110.40 EQUIPMENT & UTENSILS

- GMP: Equipment and Utensil Design
- Effective GMP:
  - New equipment approval checklist
    - Includes review by Maintenance, Sanitation, HACCP Team
  - Temporary repair policy
    - -Readily available suitable materials
  - Correct utensils and tools
  - Adequate supply of utensils and tools
  - Modify disassembly to make easier/ faster



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**21 CFR PART 110.80 PROCESSES & CONTROLS**

- GMP: Processes and Controls
  
- All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles.
  
- All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source.



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**21 CFR PART 110.80 PROCESSES & CONTROLS**

- GMP: Processes and Controls
- Effective GMP:
  - Self - Inspection Program
    - Pre-operational inspections
    - Changeover inspections
    - Post maintenance inspections
    - Vehicle inspections
    - Metal-to-Metal Inspection
  - Self-Audit Program
    - Do procedures adequately address sanitation and adulteration concerns?
    - Are procedures understood and followed?
    - Are desired results obtained?



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**21 CFR PART 110.80 PROCESSES & CONTROLS**

- GMP: Manufacturing Operations
- All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.



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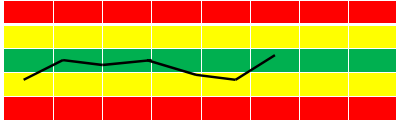
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## 21 CFR PART 110.80 PROCESSES & CONTROLS

- GMP: Manufacturing Operations
- Effective GMP:
  - Formal Process Control Program
  - Similar to HACCP
  - Identify
    - Operating limits
    - Monitoring of the process
    - Corrective actions for exceeded limits
    - Documentation



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## EFFECTIVE GMP'S

- When there is a failure
  - Determine root cause
  - 5 Why's
  - How can the system be changed to improve chances of success?
- You know WHAT needs to be done
- Strategize on HOW it will be accomplished



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## EFFECTIVE GOOD MANUFACTURING PRACTICES

Thank You



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