Microbiological Quality Assurance
MCB 402

GB AKANNI(PhD)

WHAT IS QUALITY ASSURANCE?

- Quality assurance (QA) is the total process whereby the ***quality of laboratory reports can be guaranteed***

- Quality control (QC) part of QA, which primarily concerns the ***control of errors*** in the performance of tests and ***verification*** of test results.

QC Procedures

- All materials, equipment and procedures must be adequately controlled.
- Culture media → tested for sterility and performance
- Laboratory → standard operating procedures (SOPs).
- Pre-analytical, analytical and post-analytical stages of microbiological procedures should be incorporated in SOPs.

QC Procedures

- Laboratory → well lit and dust-free air-conditioned environment.
- Environmental conditions should be monitored.
- Supervisory and technical personnel should be well qualified.
- The laboratory should participate in external and internal quality assurance schemes.

QC vs QA

Quality Control	Quality Assurance
Focused on Product	Focused on Process
Reactive	Pro-active
Line Function	Staff Function
Finds Defects	Prevent Defects
Testing	Quality Audits

QUALITY AND CRITERIA OF SAFE FOOD

(1) ***Safety***: In food, acceptable levels of a potential pathogen or its toxin must be set

(2) ***Acceptability/shelf-life:*** levels of microorganisms $\neq$ organoleptically spoilt

(3) ***Consistency:*** Food $\rightarrow$ consistent quality in terms of safety and shelf-life.

Lab: Accuracy, Precision and reproducibility

3 Microbiological criteria for food quality

The International Commission on Microbiological Specifications for Foods (ICMSF)

(1) A ***microbiological standard*** is a criterion specified in a law or regulation.

A legal requirement that foods must meet and is enforceable by the appropriate regulatory agency

For example: **International Organization for Standardization**

NAFDAC and SON

Microbiological standard for fresh meat

European Union

Meat products	*n*	*c*	*m (CFU g^{-1})*	*M (CFU g^{-1})*
Minced meat				
Salmonella[a] absent in 10 g	5	0	-	-
E. coli[b]	5	2	50	500
S. aureus[b]	5	2	100	1000
Meat preparation				
Salmonella[a] absent in 10 g	5	0	-	-
E. coli[b]	5	2	500	5000
S. aureus[b]	5	2	500	5000
Australia and New Zealand				
Packaged cooked cured/salted meat				
Salmonella[a] absent in 25 g	5	0	-	-
L. monocytogenes[a] absent in 25 g	5	0	-	-
S. aureus[b]	5	1	100	1000
Packaged heat treated meat				
Salmonella[a] absent in 25 g	5	0	-	-
L. monocytogenes[a] absent in 25 g	5	0	-	-
Fermented not-cooked comminuted meat				
Salmonella[a] absent in 25 g	5	0	-	-
E. coli[b]	5	1	0	-
S. aureus[b]	5	1	1000	10000

3 Microbiological criteria for food quality

(2) A ***microbiological specification*** is a criterion applied in commerce.

-A contractual condition of acceptance applied by a purchaser attempting to define the microbiological quality of a product/ingredient.

- Specification Not met by supplier = rejection of the batch/lower price

e.g: Certificate of conformance or Certificate of analysis

3 Microbiological criteria for food quality

(3) A ***microbiological guideline*** is used to monitor the microbiological acceptability of a product or process.

- It differs from the standard and specification in that it is advisory rather than mandatory.

For example:

a. End-product lab testing – Monthly, Weekly or daily

b. Surface and Hand swabs

ICMSF specifications

(1) A statement of the food to which the criterion applies.

- Origin, composition, and processing
- Spoilage patterns and public health problems.

(2) A statement of the micro-organisms or toxins of concern.

- Spoilage organism and health aspects

ICMSF specifications

(3) Details of the analytical methods to be used to detect and quantify the micro-organisms/toxins.

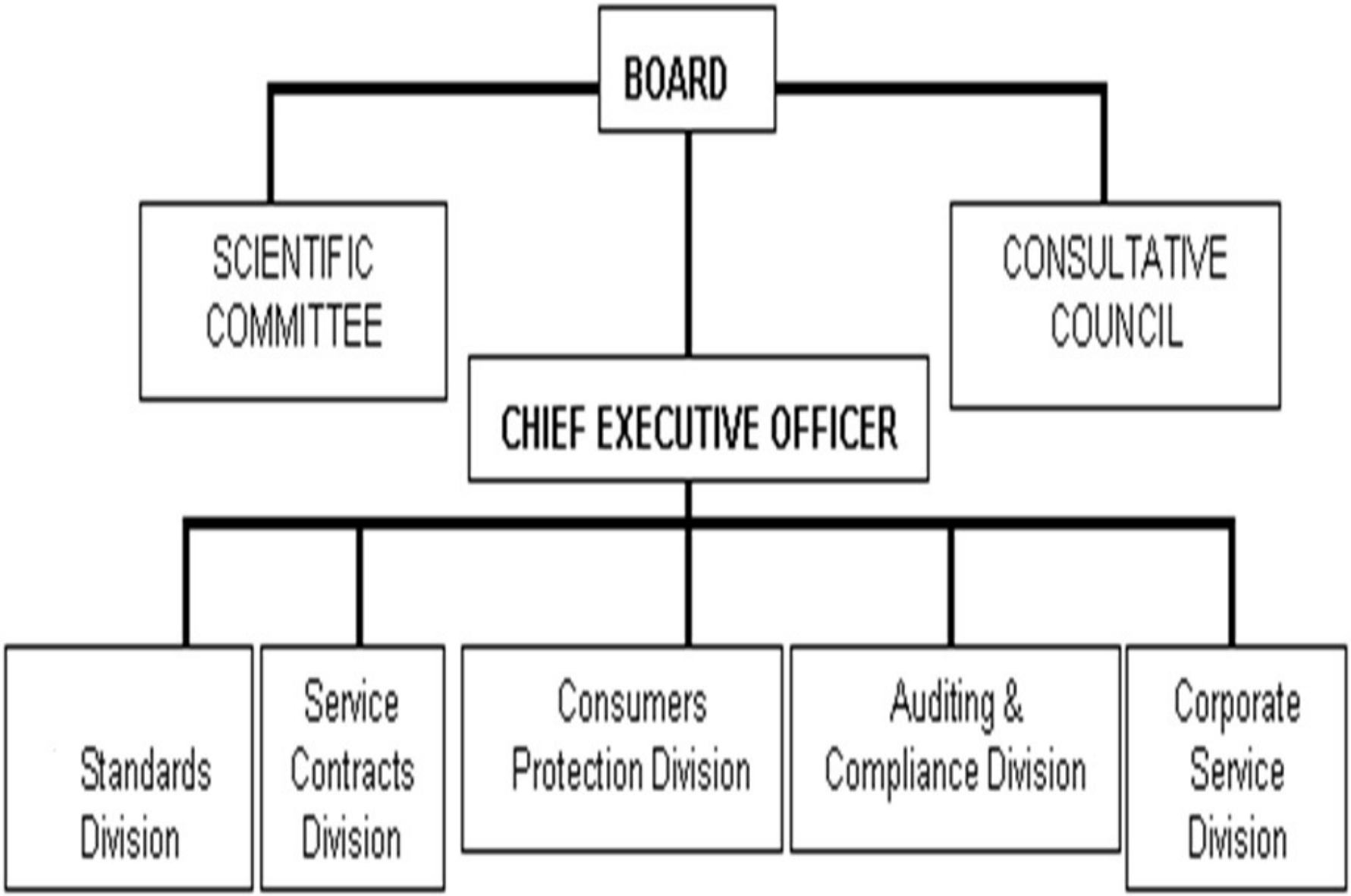
Standard methods or specifications - ISO methods

(4) The number and size of samples to be taken from a batch of food or from a source of concern such as a point in a processing line.

(5) The microbiological limits appropriate to the product and the number of sample results which must conform with these limits for the product to be acceptable

How do we achieve excellent performance in the laboratory?

Organizational structure for QA



The Quality Assurance Cycle

LABORATORY OPERATIONS

(A) Establishment and documentation of procedures and record retention

Control of Documents and Records

Documents → electronic or paper based, but the principles of document control apply to all formats.

<u>Types of Docs</u>

Policies, Processes, SOPs, Forms, and Job aids

Policy is a documented statement of the intentions or directions endorsed by management to provide efficiency and consistency

(B) Equipment qualification and maintenance

The laboratory shall have the necessary equipment to provide services

e.g general office, laboratory-specific equipment, analytical instruments, computer hardware and software

- Identifying qualified suppliers
- Approved procedures for the selection, purchase, and acquisition of equipment
- Preventive maintenance agreements for major equipment

- Reagents and supplies. The laboratory shall have written procedures for the receipt, storage, inventory control, and quality control acceptance criteria for reagents .

(C) Manage the total testing pathway

(**Process Management**)

Preanalytical → Analytical → Postanalytical

Preanalytical processes: All the steps that occur before the specimen reaches the microbiology laboratory

E.g

Specimen accessioning

Storage temperature

Processing in the laboratory.

"**Preanalytical processes are the cornerstones of valid results**"

- **Analytical processes**. The laboratory shall be responsible for selecting appropriate test methods

  4 main key activities

  - Test verification
  - Test validation,
  - Writing and reviewing SOPs,
  - Establishing the measurement of uncertainty for tests

- Postanalytical processes:

3 critical activities

- Review of the test report,
- Storage of critical samples and isolates,
- Provision for safely discarding samples and isolates when they are no longer needed

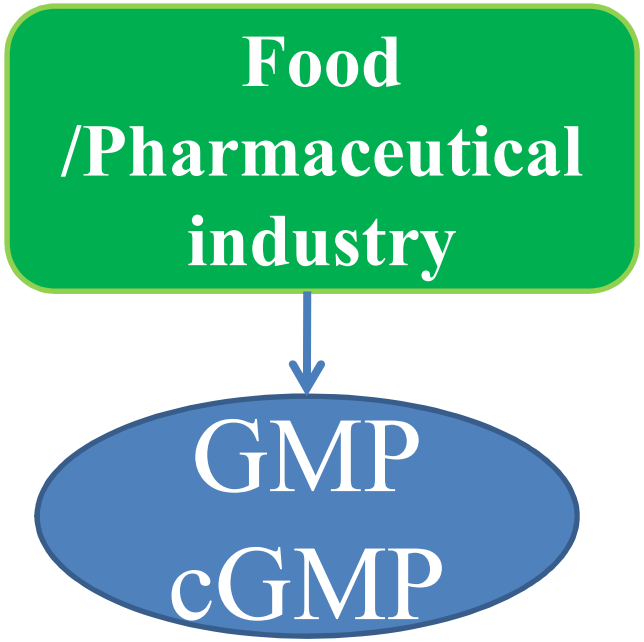
(D) Processes to manage information either electronically or manually

The laboratory produces and captures a large variety of data and information that shall be managed to ensure their ***integrity, security, and traceability***.

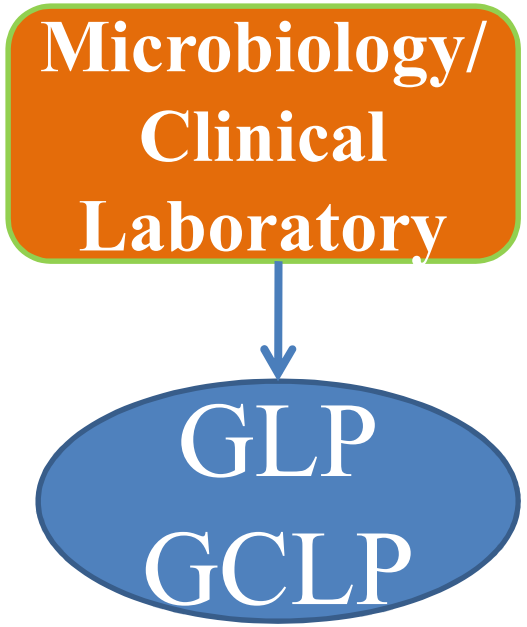
Data → instrument results, worksheets, QC results, equipment logs, epidemiological data, and many other types of data

Practical aspects: microbiological quality assurance

Practical Aspects



(current)-Good Manufacturing Practices



Good Laboratory Practices (GLP)/Good clinical laboratory practices (GCLP)

GMPs Address:

- **Environmental control (premises):**

location, design and construction of the building and its interior, equipment, water supply

- **Personnel practices:**

Personal hygiene, hand washing, clothing/footwear/headwear, injuries and wounds, evidence of illness, access and traffic patterns, chemical use

- **Receiving, handling, storage:**

Receiving of goods, storage practices; **inspection procedures** - incoming products; returned and defective products;

Allergen control; chemical storage; waste management

- **Pest control:**

Monitoring procedures for the exterior and interior of the building (eg: surveillance, fumigation) and the use of pesticides

- **Cleaning and sanitation:**

Cleaning and sanitizing procedures and pre-operational assessment

- **Equipment maintenance:**
  Preventive maintenance and calibration of all the equipment and instruments (eg: thermometers, thermocouples, metal detectors, scales, pH meters)
  • **Recall and traceability:**
  Final products - coded and labelled properly; Incoming materials - in-process and outgoing materials are traceable; recall system is in place and tested for effectiveness (mock recalls)

  • **Water safety:** water safety monitoring procedures for water, ice and steam, and water treatment procedures that ensure it is potable for use in food processing

WHY GMP IS IMPORTANT?

- Government requirement
- Ensure quality product
- Reduce rejects, recalls
- Satisfied customers
- Maintain manufacturing consistency
- Company image and reputation

GOOD CLINICAL LABORATORY PRACTICE (GCLP)

- **Organization and personnel**
  Organization Management Responsibilities:
  a) Qualified personnel, appropriate facilities, equipment and materials are available;
  b) Personnel clearly understand the job description functions to perform; provide training for these functions
  c) Health and safety precautions within the facility are applied according to national and/or international regulations;
  d) Appropriate ***standard operating procedures (SOPs)***are established and followed

- **Facilities**
  1 Trial/Clinical lab Facilities
  2 Archive lab Facilities
  3 Waste Disposal

- **Equipment, materials and reagents**
  1 Equipment
  2 Material
  3 Reagents
- **Standard operating procedures (SOPs)**
  1 General
  2 Application

- **Quality control**
- **Quality audit**
- **Storage and retention of record**
- **Traceability**
- **Confidentially**

H - Hazard

A – Analysis

C – Critical

C – Control

P – Points

History in Brief

- HACCP developed in late 1950s by a team of food scientists & engineers

  Pillsbury Company +

  Natick Research Laboratories +

  National Aeronautics and Space Administration (NASA) .

  A system ensure into the to ensure product quality & food safety for the manned space program.

- In 1971, Pillsbury presented this concept → FDA and American Public Health Association.

Pillsbury

"*come as close to **100% assurance** as possible that food products would not be contaminated with pathogens.*"

*"needed **control** over **raw materials**, **environment** and **people** as early in the system as possible…."*

Table 1.1 Overview of HACCP systems.

Date	Highlights of HACCP
1959	The Pillsbury Company develops concept for NASA
1971	US national conference on food protection (1st mention of HACCP)
1972	The Pillsbury Company in the United States began the application of its HACCP concept to the manufacture of its consumer food products
1973	The Pillsbury Company published the first HACCP text in '*Food Safety Through the Hazard Analysis and Critical Control Point System*'
1980	WHO/ICMSF report on HACCP
1983	WHO Europe recommends HACCP
1985	National Academy of Science report on HACCP
1988	Formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
1989	National Advisory Committee of Microbiological Specification for Food document endorsing HACCP approach
1990	Richmond Report advocated use of HACCP
1991	Codex HACCP draft
1992	The NACMCF system defined HACCP as 'a systematic approach to be used in food production as a means to assure food safety'
1993	EU Commission 93/43/ECC recommended use of 5 HACCP principles Codex'93 Guidelines
1995	5 HACCP principles mandatory in EU
1997	Codex Document on HACCP principles and application
1998	FAO/WHO provide guidance for regulatory assessment of HACCP
2003	FAO/WHO develop HACCP guidelines
2004	EC 852/2004 requirement for all food businesses to adopt HACCP principles in EU
2006	Legal requirements to apply HACCP in food businesses (other than primary production) across EU
2006+	Increased worldwide use of HACCP in food safety legislation

Adapted from Corlett (1998), Griffith (2006), Linton (2001), Sperber (2005).

Agenda

- Food safety
- Responsibilities
- HACCP
- Prerequisite programs
- HACCP plans
- Control measures and CCPs

Food Safety

Prevention of hazards in foods

- Physical
- Biological
- Chemical
  - Allergens

Responsibility for food safety

- Producer/grower
- Manufacturer
- Distributor
- Transporter
- Retailer
- Consumer

Farm-to-fork

Food chain

Industry Responses

- Consumer education
- HACCP and HACCP based Food safety programs for all sectors

HACCP - Answers 3 questions

Hazard
Analysis
Critical
Control
Point

- **WHAT** hazards can enter the product?
- **Where** do these hazards occur?
- **How** can we control or eliminate these hazards?

HACCP

- Science based
- Step wise process:
  - Identifies hazards
  - Installs preventative measures to eliminate or reduce hazards in foods
- **Proactive** rather than **reactive**
- Risk based

HACCP

- Does not rely on end product testing
  - hazards not be evenly distributed and can be missed in sampling
  - need to test large quantities
  - product would need to be destroyed or reworked

HACCP

- Starts from the beginning of the process
  - Receiving of ingredients, packaging
- through process steps
- to final product and shipping

Components

- Pre-requiste program
- Hazard analysis

Prerequisites

- Foundation to a HACCP program
- Includes Good Manufacturing Practices
- Addresses food safety at all stages from receiving to shipping
  - Including indirect hazards

Prerequisite program

- Premises
- Transportation and Storage
- Equipment
- Personnel/Training
- Sanitation and Pest Control
- Recall
- Allergen Control
- Supplier Quality Assurance

Premises

- Outside property and building
- Design, construction & maintenance
- Lighting
- Ventilation
- Waste disposal
- Inedible areas
- Employee & sanitary facilities
- Water/Steam/Ice

Transportation and Storage

- Food Carriers
- Temperature Controls
- Receiving and Storage
  - Incoming ingredients and packaging
  - Non-Food Chemicals
- Finished Product Storage

Equipment

- Design and installation
- Maintenance and Calibration

Personnel

- Trained for their job
- Understand food safety

Sanitation and Pest Control

- Sanitation
  - Equipment and Utensils
  - Floors
  - Locker rooms
  - Lunch rooms
  - Washrooms
- Pest control

Recall

- Product identification
- Locating product
- Returning product

Allergen control

- Identification of Allergens
- Control of allergens
  - Special handling
  - Segregate
  - Special sanitation procedures
  - Rework
  - Proper labelling

Supplier Quality Assurance

- Vendor approval process
- Product specifications
- Inspect incoming materials

Now on to the HACCP plan ….

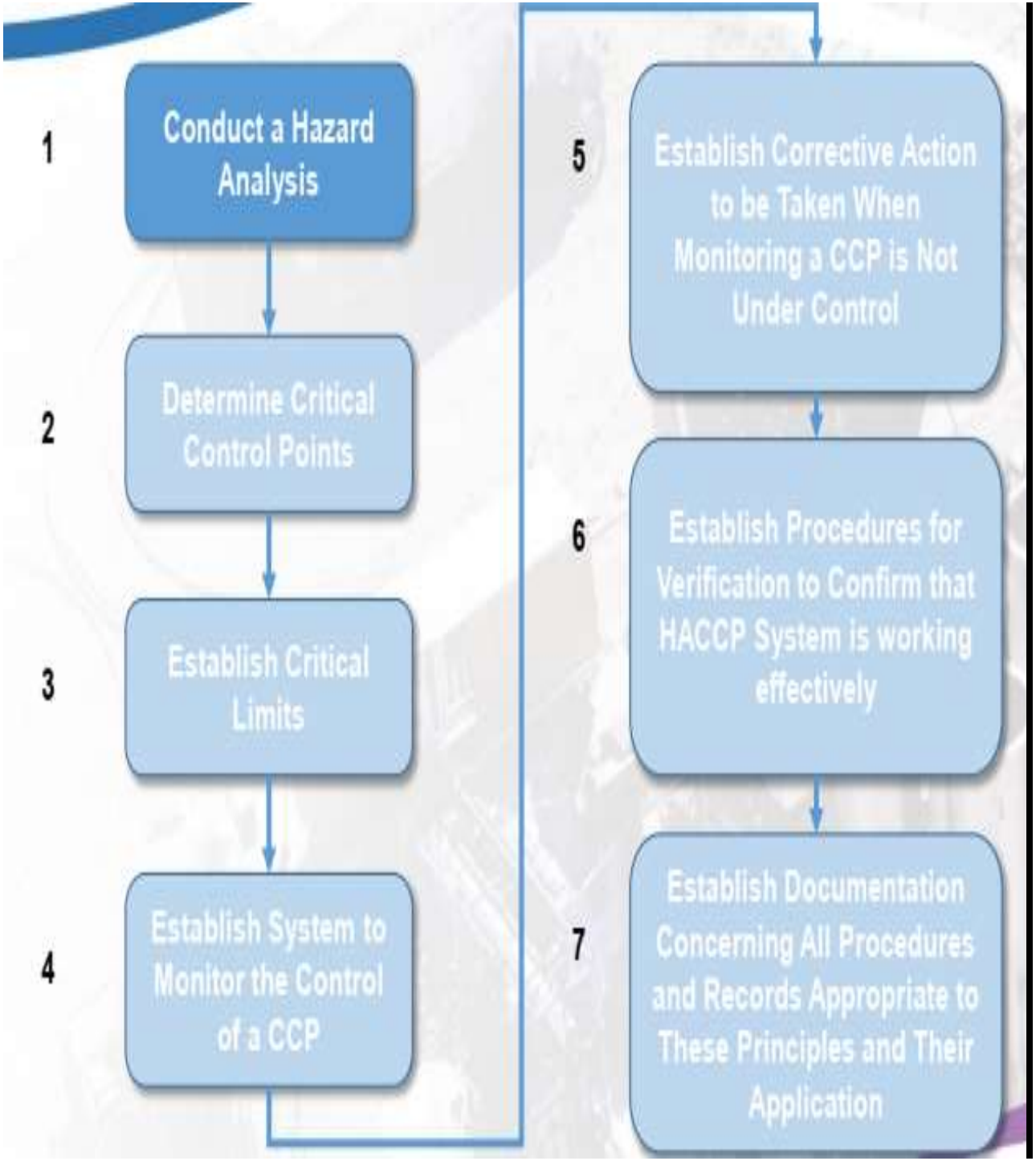
Sequence of 12 Steps (7 principles)

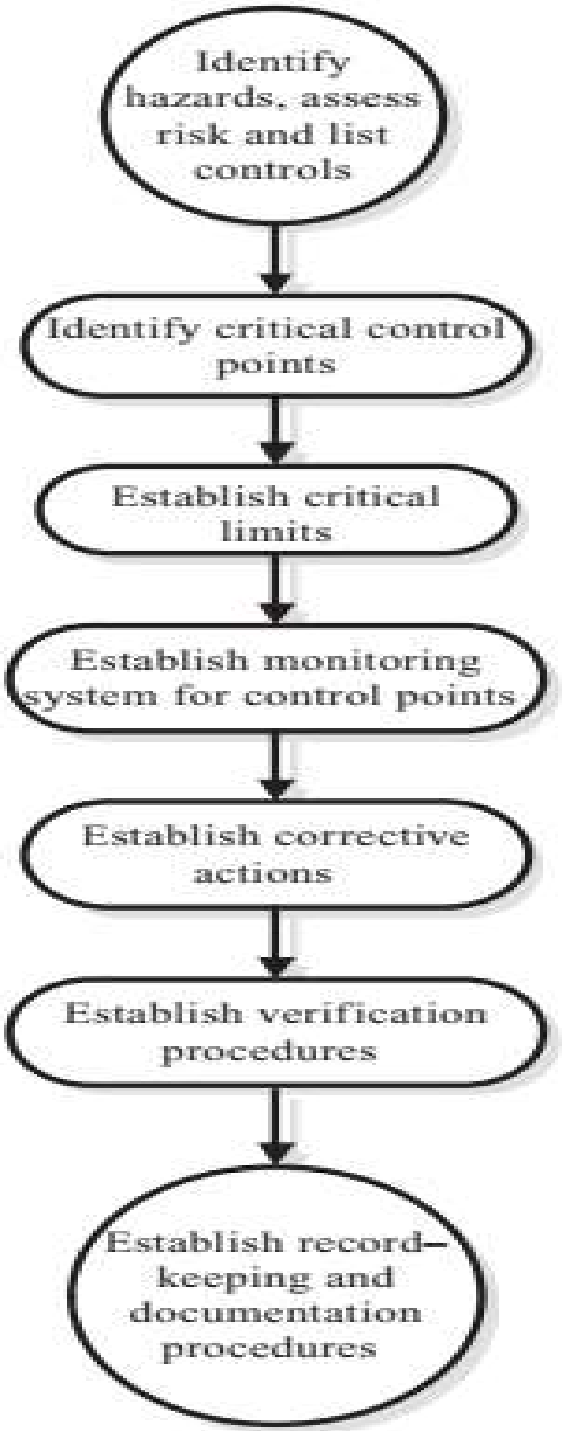
1. Assemble HACCP team
2. Describe product
3. Identity intended use
4. Construct process flow and plant schematic
5. On site verification of flow and schematic
6. List hazards associated with each process step

   (principle #1 – Conduct a hazard analysis)

Sequence of 12 steps (7 Principles)

7. Apply HACCP decision tree to determine CCP's (Principle #2 – Determine critical points)
8. Establish critical limits (Principle #3)
9. Establish monitoring procedures (Principle #4)
10. Establish deviation procedures (Principle #5 Establish corrective actions)
11. Establish verification procedures (Principle #6)
12. Establish record keeping/documentation for principles 1 - 6 (Principle #7)


1
Conduct a Hazard Analysis
2
Determine Critical Control Points
3
Establish Critical Limits
4
Establish System to Monitor the Control of a CCP
5
Establish Corrective Action to be Taken When Monitoring a CCP is Not Under Control
6
Establish Procedures for Verification to Confirm that HACCP System is working effectively
7
Establish Documentation Concerning All Procedures and Records Appropriate to These Principles and Their Application


Identify hazards, assess risk and list controls
Identify critical control points
Establish critical limits
Establish monitoring system for control points
Establish corrective actions
Establish verification procedures
Establish record–keeping and documentation procedures

HACCP team

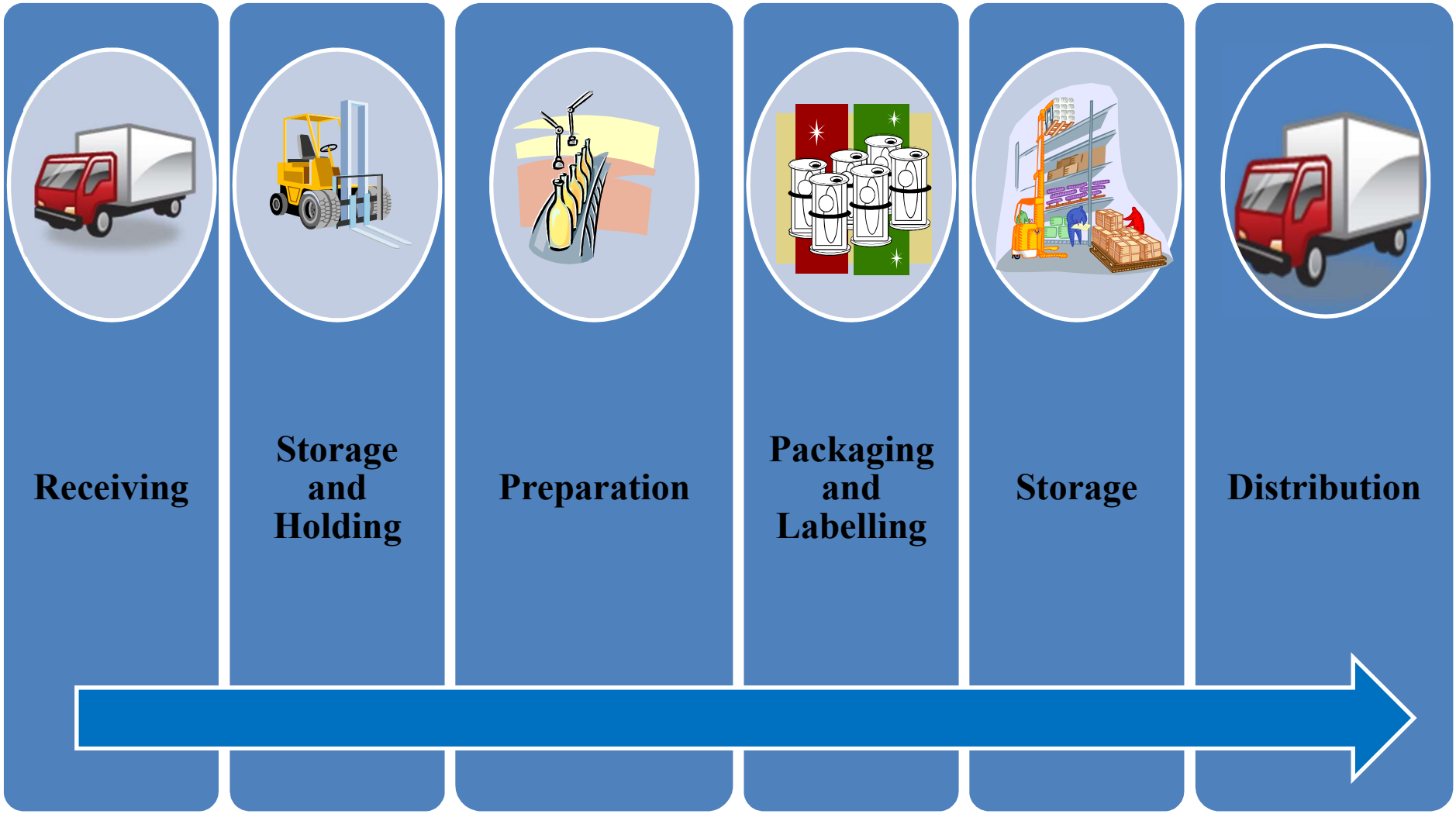
People chosen that have expertise in different areas:

- Production
- Shipping
- Quality Assurance
- Sanitation
- Maintenance
- Sales

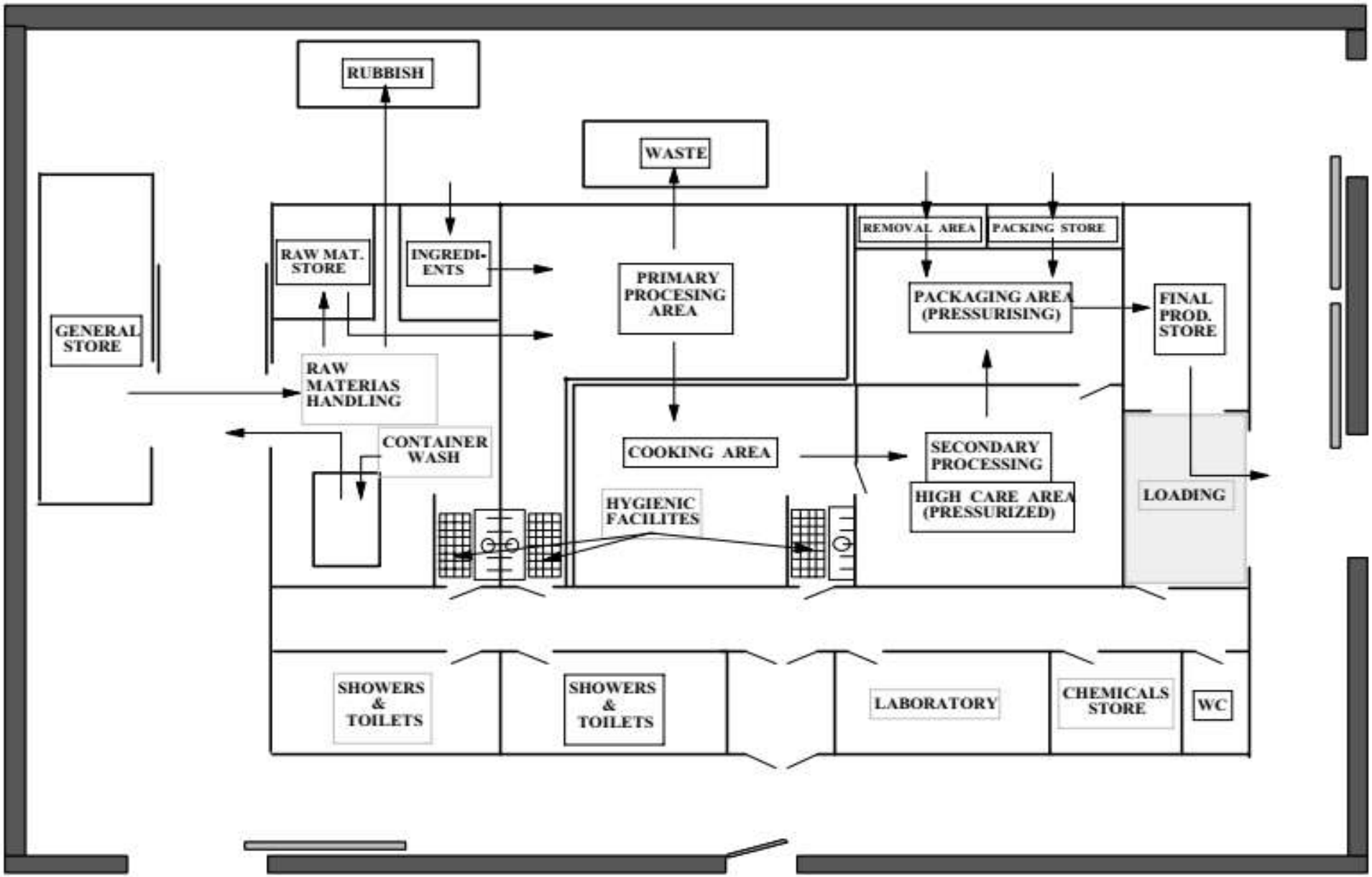
Product Description

- Product Name(s)
- Important Product Characteristics
- How it is to be used
- Packaging
- Shelf Life
- Where it will be sold (retailing conditions)
- Labelling Instructions
- Special Distribution Control
- Specific Ingredients

Define the processing steps



A simplified factory layout



Determine hazards

- Look at each input- ingredients
- Determine possible hazards
- How are they controlled?

CCPs

- Critical control points
- Place where you can prevent, remove or reduce a hazard
- if there is not step in the process that can eliminate or reduce the hazards- use labelling, cooking instructions to inform how control can be achieved

Our CCPS

- Metal detector
  - Metal is a hazard in our facility
  - Not fully controlled by any prerequisite program
  - Metal detectors specifically designed identify product containing metal
  - That product can be removed
  - No other step will remove the metal

CCPs

What is your role?

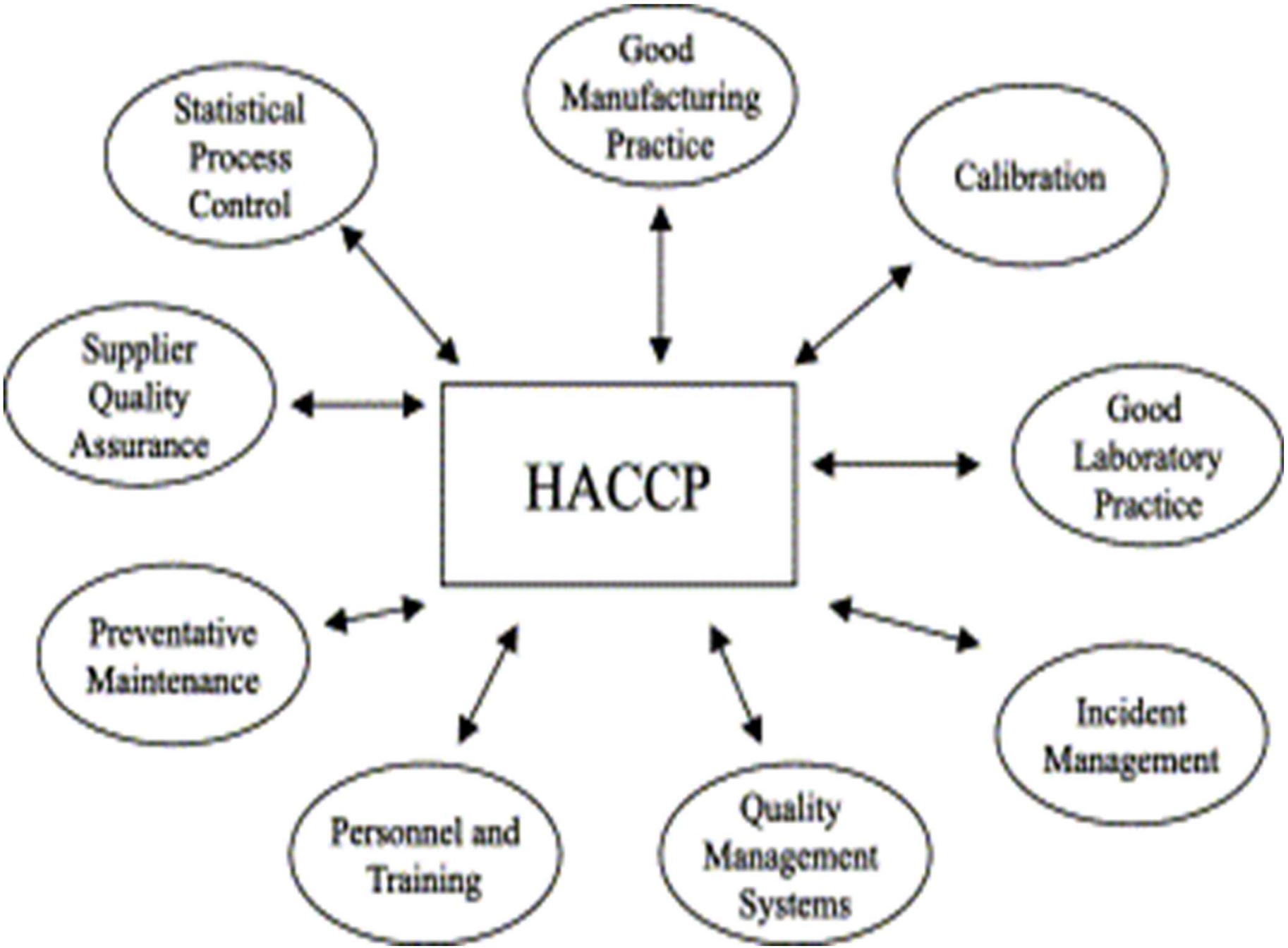
- Monitor
  - Look, smell, measure
- Record
- Corrective actions
- Verify
  - Monitor people doing activity
  - Take corrective actions when necessary
  - Complete records properly

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

- **HACCP**
  - an auto-control system which identifies, evaluates and controls hazards which are significant for food safety consistent with the HACCP principles

Identification of Critical Control Points

- A CCP is defined as a location, step or procedure at which some degree of control can be exercised over a microbial hazard
- Point where hazard can be either prevented, eliminated, or reduced to acceptable levels.
- Loss of control at a CCP would result in an unacceptable risk to the consumer or product


Statistical Process Control
Good Manufacturing Practice
Calibration
Supplier Quality Assurance
HACCP
Good Laboratory Practice
Preventative Maintenance
Incident Management
Personnel and Training
Quality Management Systems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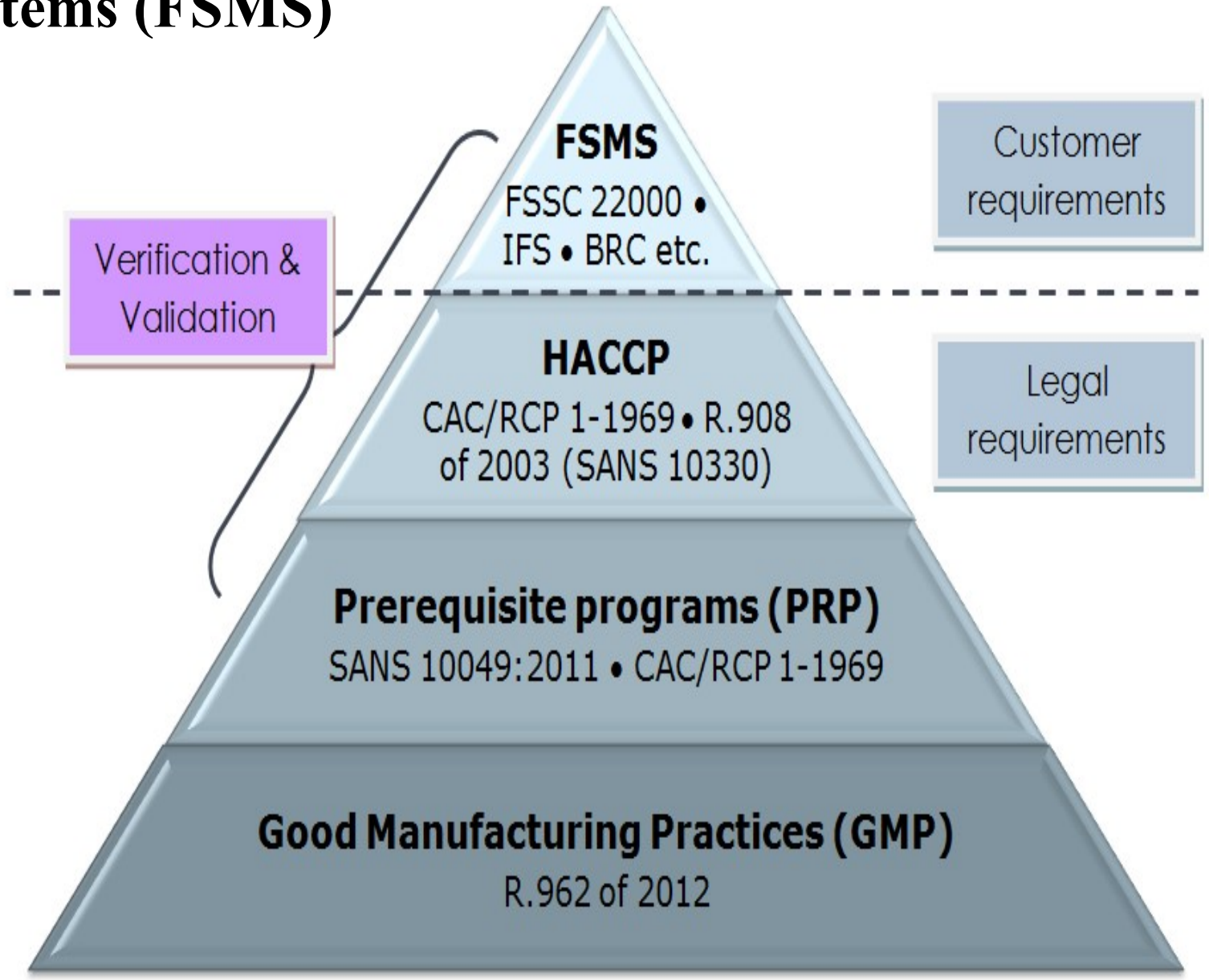
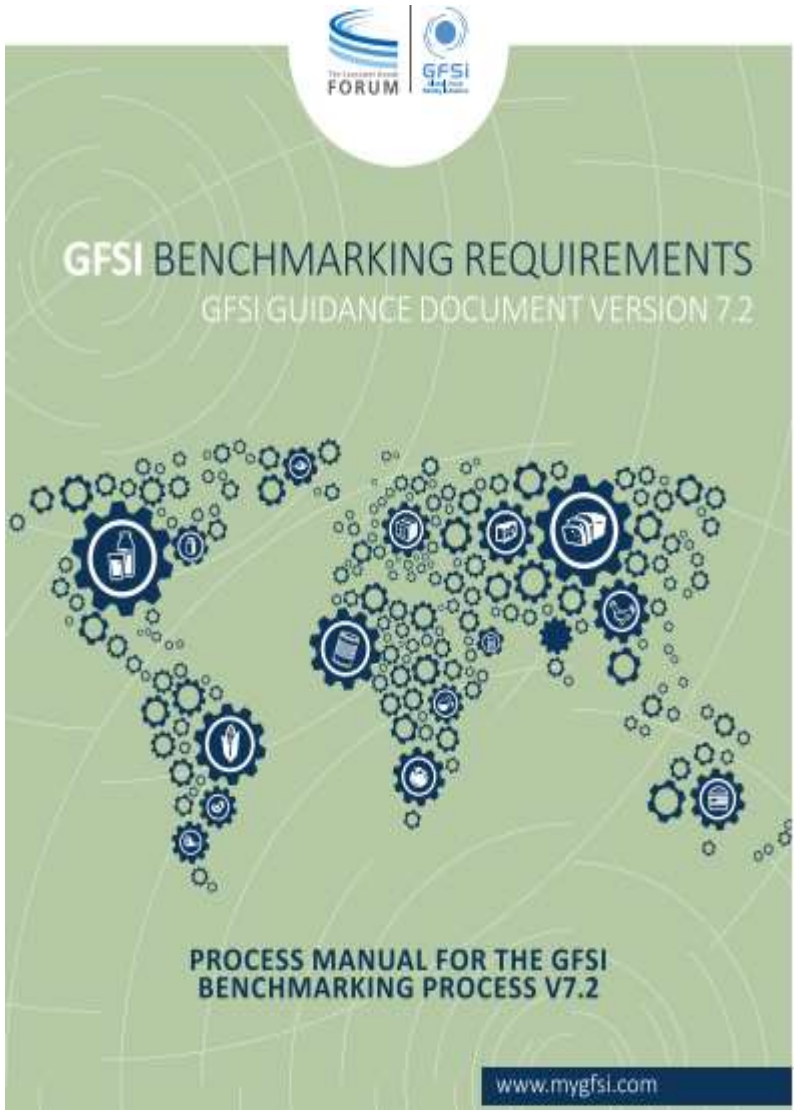
From HACCP to Food Safety Management Systems (FSMS)

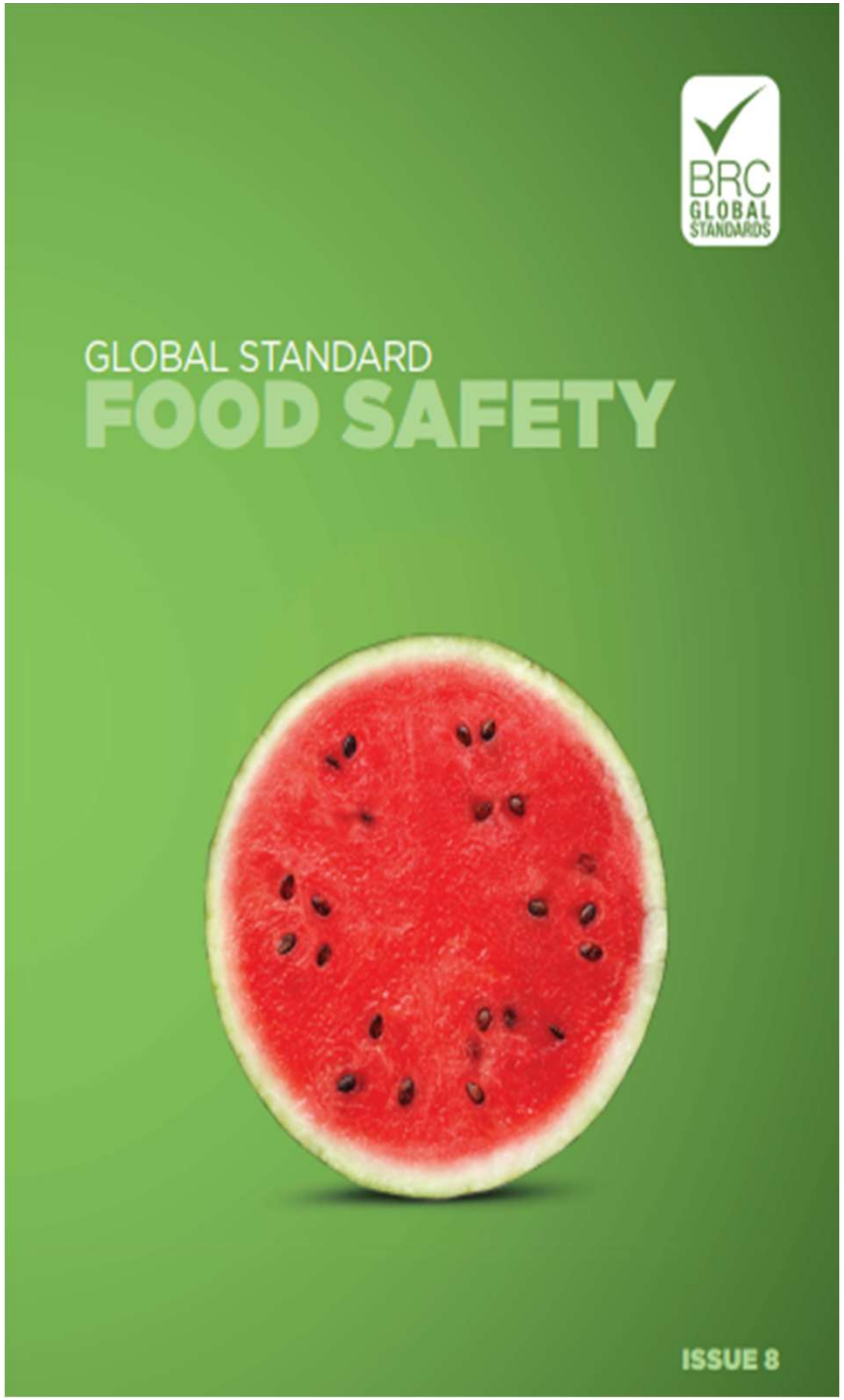


Other FS standards

- The International Featured Standard (IFS) is a **Global Food Safety Initiative (GFSI) benchmarked standard for manufacturers, wholesalers, distributors, agents and brokers**. IFS addresses food safety and management of product quality in: ... Consumer products packaging. Storage, distribution, transportation and logistics.



- The **Global Food Safety Initiative** (**GFSI**) is a private organization, established and managed by the international trade association, the Consumer Goods Forum under Belgian law in May 2000. The GFSI maintains a scheme to benchmark food safety standards for manufacturers as well as farm assurance standards.



BRC Food Safety Ensuring consumer confidence in food safety

Developed by the **British Retail Consortium (BRC),** a UK **trade** organization that represents the interests of UK retailers, the BRC's Global Standard for Food Safety was created to establish a standard for due diligence and supplier approval.

Assignment 1

Using IFS and BRC standards write the requirements by law for the following PRPs

- Personnel hygiene
- Cleaning and sanitation
- Pest control
- Allergens
- Recalls

Submission date: Thursday 21st, July 2021

Time: 12:00 am

Email: gbakanni@mtu.edu.ng

From HACCP to HARPC

- Hazard Analysis and Risk-based Preventative controls (HARPC)

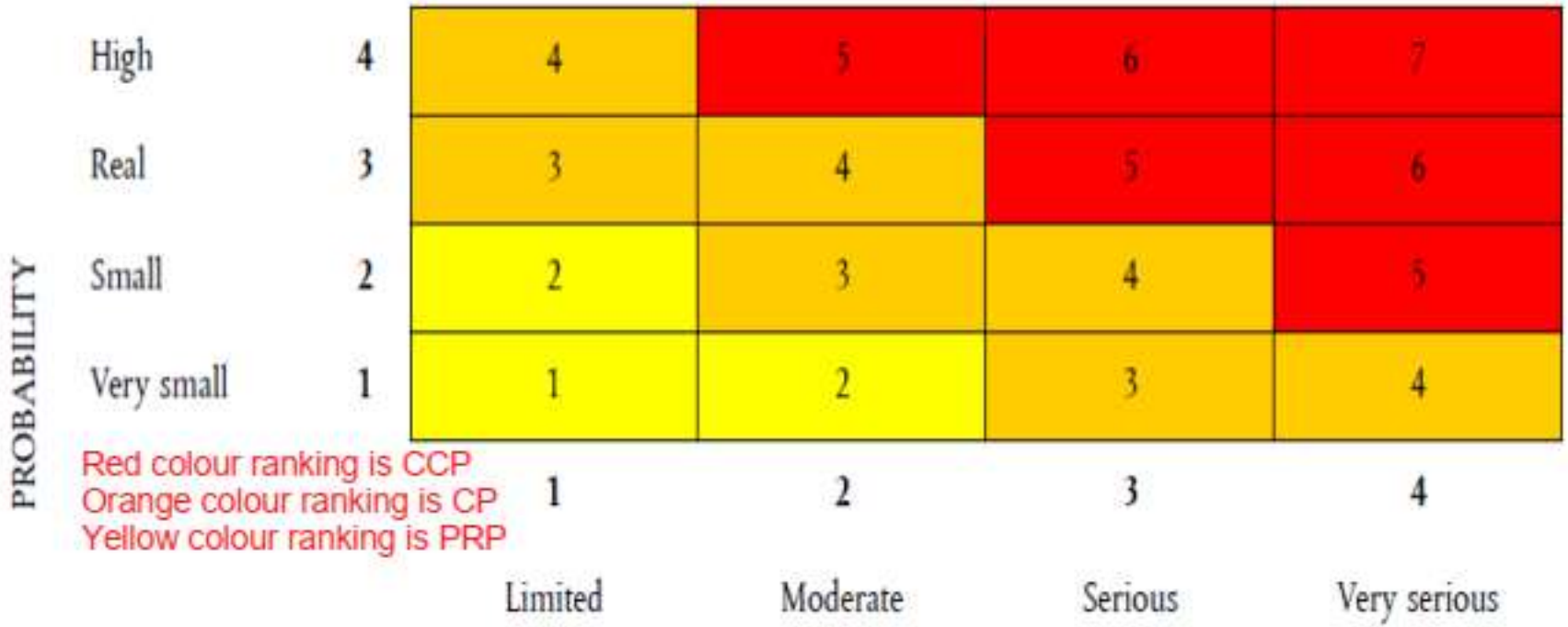
- FSMA – Food Safety Modernisation Act (USA)

Risk based Analysis

Risk = probability x effect

Scale from 1 to 7

RISK LEVEL (R = P x E): SCALE 1 TO 7

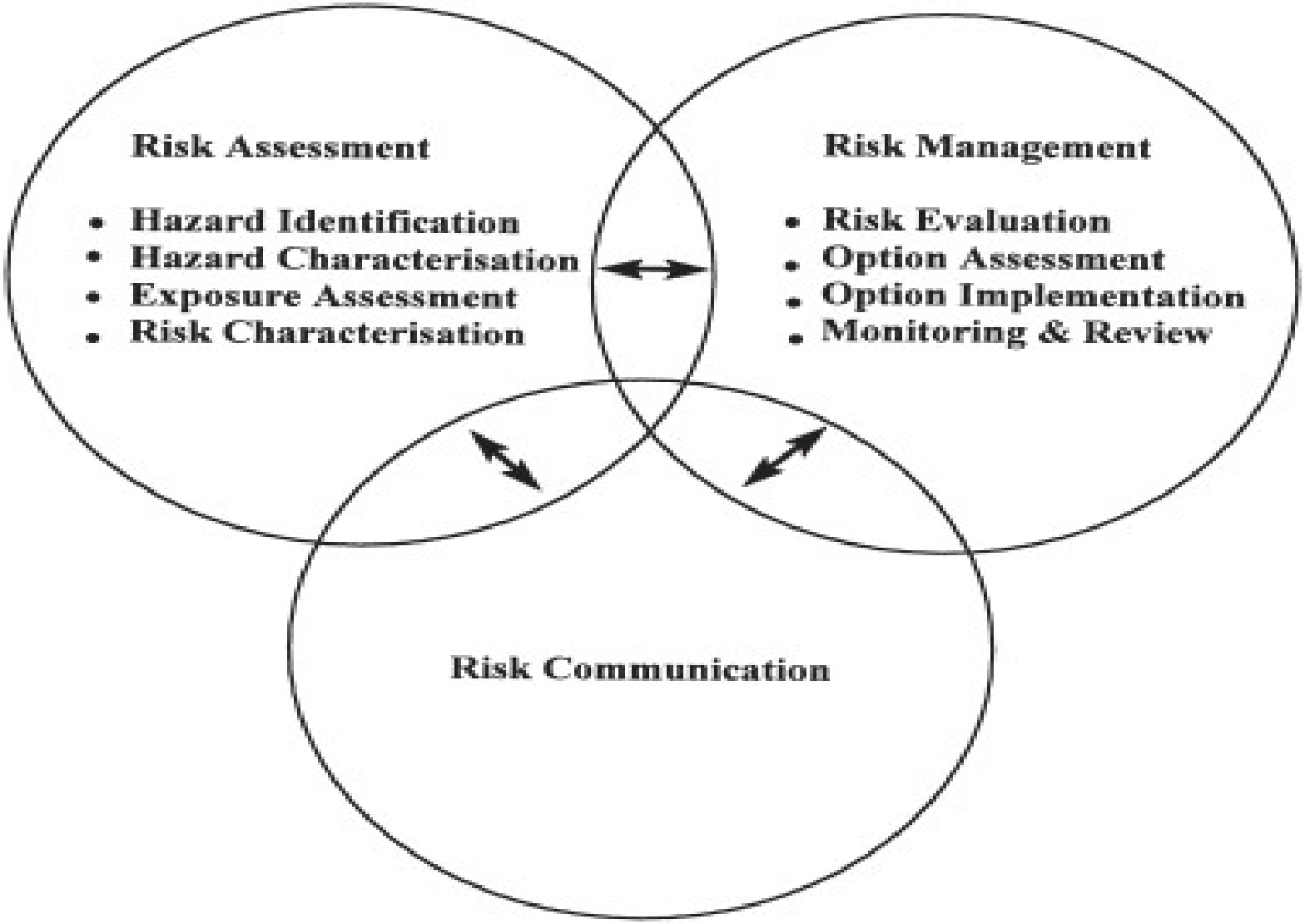


Risk assessment

- Risk assessment is the scientific component of an overall system known as risk analysis

- Risk assessment provides a quantitative estimate of the probability of occurrence and the severity of adverse health effects resulting from human exposure to foodborne disease

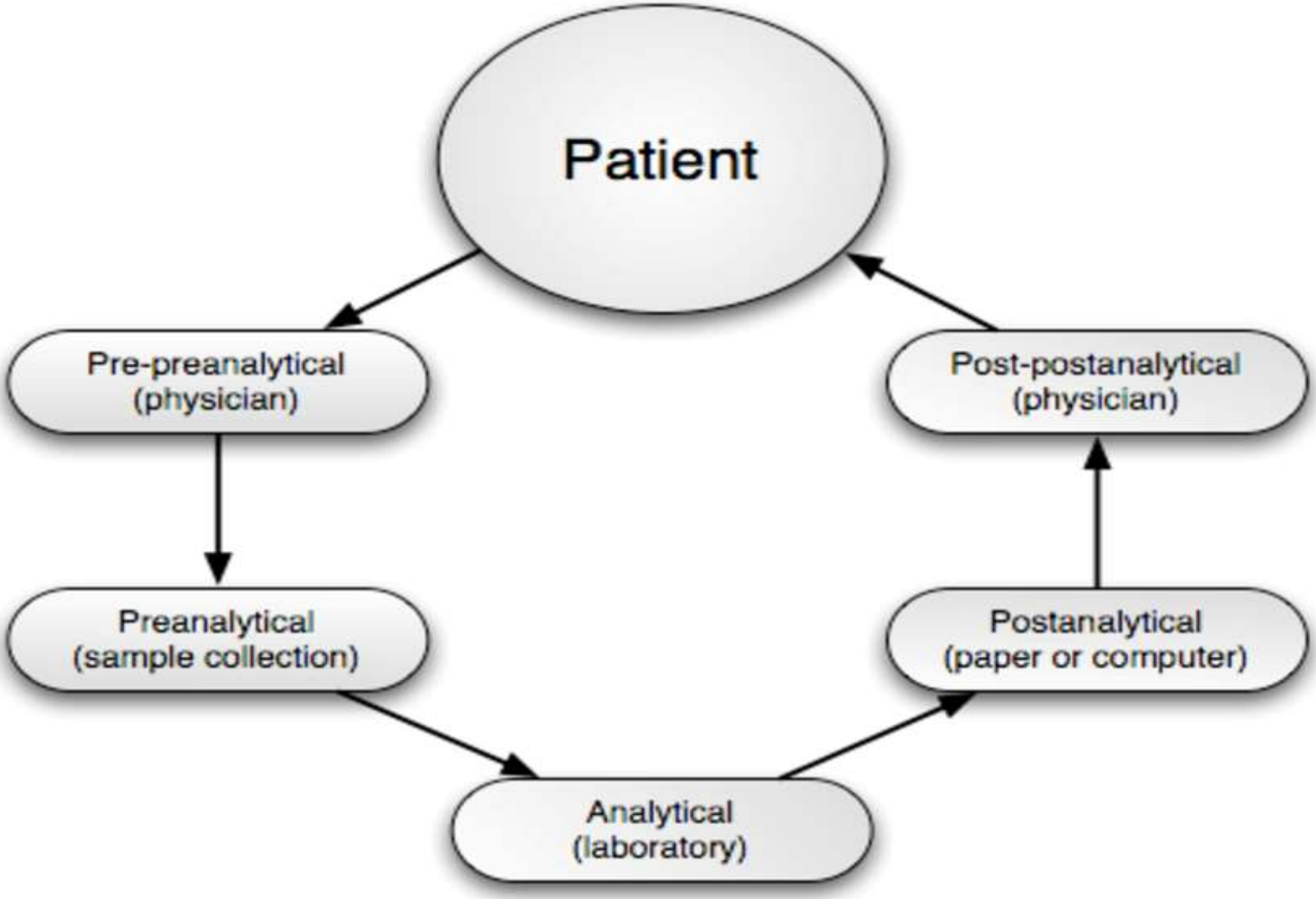
Risk analysis



QUALITY CONTROL IN CLINICAL LABORATORY


Right result
Right price
Right time
QUALITY ASSURANCE
Interpretaion based on correct reference data
Right specimen
Right patient

The total testing process

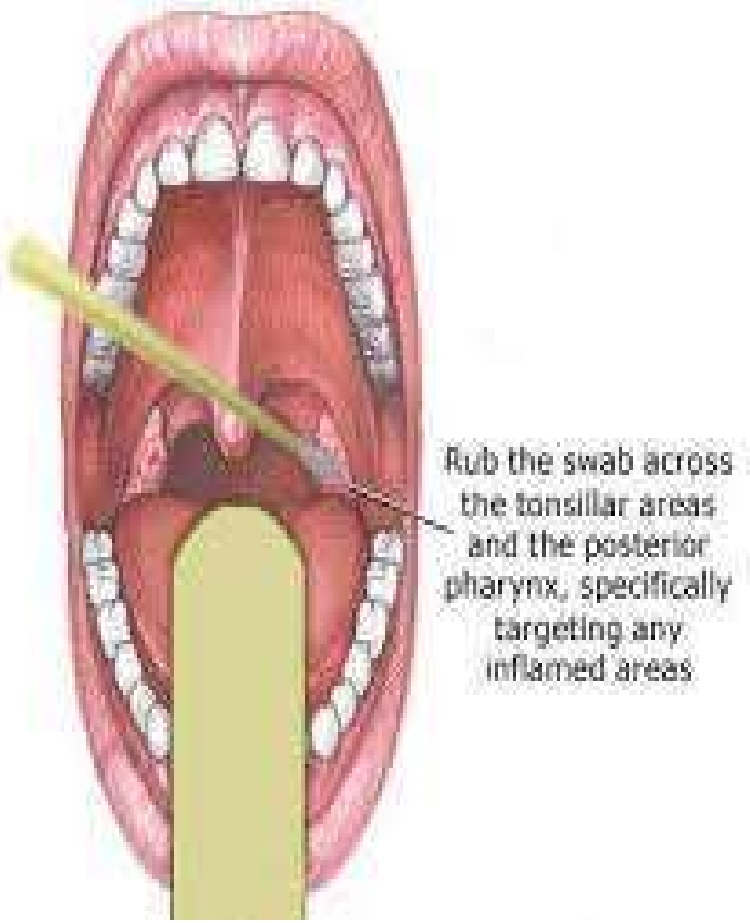


SPECIMEN COLLECTION

SITE OF COLLECTION

- Must be from the actual site
- Minimum contamination from adjacent tissues, organs or secretions
- Swabs are inferior in the collection of most specimens
- Use of aspiration needles and catheters should be encouraged
- A patient information sheet should be given to patients

for collection of urine specimens.



SPECIMEN COLLECTION

TIME OF COLLECTION

- Optimal time of collection.
- Pathophysiology of the infectious disease should be known
- Blood cultures are usually positive in the first week
- Urine and stool culture positive during 2nd and 3rd week of illness
- 24 hours collection of sputum and urine should not be done

SPECIMEN COLLECTION

QUANITY OF THE SPECIMEN

- Must be sufficient
- Guidelines should be established to define a sufficient volume.
- If quantity is low
- Tubes containing holding broth such as physiologic saline(non nutrient) or phosphate yeast glucose (PYG) should be provided.

SPECIMEN COLLECTION

DEVICE FOR COLLECTION

- Sterile containers should be used.
- Wide mouthed
- Tightly fitted caps to prevent leakage and contamination
- Swabs tipped with Dacron or Rayon polyester are better choices.

SPECIMEN COLLECTION

• Specimen should not remain in contact with swab for long duration.
• Swabs should be placed in transport media to prevent drying (upto 48 hours).
EXCEPTIONS :
• Skin scrapings and nail clipping for recovery of dermatophytes should be
submitted dry in a clean container
Prevents overgrowth of bacteria.
• Swab for recovery of Streptococcus pyogenes
Bacteria that colonize dry off.

SPECIMEN COLLECTION

PROPER LABELLING

- Identification number
- Name/Age and gender
- Source of specimen
- Clinician in charge
- Date/Hour collected
- Diagnosis
- Any antibiotics given
- Investigation required

SPECIMEN TRANSPORT

Primary objective is to maintain sample in its original state.

- Adverse environmental conditions such as Extremes of heat and cold
Rapid changes in pressure(during air transport)
Excessive drying should be avoided
- For prolonged delay (>4 days) specimens should be frozen at
-70 deg.
- Samples for recovery of mycobacteria and fungi should be shipped immediately

SPECIMEN RECEIPT & PRELIMINARY OBSERVATION

Area should be designated for receipt of specimens.

- Initial observation and handling in the biosafety cabinet.
- Personnel should wear protective clothing
- Lab Coats
- Rubber gloves and
- In some cases custom fitted masks