FOOD SAFETY MANAGEMENT SYSTEMS (FSMS): REQUIREMENTS FOR ANY ORGANISATION IN THE FOOD CHAIN (ISO 22000:2005)

> Dr.R.MANAVALAN, M.Pharm., Ph.D. Professor and Research Director, Department of Pharmaceutics, RVS College of Pharmaceutical Sciences, Sulur,Coimbatore-641402 Tamilnadu,India. Date: 27.10.2015 AT GMP SUMMIT 2015, HYDERABAD

Legal authorities combine food and drugs under legal control to ensure safety (condition of being protected from hazards – danger/risk) Food Any substance that people or animal eat and drink (plants absorb) to maintain life and growth.

#### **FOOD CHAIN:**

Sequence of stages in the

1. production, processing,

2. distribution, storage

3. and handling of a food and its ingredients from primary production to consumers **FOOD SAFETY HAZARD (Danger/Risk):** Biological, Chemical or physical agent, Allergens in food or condition of food cause adverse health effect( Infection-Allergy- Diarrhoea- Death) **FOOD SAFETY:** 

Concept that food will not cause hazard to the consumer

FSMS in the food chain care developed in the year 2005 called ISO 22000:2005

Revised in September 2015 (FSMS 22000:2015)

The standards ensures food safety at any stage of food chain (Food manufacturers to consumers)

Self declaration or third party certification
(Value addition)

#### HAZARD ANALYSIS:

Identification, acceptable level determination, assessment (To decide to eliminate or reduce to acceptable level) CONTROL MEASURES: Activity used to prevent or eliminate food safety hazard or reduce to accelerable level

#### MONITORING:

Conducting a planned sequence of observations or measurements to confirm **control measures** are operated as intended PRE REQUISITE PROGRAMME( PRP):

**Basic conditions and activities** necessary to maintain hygienic condition throughout food chain for production, handling of safe end products

OPERATIONAL PRP:

PRP identified by the hazard analysis **essential to control** the likelihood of producing food safety hazards in the production or in the processing environment

CRITICAL CONTROL POINT( CCP):

Steps at which, control is essential to prevent or eliminate food safety hazards or to produce to acceptable limit

#### **CORRECTION:**

Action to eliminate detected non conformity

**\* CORRECTIVE ACTION:** 

Action to eliminate the cause of detected non conformity

#### **VALIDATION:**

Obtain evidence that control measures managed by HACCP and OPRPS are capable of being effective.

#### VERIFICATION:

Confirmation by objective evidence that requirements are fulfilled

#### **INTERNATIONAL STANDARDS**

- Organization shall define scope of FSMS and safety policy
- Safety hazards are identified, evaluated and controlled
- Communicate appropriate information throughout food chain regarding safety
- Incorporate most recent information of food safety hazards
- Shall establish control over outsourced process(es)

Documentation ; SAFETY policies, **Objectives, Procedures and Records** Implementation and updating of FSMS Documents are controlled (Approve prior to use) Records Maintained and controlled as an

evidence of effective operation

- Management responsibility , policy, meeting ,statutory and legal requirements , customer requirements, management reviews, communicated and implemented at all levels, measurable objectives, FSMS planned, Responsibilities and authorities, effective communication
- Food SAFETY team leader appointed to manage team, impart training and education , system implemented, reported to top management

# Effective external communicationwithsuppliers, contractors , consumers, legalauthorities and related organizationInternal communications with personnels

- Products, new products
- Raw materials, ingredients and services
- Knowledge on food safety, hazards and control
- measures
- Complaints about food safety
- Emergency preparedness and responsibility
- Maintain procedure to manage potential
- emergency situations and accidents

#### MANAGEMENT REVIEW AT PLANNED INTERVALS

- Inputs: Follow up action from previous review, results of verification, customer feed back, external audits
- Output: Assurance of food safety, improving the effectiveness, resource needs, revision and or policies and objectives.
- Provision of resources. Human power, assistance of external experts
- Imparting competencies awareness training to personnels

Set Effective infra structure and work environment Planning and realization of safe products Stablish, implement and maintain PRP, based on statutory and regulatory requirements, customer requirements, CODEX **ALIMENTARIUS COMMISSION** principles, national international or sector standards

#### **CODEX PUBLICATIONS**

The organization shall consider the following when establishing

these programmes

a. Construction and layout of buildings and associated utilities

b. Layout premises, including work space and employee facilities

c. Supplies of air, water, energy and other utilities

d. Supporting services, including waste and sewage disposal

e. The suitability of equipment and its accessibility for cleaning,

maintenance and preventative maintenance

- f. Management of purchased materials( e.g raw Materials, ingredients, chemicals and packaging), supplies( e.g water, air, steam and ice), disposals( e.g waste and sewage) and handling of products( e.g storage and transportation) g. Measures for the prevention of cross contamination h. Cleaning and sanitizing i. Pest control j. Personnel hygiene
- k. Other aspects as appropriate

Verification of PRP(s) shall be planned and PRP(s) shall be modified as necessary. Records of verifications and modifications shall be maintained.

#### HAZARD ANALYSIS BY FOOD SAFETY TEAM

- a) **RAW MATERIALS, INGREDIENTS AND PRODUCT CONTACT MATERIAL** 
  - 1. Biological, Chemical and Physical characteristics
  - 2. Composition of formulated ingredients
  - 3. Origin
  - 4. Method of production
  - 5. Packaging and delivery methods
  - 6. Storage conditions and shelf life
  - 7. Preparation and/or handling before use or processing

8. Food safety related acceptance criteria or specifications of purchased materials and ingredients appropriate

#### b) characteristic of end product and

#### **INTENDED USE**

- 1. Product name and similar identification
- 2. Composition
- 3. Biological, Chemical and physical characteristics relevant
  - for food safety
- 4. Intended shelf life and storage conditions
- 5. Packaging
- 6. Labelling relating to food safety and or instructions for handling, preparation and usage
- 7. Methods of distribution

#### **ESTABLISHING HACCP PLAN**

- Food safety hazards to be identified and controlled at each CCP
- Control measures, critical limits established
- Monitoring procedures
- Correction and corrective action if critical limits
   exceeded
- Responsibilities and Authorities
- Record of Monitoring

#### **STANDARD ALSO ADDRESSES:**

- Validation and verification for all aspects
- Traceability system
- Control of non conformities through correction and corrective action
- Handling of potentially unsafe products
- Internal audits
- FSMS is to be continually improved and updated

# Why we should care about safe food

<u>WHO</u> estimates that foodborne and waterborne diarrheal diseases together kill 2.2 million people annually

Foodborne diseases and threats to food safety are a constantly growing public health problem.

#### What is safe and suitable food?

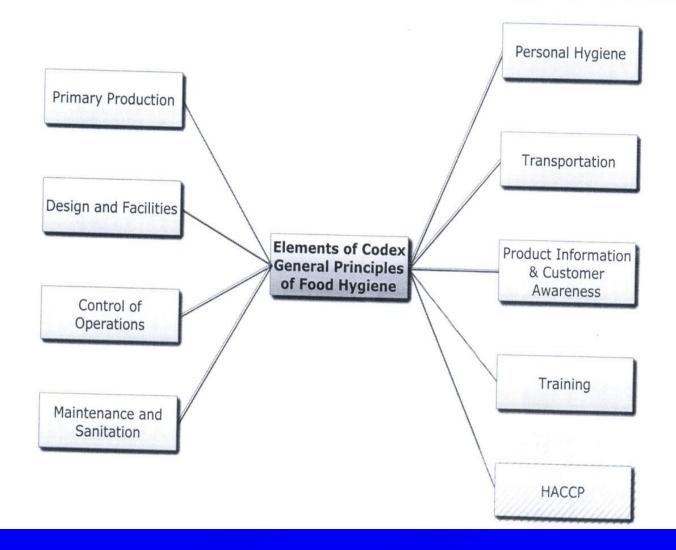
# Safe food

free from biological, chemical and physical matter that could cause illness or injury

## Suitable food

produced, prepared, and packaged according to regulatory standards, and/or specific customer requirements , or that meets a defined claim

# Codex General Principles of Food Hygiene cover all areas of concern to food safety



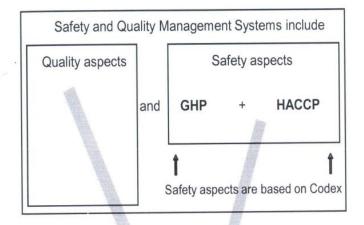
# Codes of good practice are applied in food legislation

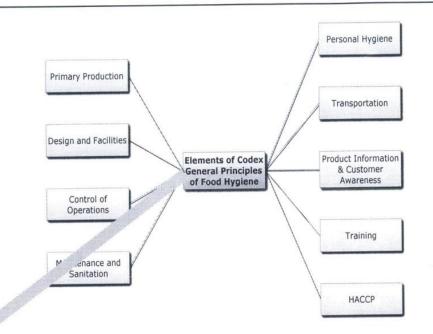


Many governments incorporate Codex guidelines and recommendations into their food legislation.

Failure to comply with the legal requirements may result in fines, closure or even jail.

# Demonstrating GMP requires documentation







Demonstrating compliance with GMP procedures requires writing down how all aspects and areas of concern are managed.

GMP Programmes are a source of collected know-how of an organization

A GMP programme provides a framework to manage food safety and for each covered production site or product should describe

- organizational structures and responsibilities,
- procedures and processes, and
- available resources.

Create a valuable internal source of know-how

# The effective use of GMP know-how is a competitive advantage

Following good practices will contribute to the economic viability of a food business by

- raising customer confidence,
- minimising risk of costly food recalls,
- creating a workforce that understands the concept of safe food production, and
- reducing waste during the whole production process

# Management must be aware of food safety risks

Management has different possibilities of assessing food safety concerns:



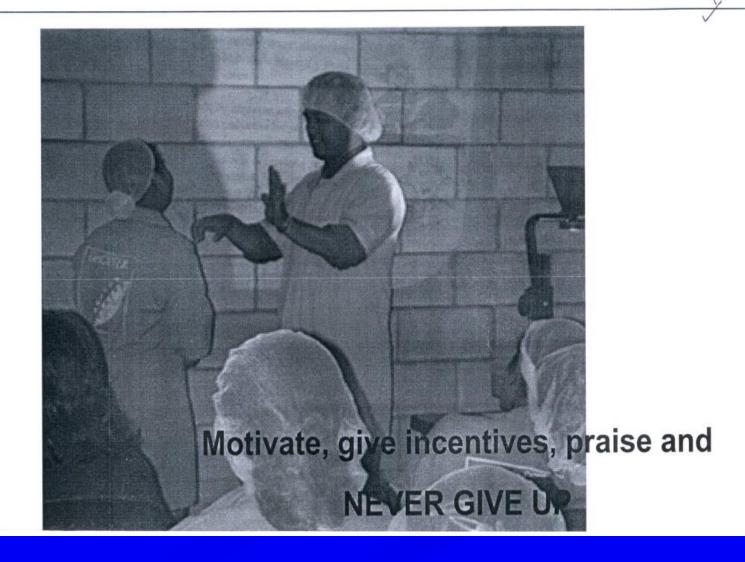
← Customer complaints

- ← Discussion with staff involved in food safety
- ← Audit feed-back
- Evaluating number of food safety mistakes made in each department

Management tools to implement a standard of food safety

- Written and oral communication
- Authority to personnel
- End-of-year evaluation
- Audits
- Budgeting resources

### Management must promote effective training



# Introduction to Food Safety Management and GMP: Conclusions

- Foodborne diseases and threats to food safety are a growing public health problem.
- Codes of good practice cover the fundamental principles, procedures and means needed for producing safe food.
- The management of food safety and quality is demonstrated by establishing documented GMP programmes.
- Governments can consider using the <u>Codex General Principles of</u> <u>Food Hygiene</u> as a basis for their food safety policies.
- A business' commitment to food safety starts at management level.



# **THANK YOU**