Good Manufacturing Practice (GMP)

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TRADITIONAL FOOD IN COMBATING FOODBORNE PATHOGENS 2011
World Food Programme

“Food quality control is necessary to ensure that food aid supplies are safe, of good quality and available in adequate amounts, in time, at affordable prices to ensure an acceptable nutritional and health status for all population groups”

- Food Quality Systems - HACCP, GMP, ISO & Codex Alimentarius
Terms

- GMP (Good Manufacturing Practice) is a system to ensure that products meet food safety, quality and legal requirements.
- HACCP (Hazard Analysis and Critical Control Point) can be part of GMP and is a systematic program to assure food safety.
GMP video

http://www.youtube.com/watch?v=4wTIP-q2-sw
GMP

- Water
- Facilities for personal hygiene
- Air quality and ventilation
- Lighting
- Storage
- Operation controls
- Time and temperature control
- Cross contamination
- Raw materials
- Packaging

- Product information
- Traceability
- Pest control
- Personal hygiene
  - No blower!
- Transportation
- Training
- Food marketing
- Food services
- Verification
GMP

- GMP contains ten principles that introduces employees to critical behaviors established by FDA and industry leaders to maintain good manufacturing practices in plants.
Ten GMP Principles

1. Writing procedures
2. Following written procedures
3. Documenting for traceability
4. Designing facilities and equipment
5. Maintaining facilities and equipment
6. Validating work
7. Job competence
8. Cleanliness
9. Component control
10. Auditing for compliance
HACCP

- HACCP is an acronym for *Hazard Analysis and Critical Control Point*
- Food safety program
- Developed in 1960s for NASA
  - To ensure the safety of food products that were to be used by the astronauts in the space program.
HACCP

- A systematic process control system designed to determine potential hazards and implement control measures to reduce or eliminate the likelihood of their occurrence.

- Focus is on hazard prevention, rather than hazard detection.
HACCP

- Basically:
  - Determining the step or steps that the really serious problems occur or could occur in your production process
  - Monitoring these steps so you know there are problems
  - Fixing any problems that arise
How to make HACCP work?

- Must make the commitment
- Must let everyone get involved
- Must be able to document all production steps
- Must be able to monitor ... simple / validate
Prerequisite Programs

- Applicable to the overall manufacturing environment
- Includes Good Manufacturing Practices
- Foundation for an effective HACCP program
Prerequisite Programs

- Prerequisite programs to have in place before starting HACCP
  - Procedures, including GMPs, that address operational conditions providing the foundation for the HACCP system
Examples of Common Prerequisite Programs

- Facilities
- Production equipment
- Standard operating procedures
- Supplier controls
- Production specification
- Personnel policies
- Traceability and recalls
Eight Key Sanitation Conditions and Practices:

- Safety of water
- Condition and cleanliness of food-contact surfaces
- Prevention of cross-contamination
- Maintenance of hand-washing, hand-sanitizing and toilet facilities
- Protection from adulterants
- Labeling, storage and use of toxic compounds
- Employee health conditions
- Exclusion of pests
HACCP process 1

Preliminary Steps:

- Task 1 - Establish a HACCP team
- Task 2 - Describe the product
- Task 3 - Identify the product's intended use
- Task 4 - Draw up the commodity flow diagram
- Task 5 - On site confirmation of flow diagram
Basic Flow Diagram Example

Incoming materials → Processing → Packaging → Storage → Distribution
HACCP process 2

- Task 6 - Identify and analyse hazard(s) - (Principle 1)
- Task 7 - Determine the critical control points (ccps) - (Principle 2).
- Task 8 - Establish critical limits for each ccp - (Principle 3)
- Task 9 - Establish a monitoring procedure - (Principle 4)
- Task 10 - Establish corrective action - (Principle 5)
- Task 11 - Verify the HACCP plan - (Principle 6)
- Task 12 - Keep record - (Principle 7)
1. Conduct a Hazard Analysis

- Hazard identification
- Hazard evaluation
  - Likelihood of occurrence
  - Severity

- Safety concerns must be differentiated from quality concerns.
Hazard Identification

- List potential hazards at each operational step in the process from receipt of raw materials through release of the finished product

- All potentially significant hazards must be considered
Hazards List

- **Biological Hazards**
  - Pathogenic microorganisms (e.g., bacteria, viruses)
  - Parasites

- **Chemical Hazards**
  - Natural toxins
  - Chemicals
  - Pesticides
  - Drug residues
  - Unapproved food and color additives
  - Decomposition (safety only, e.g., histamine)

- **Physical Hazards**
  - Metal, glass, etc.
Hazard Analysis

A hazard must be controlled if it is:
- Reasonably likely to occur, and
- Likely to result in an unacceptable risk to consumers

e.g., *Listeria monocytogenes* in ready-to-eat food
Control Measures

- Actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level

- Bacterial Hazards
  - Time/temperature control
  - Heating and cooking processes
  - Cooling and freezing
  - Fermentation and/or pH control
  - Addition of salt or other preservatives
  - Drying
  - Source control
2. Determine the Critical Control Points

- A point, step or procedure at which control can be applied and is essential to prevent or eliminate a food-safety hazard or reduce it to an acceptable level
Control Point

- Any point, step or procedure at which biological, physical or chemical factors can be controlled
CCPs vs. Control Points

- **Control Points**
  - Points where quality factors can be controlled
  - Points where non-HACCP regulatory requirements can be controlled

- **CCPs**
  - Points where food-safety hazards can be controlled
CCPs are product- and process specific

They may change with differences in:

- Plant layout
- Formulation
- Process flow
- Equipment
- Ingredient selection
- Sanitation and support programs
CCP Decision Tree

- **Q1**: Does a control measure(s) exist at this step or subsequent steps in the process flow for the identified hazard?

- **Q2**: Does this step eliminate or reduce the likely occurrence of a significant hazard to an acceptable level?

- **Q3**: Could contamination with an identified hazard or hazards occur in excess of acceptable levels, or could these increase to unacceptable levels?

- **Q4**: Will a subsequent step eliminate the identified hazard(s) or reduce the likely occurrence to an acceptable level?
3. Establish Critical Limits

- Critical Limit
  - A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level, the occurrence of a food-safety hazard.
Options for Controlling Hazards

- Often a variety of options exist for controlling a particular hazard
- The selection of the best control option and critical limit is often driven by practicality and experience
4. Critical Control Point Monitoring

- To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification
Purpose of Monitoring

- To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments
- To identify when there is loss of control (a deviation occurs at a CCP), and
- To provide written documentation of the process control system
Monitoring

- **What**: Usually a measurement or observation to assess if the CCP is operating within the critical limit.
- **How**: Usually physical or chemical measurements (for quantitative critical limits) or observations (for qualitative critical limits). Needs to be real-time and accurate.
- **When (frequency)**: Can be continuous or intermittent.
- **Who**: Someone trained to perform the specific monitoring activity.
What will be Monitored?

- Measuring a characteristic of a product or process to determine compliance with a critical limit
  - Cold-storage temperature
  - pH of an acidifying ingredient
  - Line speed
Monitoring

- Must provide rapid results
  - Microbiological testing is seldom effective
- Physical and chemical measurements are preferred monitoring methods
  - Time and temperature
  - Water activity
  - Acidity (pH)
  - Sensory examination
Monitoring

- Examples of monitoring equipment
  - Thermometers
  - Clocks
  - pH meters
  - Water activity meters
Continuous monitoring is preferred:

- Continuous monitoring procedures:
  - Temperature recording chart
  - Metal detector
  - Dud detector
- Continuous records need to be observed periodically
**Monitoring Frequency**

Non-continuous Monitoring:
- Non-continuous monitoring must be used when continuous monitoring is not possible.
- Frequency of non-continuous monitoring:
  - How much does the process normally vary?
  - How close are normal values to the critical limit?
  - How much product is the processor prepared to risk if the critical limit is exceeded?
Who will Monitor?

Those responsible for monitoring should:

- Be trained in CCP monitoring techniques
- Fully understand the importance of CCP monitoring
- Have ready access to the monitoring activity
- Accurately report each monitoring activity
- Immediately report critical limit infractions so that immediate corrective actions can be taken
5. Establish Corrective Actions

- Procedures to be followed when a deviation occurs

- Options Include:
  - Isolating and holding product for safety evaluation
  - Diverting the affected product or ingredients to another line where deviation would not be considered critical
  - Reprocessing
  - Destroying product
Corrective Action Components

- To correct and eliminate the cause of the deviation and restore process control
  - Bring CCP back under control
  - Determine cause of deviation to prevent future recurrence
- To identify the product that was produced during the process deviation and determine its disposition
6. Establish Verification Procedures

Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan.
“Only marked is done”

- Verification provides a level of confidence that the HACCP plan:
  - is based on solid scientific principles,
  - is adequate to control the hazards associated with the product and process, and
  - is being followed
Elements of Verification

- Validation
- CCP verification activities
  - Calibration of monitoring devices
  - Calibration record review
  - Targeted sampling and testing
  - CCP record review
- HACCP system verification
  - Observations and reviews
  - Microbiological end-product testing
- Regulatory agencies
Validation

- The element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards

- Who validates the HACCP plan?
  - HACCP team
  - Individual qualified by training or experience

- What does validation involve?
  - A scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy
Validation Frequency

- Initially
- When factors warrant, e.g.,
  - Changes in raw materials
  - Changes in product or process
  - Adverse review findings
  - Recurring deviations
  - New information on hazards or control measures
  - On-line observations
  - New distribution or consumer handling practices
Verification of CCPs

- Calibration
- Calibration record review
- Targeted sampling and testing
- CCP record review
HACCP System Verification

- Determines if the HACCP plan is being followed
- Annually
- Occurrence of a system failure or significant change in product or process
Verification Activities of the HACCP System

- Check the accuracy of the product description and flow chart
- Check that CCPs are monitored as required by the HACCP plan
- Check that processes are operating within established critical limits
- Check that records are completed accurately and at the time intervals required
Verification Procedures by an Agency Include:

- Review of the HACCP plan and any modification
- Review of CCP monitoring records
- Review of corrective action records
- Review of verification records
- Visual inspection of operations to determine if the HACCP plan is followed and records are properly maintained
- Random sample collection and analysis
7. Establish record-keeping and documentation procedures

Four Kinds of HACCP Records:

1. HACCP plan and support documentation used in developing the plan
2. Records of CCP monitoring
3. Records of corrective action
4. Records of verification activities
CCP Monitoring Records

- Kept to demonstrate control at CCPs
- Used to determine if critical limits have been violated
Verification Records

- Modifications of the HACCP Plan
- Audits of supplier compliance with guarantees or certifications
- Calibration records
- Microbiological tests
- In-house, on-site inspections
- Equipment evaluation tests
Record Monitoring Information

- Monitoring information should be recorded at the time the observation is made.
- Computerized records: Include controls to ensure that records are authentic, accurate and protected from unauthorized changes.
- Review: All monitoring records of critical control points shall occur within 1 week of the day the records are made.
Advantages of HACCP

- Focus on identifying and preventing hazards from contaminating food
- Based on sound science
- Permits more effective and efficient government oversight
- Places responsibility for ensuring food safety on the processor or distributor
- Helps companies compete more effectively in the marketplace
Benefits of HACCP

The main benefits of HACCP are:

- **S** aves your business money in the long run
- **A** voids you poisoning your customers
- **F** ood safety standards increase
- **E** nsures you are compliant with the law
- **F** ood quality standards increase
- **O** rganises your process to produce safe food
- **O** rganises your staff promoting teamwork and efficiency
- **D** ue diligence defence in court.

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Some links

- http://www.foodallergens.info/Manufac/GMP.html
- HACCP - Making Food Products Safe, Part 1
  - http://www.youtube.com/watch?v=7nbjd_TnU8o
- HACCP - Making Food Products Safe, Part 2
  - http://www.youtube.com/watch?v=gRJ7q_2Vkrc&feature=related