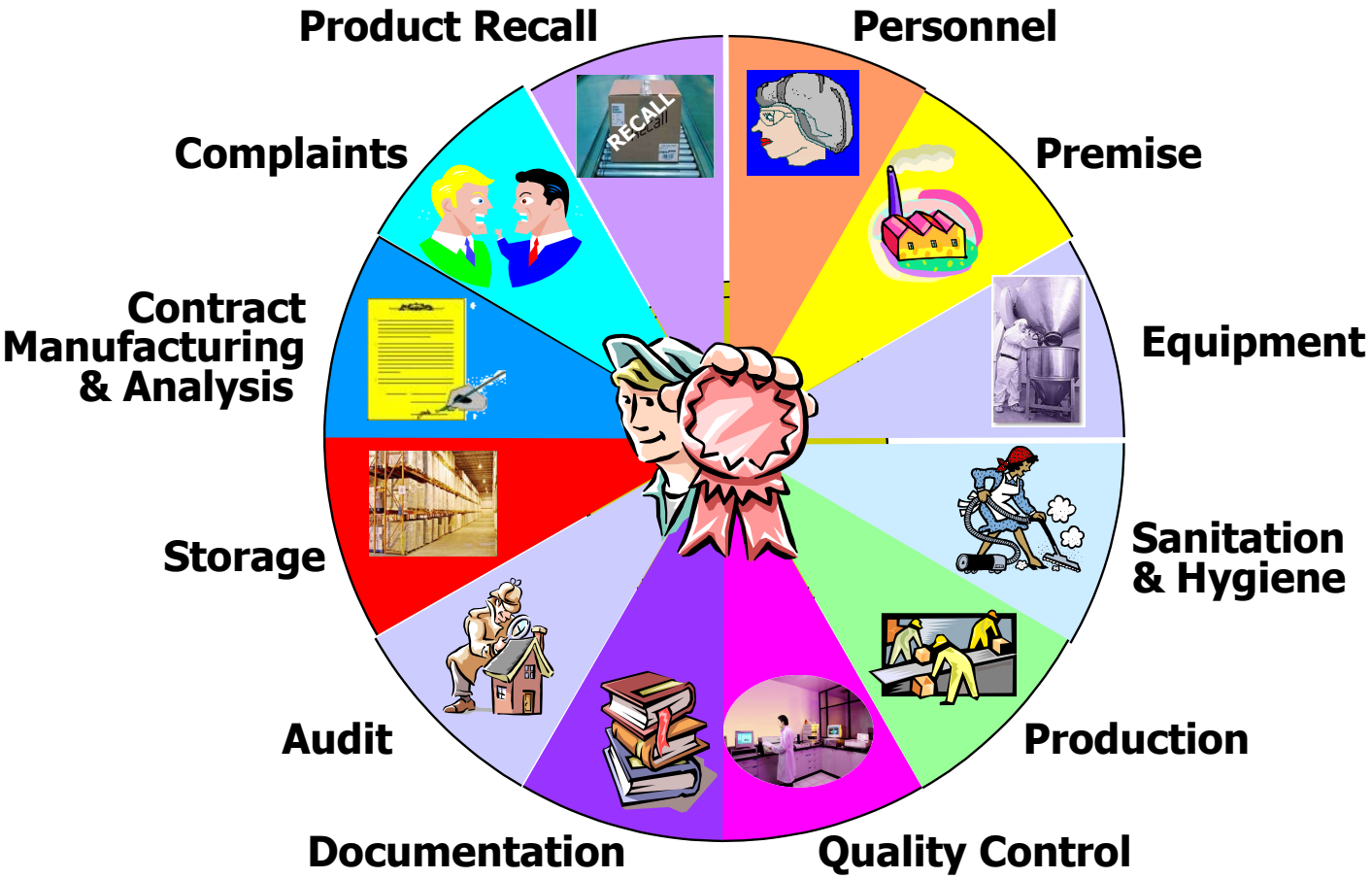
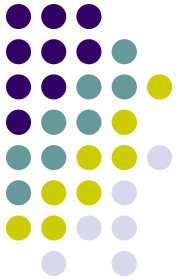
TRAINING COURSE

GMP AUDITOR TRAINING



CONTENT OF PRESENTATION



I. Introduction

- Objectives
- Description of GMP Audit
- Scope of GMP Audit
- Benefits of GMP Audit
- The key principle of GMP Audit
- The role of GMP Auditor

2. Managing the GMP Audit program

- Process Flow for Managing of an audit program
- Authority of audit program
- Establishing the audit program
- Audit program implementation
- Monitoring and Reviewing the audit program

3. Audit Activities

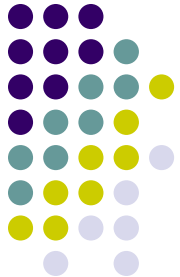
- Overview of Audit Activities
- Initiating the audit
- Conducting Document Review
- Preparing for On site audit activities
- Conducting on-site audit activities
- Preparing, approving & distributing the audit report
- Completing & Conducting Follow up

4. Audit Format

5. Conclusion

INTRODUCTION

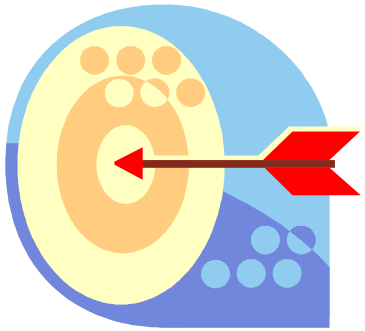
INTRODUCTION



- Good Manufacturing Practice (GMP) is the part of Quality Assurance that ensures that products are produced and controlled consistently and reliably. This consistency of production and control is essential. It can only come about by having clear descriptions of the way in which the work will be done.
- GMP specifically addresses risks of cross-contamination and mix-up that cannot be fully controlled by testing of the final product.
- These risks can best be controlled by having a properly managed system of working that takes them into account. This means that the quality checking system must be designed with these risks in mind and set out to find whether any errors have occurred.

OBJECTIVES

- To define the activities and requirements of GMP Audit
- To identify the roles and benefits of GMP Audit in a Food Safety Management System
- To learn how to plan, perform and monitor GMP Audit



DEFINITION

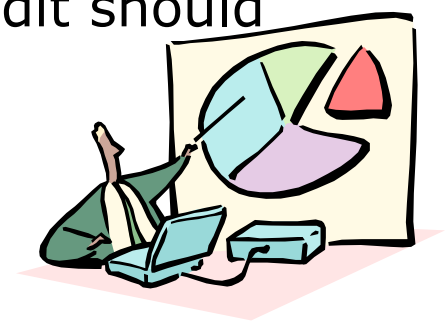
- "GMP Audit" is an independent examination of a quality system
- It measures the effectiveness of an organisation's Food Safety Management System.
- It is a documented and systematic tool
- It should be done periodically by independent and qualified people
- "Audit" itself is **a checking system**, NOT **a quality assessment**
- As a communication tool of management policies. All personnel have to understand and do their jobs well

ROLES OF AUDIT

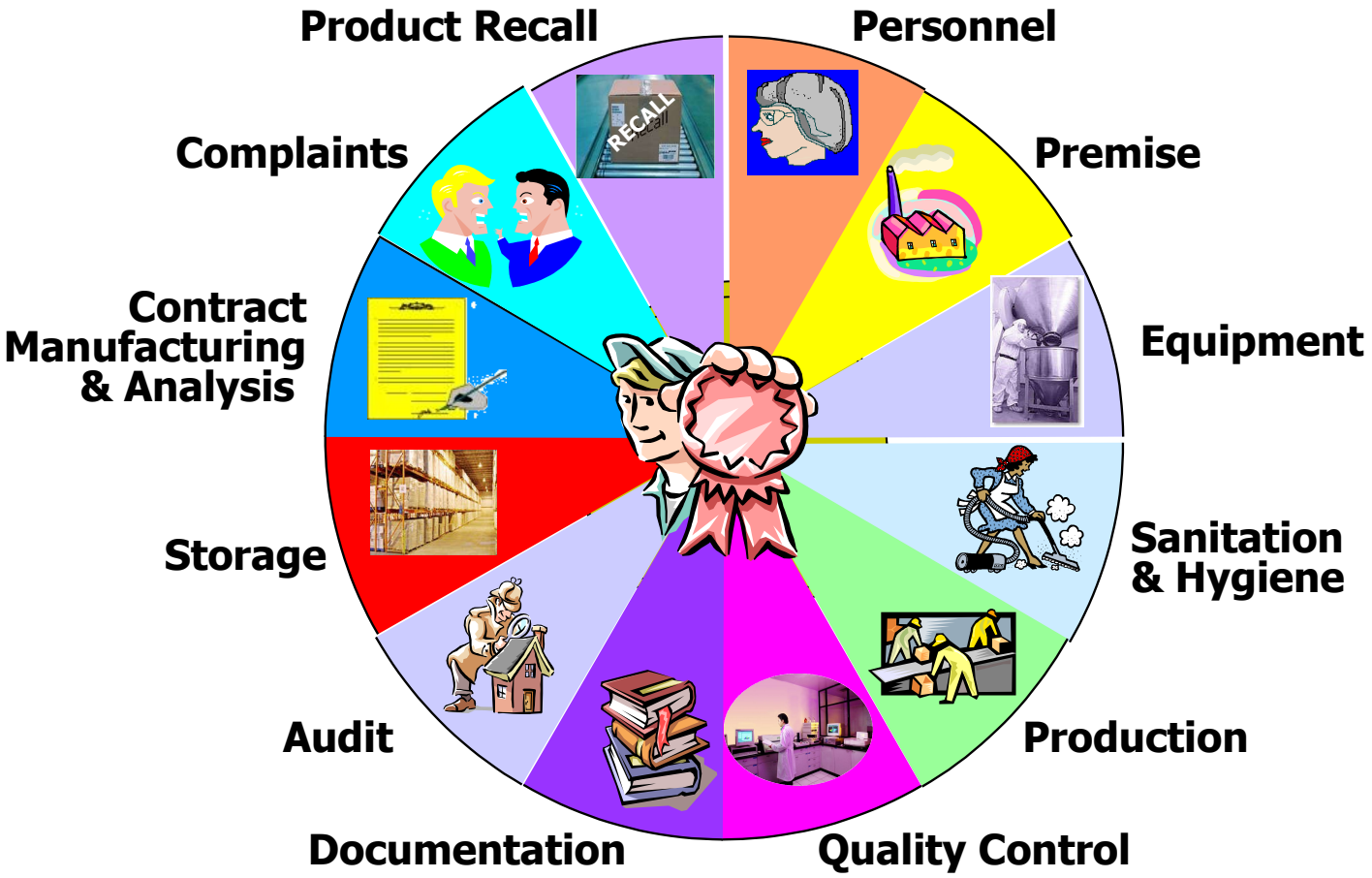
- ✓ As a powerful tool to measure the effectiveness of Food Safety Management System
- ✓ Evaluates manufacturer's compliance with GMP in all aspects related production and quality control
- ✓ Detects any shortcomings in the implementation of GMP
- ✓ Recommend the necessary corrective and preventive actions

SCOPE OF GMP AUDIT (1)

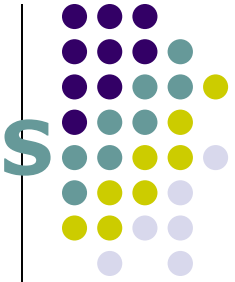
- Ensures GMP Audit plan covers all the areas as per required frequency
- GMP Audit should include all points related to Following Modules –
  - Personal Hygiene
  - Cleaning & Sanitation
  - Pest Control
  - Premises
  - Production
  - Quality Control
- Ensures corrective actions agreed in last audit should be reviewed



SUMMARY GMP


Product Recall
Personnel
Complaints
Premise
Contract Manufacturing & Analysis
Equipment
Storage
Sanitation & Hygiene
Audit
Production
Documentation
Quality Control
RECALL

BASIC PRINCIPLES OF
GOOD MANUFACURING PRACTICES



- Part of QA which ensures that products are **consistently produced and controlled** to the quality standards appropriate to their intended use.

- Minimize risks :
  - cross contamination
  - mix up

- Ensure products/materials are traceable to the original source.

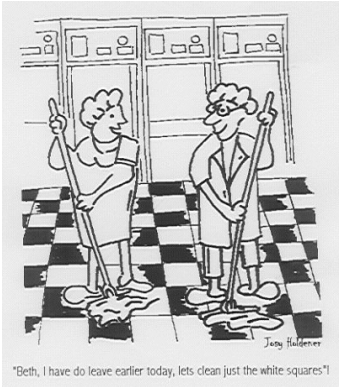
- Product testing is not reliable way to assure product quality. Should BUILD quality into the product!

- Production and quality control functions should be independent of each other.

BASIC PRINCIPLES OF GOOD MANUFACURING PRACTICES (1)

- All manufacturing process are clearly defined and systematically reviewed.
- All necessary facilities/resources for GMP should be provided :

  - adequate, qualified and well-trained personnel
  - suitable premises and sufficient space
  - suitable location
  - good personal hygiene and proper sanitation
  - suitable equipment and services



BASIC PRINCIPLES OF
GOOD MANUFACURING PRACTICES (2)

- All necessary facilities/resources for GMP should be provided :
  - clearly defined manufacturing processes using unambiguous language
  - good documentation system
  - appropriate storage and transport
  - systematic internal quality audit
  - proper product recall system
  - right handing of complaints
  - comprehensive corrective and preventive action

BASIC PRINCIPLES OF QUALITY CONTROL (1)

- QC is part of GMP.
- QC is concerned with sampling, specification and testing.
- Manufacturer should have a QC department.
- QC should be headed by an appropriately qualified and experienced person.
- QC should be independent from production and other departments.
- Ensure that the necessary and relevant tests are actually carried out.
- Ensure that no materials or products will be released for sale or supply, until their quality have been evaluated and judged to be satisfactory.

BASIC PRINCIPLES OF QUALITY CONTROL (1)

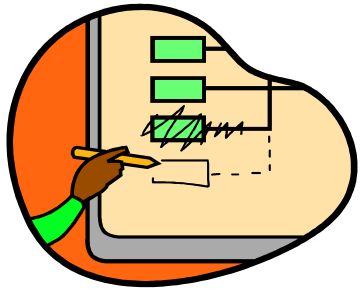
- Adequate facilities, trained personnel and approved procedures should be available for sampling, inspecting and testing and, where appropriate, environment monitoring.

- Sampling by QC personnel & testing by approved methods.
- Approved test methods.

- Maintenance of QC records & fai estigati

BASIC PRINCIPLES OF QUALITY CONTROL (2)

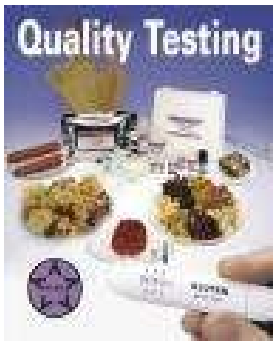
- Ingredients comply with regulatory specification (grade, composition, strength)
- Review and evaluation of production documentation
- Assessment of process deviations
- Release of batches by authorized person
- Sufficient reference samples of starting materials and finished products



OTHER DUTIES OF QC

- Establish QC procedures
- Manage reference standards
- Ensure correct labeling
- Stability testing (if applicable)
- Complaint investigation
- Environmental monitoring

QUALITY CONTROL ACTIVITIES



QC should cover the following:

b. Sampling
c. Specification
d. Testing
e. Release procedures
f. Recalls and complaints
g. Decision making in all quality matters
h. Definition of product quality
i. Laboratory operations
j. Release authorization
k. Investification and reporting

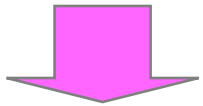
QA VS QC

- The terms *quality assurance* and *quality control* are often used interchangeably to refer to the actions performed for ensuring the quality of a product, service, or process.
- Both terms, however, have many interpretations because of the multiple definitions for the words "assurance" and "control."
- The definitions below, for example, point toward a specific distinction between these two terms:

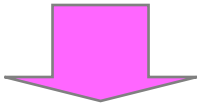
Assurance : The act of giving confidence, the state of being certain, or the act of making certain.	**Quality assurance** : All the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence a product or service will fulfill requirements for quality.
Control : An evaluation to indicate needed corrective responses; the act of guiding or the state of a process in which the variability is attributable to a constant system of chance causes.	**Quality control** :The operational techniques and activities used to fulfill requirements for quality.

QUALITY RELATIONSHIP

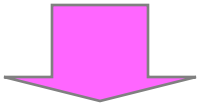
Quality Management



Quality Assurance



G.M.P.

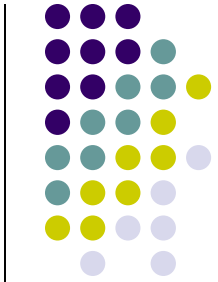


Quality Control

BENEFITS OF GMP AUDIT

- Tells you the hygiene standard of area
- Identify the root of a problem and plan for corrective and preventive actions with timeline
- Achieve better allocation of resources
- Able to avoid potentially big Food Safety Risk
- Learn what an auditors look for
- Continuous improvement

KEY PRINCIPLES OF GMP AUDIT



Approaches towards GMP Audit:

- Independent
- Evidence-based approach

All activities related to Audit should:

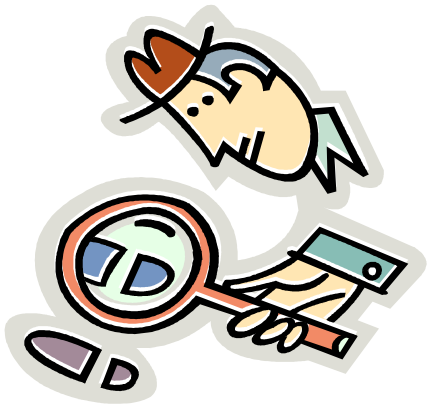
- be reviewed by an independent party
- be a self-appraisal system
- have a sampling plan and tracking system
- be open, constructive and effective

Strategies in conducting audit:

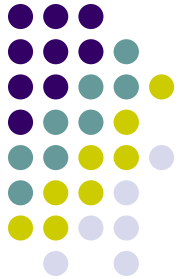
- Ask with the basic audit questions about the quality system in place
- Start with ***what, why, how, who, where, when***

PRINCIPLE OF AN AUDITOR

- Ethical
- Professional
- Fair



Auditing Techniques



Do

- Stop talking
- Calm the Auditee
- Focus on listening
- Remove distractions
- Empathize
- Patience
- Hold your temper
- Question
- Be humble
- LISTEN

Don't

- Judge
- Embellish
- Inattentive
- Speak unclearly
- Talk excessively
- Phrase yes/no questions
- Display an attitude
- Argue
- Criticize
- Answer your question

GUIDANCE WHEN CONDUCTING AN AUDIT

- Auditing should be seen as a positive process not a fault finding
- Audits need to be documented
- Prior to the audit date, an auditor needs to review the quality system documentation, corrective and preventive actions, and past audit findings.
- During an audit, an auditor need to see evidences that the processes are being done in accordance to procedures and policies

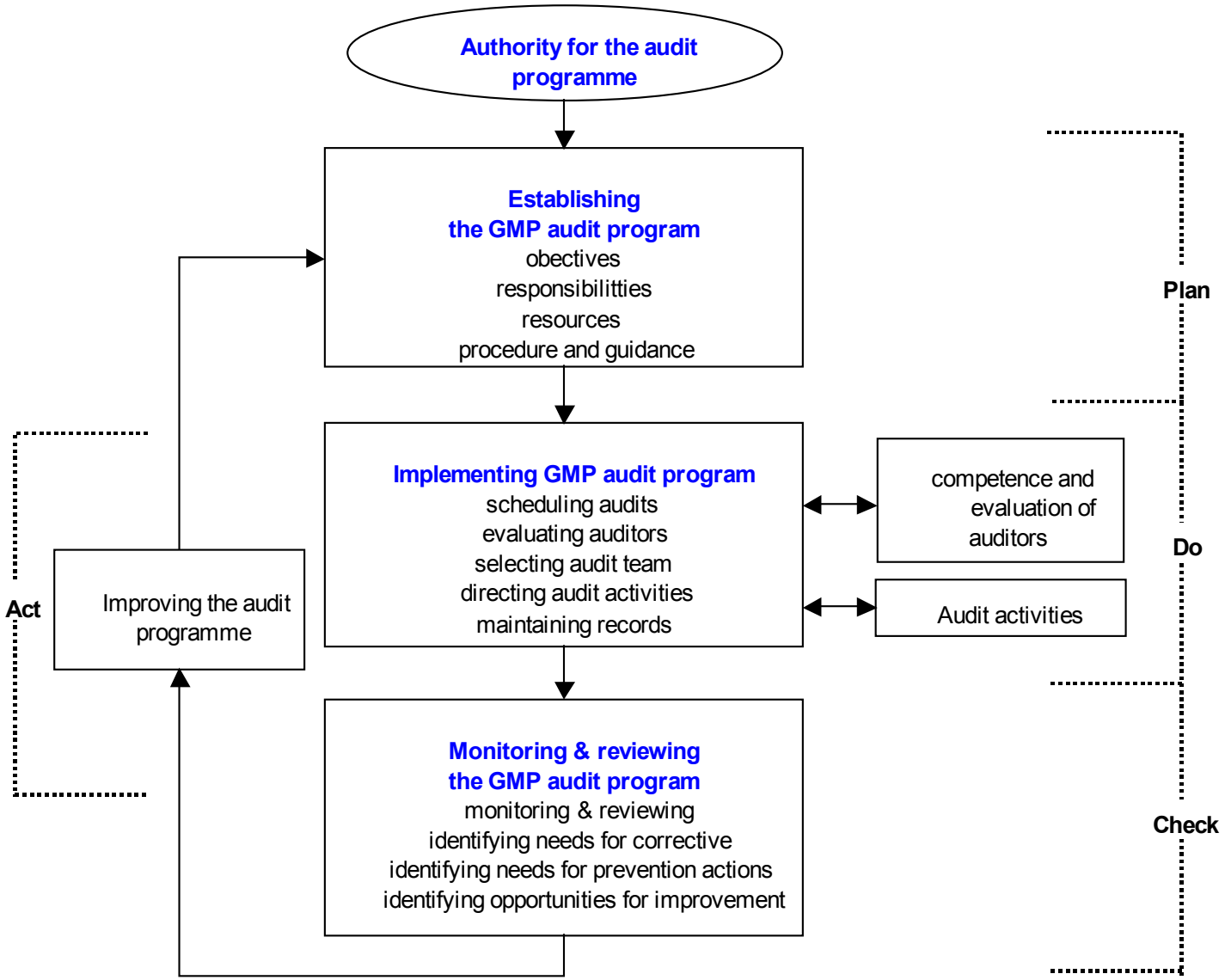
GUIDANCE FOR AUDITEE

When being audited:

- Volunteer information
- Report deficiencies and difficulties if you know of any
- Be honest, open and cooperative
- Ensure that underlying causes are identified
- Ask the auditor if you’re not sure

MANAGING GMP AUDIT

FLOW CHART OF AUDIT



RESOURCES FOR AUDIT

Considerations should be given to the following:

- ✓ Resources
- ✓ Audit techniques
- ✓ Processes to achieve and maintain the competency of auditors and to improve their performance
- ✓ Competency and availability of auditor
- ✓ Available time for auditing

AUDITING ACTIVITIES

OVERVIEW OF AUDIT ACTIVITES

Planning and scheduling audit

↓

Conducting document review

↓

Preparing for on-site activities

↓

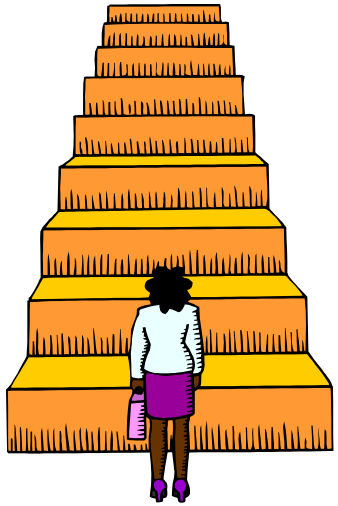
Conducting audit

↓

Prepare audit report

↓

Conducting follow-up



AUDIT ACTIVITIES

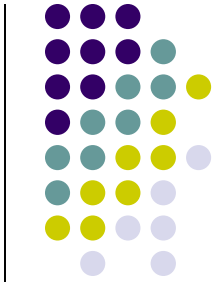
- Forming an audit team and assign roles and responsibility and agreed on the scope
- Conducting document review

  - ✓ Review documents (SOPs, audit findings, corrective action/preventive action, etc.), check the integrity of the quality system and various controls are effective

- Preparing for the on-site audit activities

  - ✓ *Preparing audit plan*
  - ✓ *Assigning work to the auditors*
  - ✓ *Preparing work documents*
    (eg. audit checklists, sampling plans, forms for recording information; questionnaires)

AUDIT DOCUMENTATION



- Audit plan

  - ✓ should be sent to Auditee prior to audit activity
  - ✓ findings from the last audit should be also mentioned

- Audit note should include

  - ✓an audit questionnaire
  - ✓all records and comments during the audit

- Audit report is an

  - ✓official document to report the audit findings

EXAMPLE OF AN AUDIT CHECKLIST

- Audit format for an audit checklist

Sr. No.	Section – Personal Hygiene	Applicable		Type		Rating				Remarks
		Yes	No	PRP	FSR	A	B	C	D	
1	Almarai Uniform Protocol must be followed by each employee									
2	Smoking / Eating is not allowed inside the manufacturing areas.									
3	All employees must undergone thro Baladiah Medical test									
4	All cuts & grazes on exposed skin shall be covered									
5	Is regular fogging conducted? Are records available for review?									
6	Offices / Workplace shall be kept clean & tidy									

Definitions

- **PRPs -** These are basically the generic controls in any type of food business operation. These are to be applied in all types of food business so as to maintain a hygienic environment to reduce the risk to the Food Safety.

  Example – GMP, Calibration, Cleaning & Sanitation etc

- **Food Safety Risk** – are the conditions where PRPs based on operational conditions will have direct impact on Food Safety of Product. These points are critical for Food Safety and should be control to prevent any hazard to product.

  Example – Pest on equipment can lead pest contamination in product, broken glass, hanging wires on filler can lead to foreign body risk.

Definitions

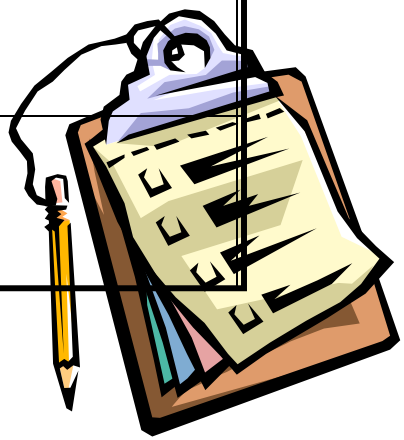
Abbre #	Categories	Definitions	Score
A	**Satisfactory**	Meets the requirement throughout the department	5
B	**Minor Deviation**	Few incidence where department was not able to fulfill the requirements (Based on situation & incidence criticality)	3
C	**Major Deviation**	More no of incidences where the department was not able to fulfill the requirements (Based on situation & incidence criticality)	0
		Corrective Actions not taken place for last audit	
D	**Critical**	A single incidence causing Food Safety Risk to product e.g. Broken Glass on floor, pest on equipment, Foreign body issue	-3
		Corrective Actions not taken place for consecutive last two audits	

EXAMPLE OF AN AUDIT CHECKLIST

CHECKING LIST FOR GMP ASSESSMENT

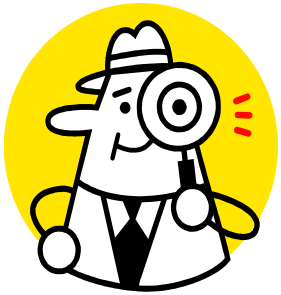
Date : **Location** : **Warehouse**
Auditor : **Auditee** :

DESCRIPTION	GMP.REF.	PARAMETER	AUDIT FINDING
Personnel	1.2.1 5.1.2 2.1.5	- Organization structure - Personnel hygiene - Training record	
Storage area	10.1.1 3.1 3.6 3.9 & 3.10 3.12.2	- Design and layout of defined area - Flow of personnel and goods - Structure of the storage area, based on GMP - HVAC system - Record of monitoring parameter	
Sanitation	3.1 5.3	- Pest record program - The map of bait - The cleanliness of weighing apparatus	
Documentation	4.3 10.2.2.3 10.2.2.1	- Record of maintenance and calibration of weighing apparatus - The effectiveness of label system - Inventory stock control	



AUDITING ACTIVITIES (1)

- **Conducting on-site audit activities**
  - ❖ Conduct opening meeting
  - ❖ Good communication during the audit
  - ❖ Roles of escort and observer
  - ❖ Steps in conducting on site audit:
    - ✓ Interviews with different personnel
    - ✓ Carry out both horizontal and vertical audits. Focus on safety and quality of product.
    - ✓ Use “Trace-back” method



AUDITING ACTIVITIES (2)

- **Generating audit findings**
  - ✓ Either PRP or Food Safety Risk
  - ✓ Either conformity or non-conformity
  - ✓ Sort out isolated or systemic deficiencies

Isolated deficiency:

Tends to happen randomly; no meaningful pattern; rarely happens

Systemic deficiency:

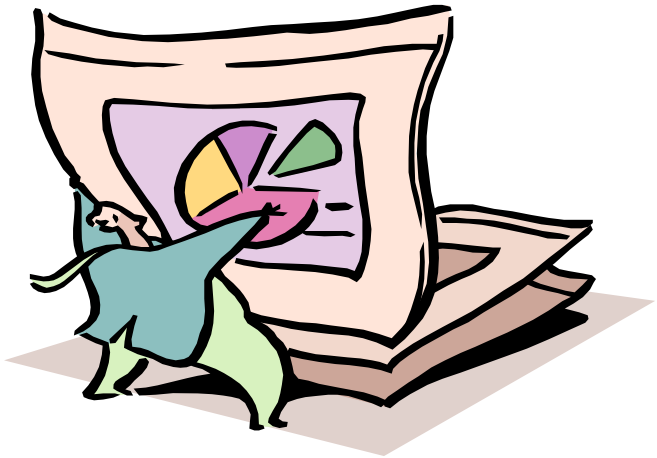
Could be connected to a particular process, product, material, person or organisation; shows pattern; happens more than once

AUDIT MONITORING

The audit finding can be classified into 2 groups:

- **Compliance :**
  - Satisfactory /Adequate
  - Outstanding

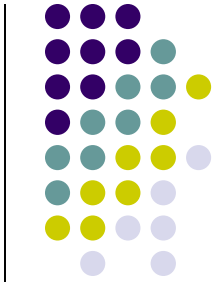
- **Non-compliance :**
  - Critical deficiency
  - Major deficiency
  - Minor deficiency



AUDIT REPORT

- Objectives
- Audit scope
- Identification of trained auditor
- Date and place where the on-site audit activities were conducted
- Audit criteria and findings
- Conclusions

AUDIT REPORT

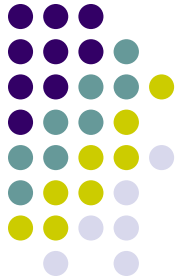


- ✓ Only Standard formats can be used for Audit Report
- ✓ Usually include name and location of auditee, date of audit, audit plan, audit observations, classification of non-compliances, recommendations or expectations
- ✓ Should write against a standard
- ✓ Focus on deficient conditions and not people
- ✓ Include any positive observations
- ✓ Keep the audit report simple and clear

AUDIT REPORT: AN EXAMPLE

Sr. No.	Section – Personal Hygiene	Applicable		Type		Rating				Remarks
		Yes	No	PRP	FSR	A	B	C	D	
1	Offices / Workplace shall be kept clean & tidy	√		√			√			Audit in Blending Room
2	Do floor drains appear clean, free from odors and well maintained?	√		√	√			√		Audit in Fresh Filling (Drain is near to recovery area
3	Smoking / Eating is not allowed inside the manufacturing areas.	√		√	√				√	Audit in any production area
4	Almarai Uniform Protocol must be followed by each employee	√		√			√			Audit in Down line
5	All employees must undergone thro Baladiah Medical test		√							Audit in Outbound
6	Is regular fogging conducted? Are records available for review?	√		√	√				√	Audit in RCC Fermentation room
7	Drains shall be fitted with screens & traps to pest entry	√		√			√	√		Audit in CHP Filling

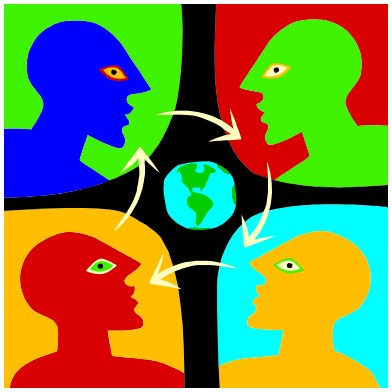
CLOSURE



Follow-up and closing of loop:

- Receive a satisfactory response from auditee and their commitment to correct for any deficiency
- Ensures CAPA identify the root cause and they are satisfactory, accomplished and documented
- Timeframe for CAPA is being followed
- Verify and track CAPA by scheduling a follow-up audit and/or requesting for an updated SOP

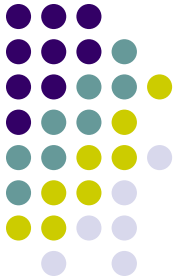
CONCLUSIONS



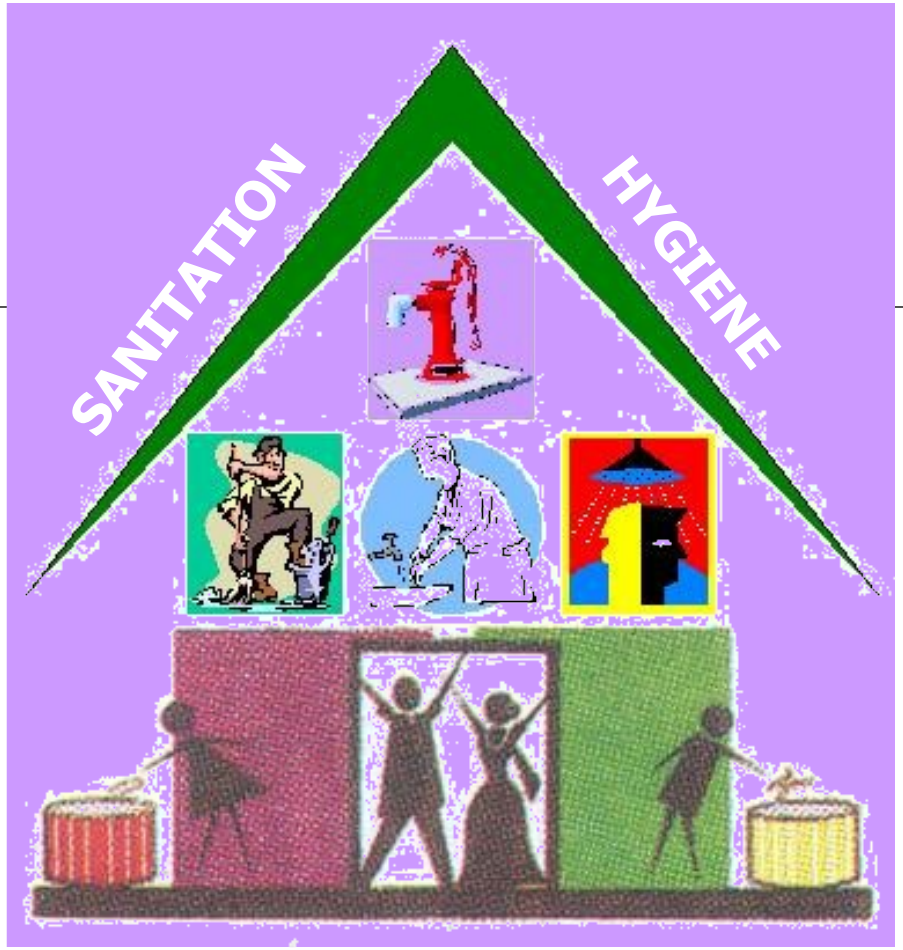
Nobody likes to be audited……

It is a means to have continuous improvement

GMP Audit Modules



- Personnel Hygiene
- Waste Management
- Premises
- Equipments
- Cleaning & Sanitation
- Production Controls
- Quality Controls
- Documentation
- Good Storage Practices
- Good House Keeping



PERSONNEL HYGIENE

PERSONNEL HYGIENE (1)

- All personnel must undergo health examination
- Trained in the practice of personnel hygiene
- Illness or open wounds – not allowed
- Report to supervisors any conditions adversely affect the product quality

PERSONNEL TRAINING (1)

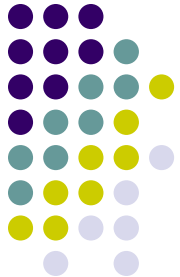
- Training, in accordance with a written programme for
  - all personnel whose duties take them into production; or
  - into control laboratories; and
  - for others whose activities could affect the quality of the product

- On induction and continuing
  - on theory and practice of GMP;
  - approved by either the head of Production or QC as appropriate
  - training records should be kept
  - training before undertaking any new task

PERSONNEL HYGIENE (2)

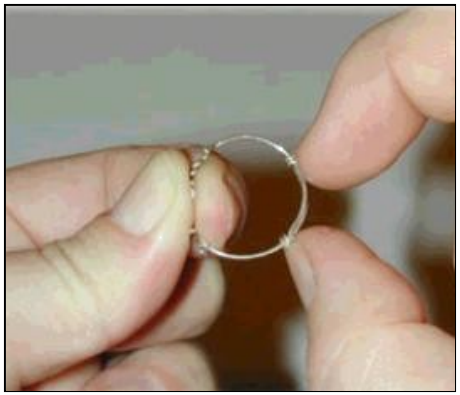
- Avoid direct contact of operator’s hands and products including starting/ packaging materials
- Wear clean Overall or uniform
- Smoking, eating, drinking, chewing and keeping materials not related to production not permitted
- Use of protective clothing in production areas

PERSONNEL TRAINING (2)



- Staff in special areas, e.g.
  - working with hazardous materials should be given specific training
- The concept of QA and its understanding and implementation should be fully discussed during training
- Practical effectiveness should be periodically assessed e.g. assessment tests, number of rejects, product complaint, return products

REGULATION IN PRODUCTION AREA



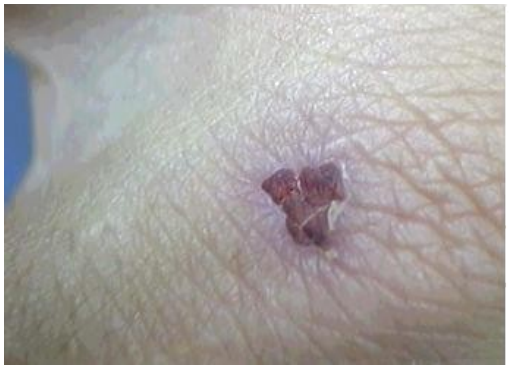
- Prohibit use of rings, earring, and other jewelries in production area

- Hair combing is not allowed in the manufacturing area.

- Prohibit use of artificial eyelash, synthetic nail, and other beauty accessories that can fall into the products.

PERSONNEL WITH ILLNESS

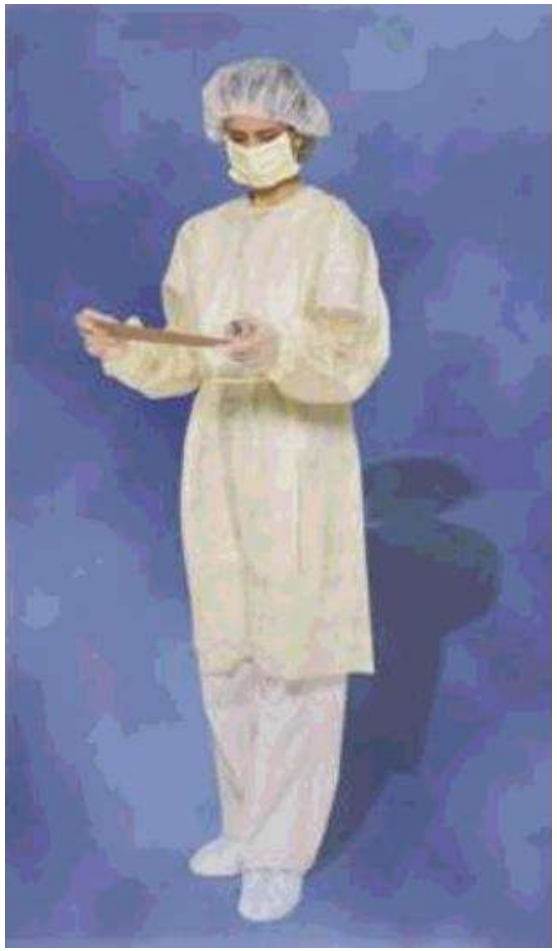
- Personnel should be instructed and encouraged to report to their immediate supervisor when they are ill or when they see any conditions that may adversely affect the product quality.



PROPER ATTIRE

- All authorized personnel entering the production areas should practice good personal hygiene including wearing of proper attire, suitable headwear and footwear.

- To avoid cross contamination, personnel should not move between areas producing different products.

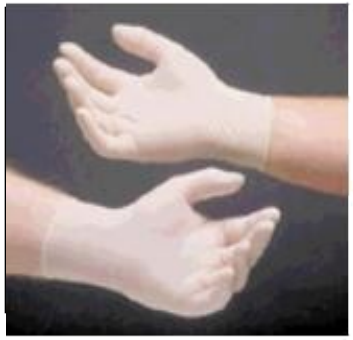


SAFETY ATTIRE

- Avoid direct physical contact with the product to protect from contamination.
- Personnel should wear protective attire when working with hazardous materials

Dust mask

smoke mask



gloves

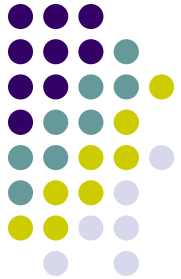
goggles

moustache & beard cover

VISITOR OR UNTRAINED PERSONNEL

- Must be given information in advance, particularly about
  - personal hygiene; and
  - protective clothing requirements
- Must be accompanied and *closely supervised* at all times

BENEFITS – Personnel Hygiene



For personnel :

- To prevent contamination risk that effect personnel health

For product :

- To prevent contamination of the products
- To maintain the high standard of product quality

For company :

- To save on cost, avoid reworks and rejects
- To avoid consumer complaints
- To avoid potential product recall

For consumers :

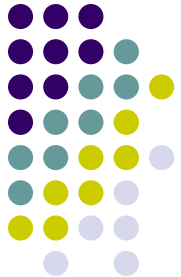
- To get safe and good quality product

WASTE MANAGEMENT

Waste material should be placed in suitable container and regularly collected for disposal outside the production areas.

- Regular & timely collection of garbage
- Garbage bins must be properly covered at all times
- No food wrapper to be thrown in garbage cans inside the production area
- Do not use product shipping cases as garbage bins

WASTE MATERIALS HANDLING



- All waste materials should be properly handled
- Should be stored properly and in a safe place
- Toxic and flammable materials should be stored in a suitable designed, separated and enclosed area
- Should not be allowed to accumulate

PREMISES


LATRINE
1 km
SEE !
If WE brought in SANITATION
they wouldn't have this CHANCE
to SOCIALIZE !

PREMISES DESIGN (1)

The design of the premises depends on the manufacturing activities. However, in general terms, all areas should be designed in such a way that prevents the build-up of dirt and dust.

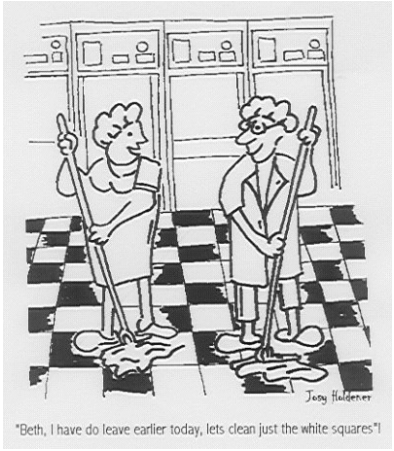
The plant facilities shall:

- provide sufficient space for equipment and storage of materials as necessary for the maintenance of sanitary operations and safe production.
- provide adequate lighting, ventilation or control equipment to minimize contamination.
- have an effective pest control program.
- check pests and pest infestation on a regular basis.
- provide, where necessary, adequate screening or other protection against pests.

PREMISES DESIGN (2)

Buildings / facilities should be so constructed that :

- floors, walls, and ceilings may be adequately cleaned and kept clean, and kept in good repair;
- floor must be hard, smooth and impervious, sloping sufficiently towards a drain thus allowing cleaning with water;
- the grounds shall be kept in a condition that will protect the product against contamination, and to include proper storage of equipment, removing litter and waste;
- drains are kept to a minimum amount. Their design must prevent the possibility of back-flow. Open channels should be easy to clean and sanitize.



PREMISES DESIGN (3)

In addition:

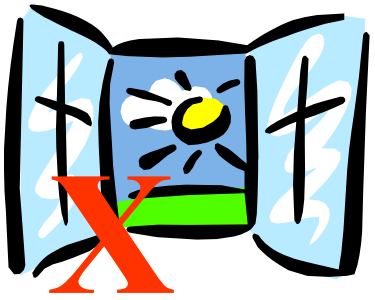
- There must be a written cleaning and sanitization procedure indicating who is responsible for its execution, the materials used and methodology. The procedure should be appropriate to the area being cleaned.
- There should also be a written record of cleaning that has been performed.
- There should be maximum protection against the entry of insects or other animals. For loading bays in particular, there needs to be protection against the weather and flying animals.

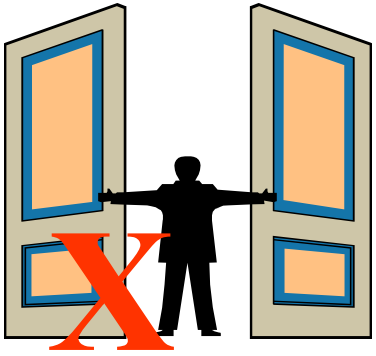
Air curtain

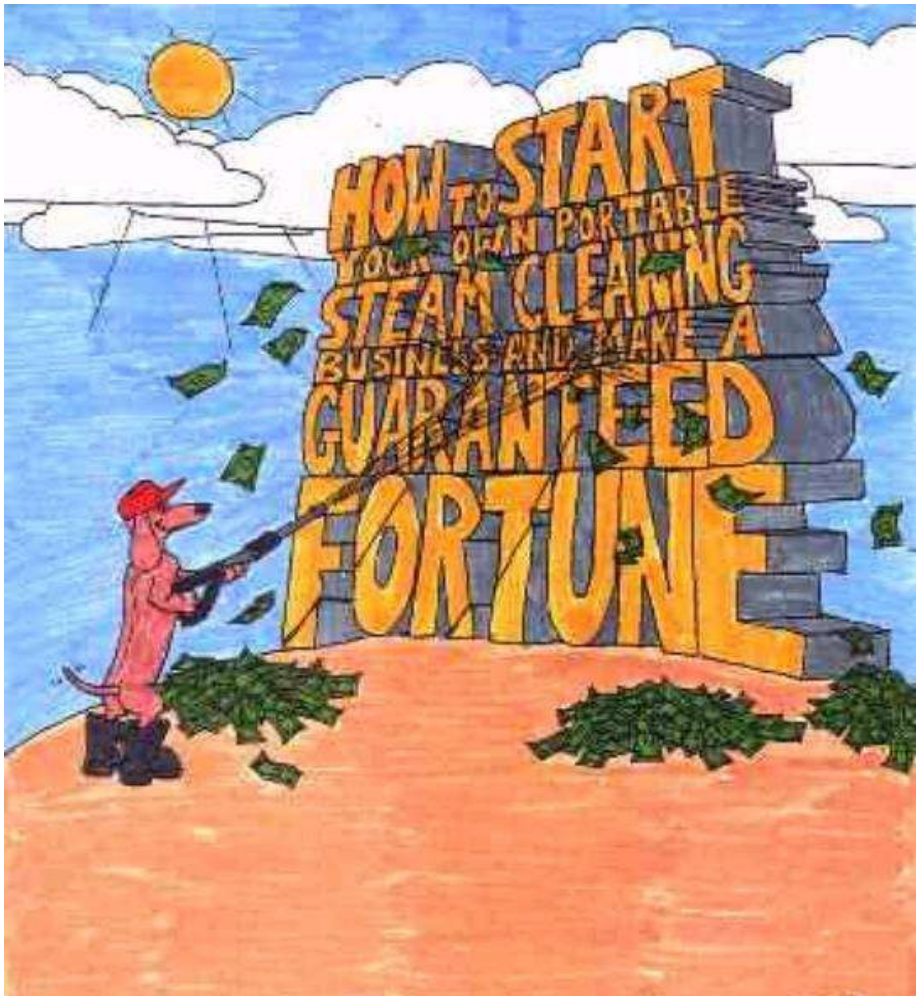
CLOSED DOORS & WINDOW

- Facilities must be well maintained to prevent any contamination to get into the production area.

- Doors and windows must always be kept closed at all times in the production area. Screens must be installed on windows or any other openings.







SANITATION & CLEANING

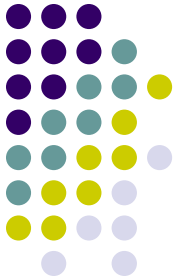
CLEANING PRINCIPLES

Cleaning and sanitation is a key consideration when designing premises and equipments to operate in a Food industry.

Proper cleaning plays an important role. The methods used to establish a clean manufacturing environment vary from company to company. The goal is always the same, to acquire the level of cleanliness to maintain a high product quality while minimizing costs.

To understand the concept of cleanliness, it is necessary to define some common words used in the industry. Most important are the words *clean*, *sanitation*, *hygiene*, and *sterile*.

CLEANING PRINCIPLES



- Cleaning operations shall be performed in a manner to prevent contamination of materials and products.
- Cleaning practices can be divided by :
  - ✓ “deep cleaning”,
  - ✓ “housekeeping cleaning”, and
  - ✓ “maintenance cleaning”.
- All cleaning compounds and sanitizers shall be properly labelled and stored in a locked compartment, away from production and storage areas.
- Cleaning equipment and tools shall be supplied and be readily available for use. All cleaning equipments shall be maintained and stored in such a way as not to contaminate product or equipment.

BENEFITS – Sanitation & Cleaning

For personnel :

- To prevent contamination risk that effect personnel health

For product :

- To prevent contamination of the products
- To maintain the high standard of product quality

For company :

- To save on cost, avoid reworks and rejects
- To avoid consumer complaints
- To avoid potential product recall

For consumers :

- To get safe and good quality product

PROCESS CONTROL

NO EATING, DRINKING & SMOKING

- ✓ "**No Eating**", "**No Drinking**", "**No Smoking**", and "**No Chewing Gum**" policy shall be strictly implemented as well as no spitting on the floor.
- ✓ Food shall not be kept in production, warehouse or laboratory area.

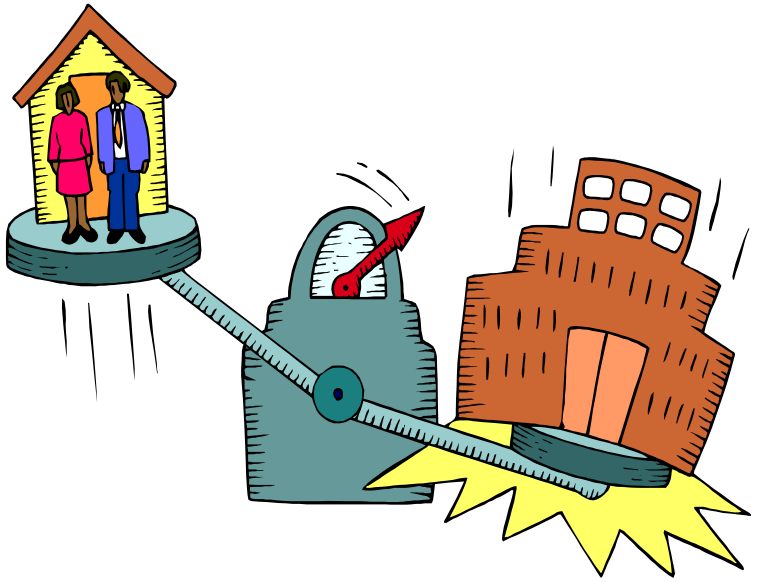
PREVENTION OF CONTAMINATION

- Prevention of contamination should be done in every step of manufacturing processes
- Type of contaminant can vary, starting from dust, gases, vapors, spray, residues from equipment, insect, microbes, or may come from operators clothing.
- Area where some susceptible products are processed, such as neutral pH product should be monitored periodically for its microbial content.
- Cross-contamination should be avoided through proper application of preventive measures
- Measures to prevent cross-contamination and their effectiveness should be checked periodically .

WEIGHING & MEASUREMENT

- Weighing should be carried out :
  - in defined areas
  - using calibrated equipment.

- All weighing and measurement carried out should be:
  - recorded
  - counter checked



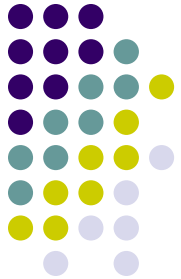
IN-PROCESS CONTROL

- Done within the production area and by production people and/or Quality Control
- Should be recorded and done as per approved/written SOP
- Sampling done to verify:
  - physical aspects (weight, volume, amount, etc)
  - text on labels
  - other performance requirements
- Sampling maybe conducted based on need :
  - during processing activity
  - during packaging (filling & packing) activities
    - ✓ random,
    - ✓ sequential, or
    - ✓ statistical
- Samples taken away from the packaging line should not be returned if containers were opened
- Record of in-process control should be part of the Production Run.

CALIBRATION

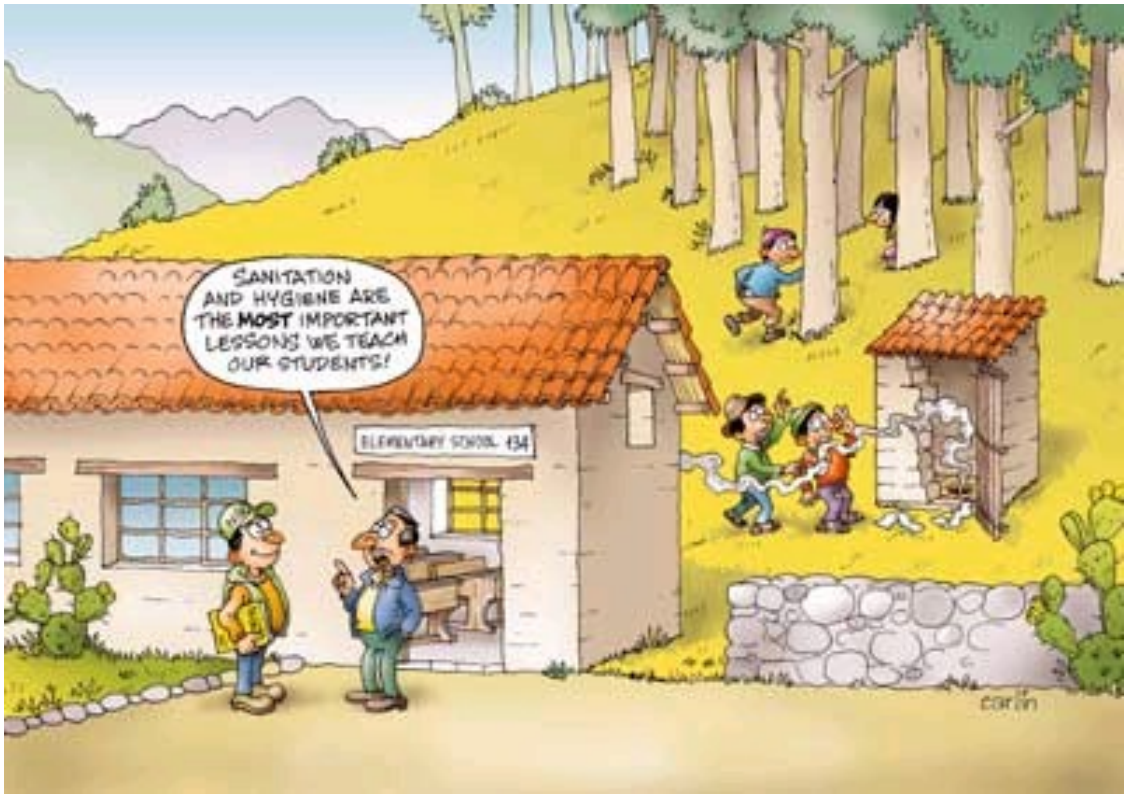
- To maintain the accuracy and precision of test equipment at all times.
- To ensure highest level of confidence in all measurement that affect materials disposition decision, with unbroken chain of traceability to national standard.
- To determine whether the equipment is still fit for its intended purpose.
- It is based on the comparison of a primary standard or instrument of known accuracy with another equipment (to be calibrated)
- It is used to detect, correlate, report or eliminate by adjustment of any variation in the accuracy of the equipment being calibrated.

EQUIPMENT CLASSIFICATION



- Critical equipment:
  - Direct measurement that affect the final product quality
  - Measurement on critical process parameters in the process specification such as Pasteurizer
- Non critical equipment:
  - Indirect measurement that will not directly affect the final product quality
  - Shall be maintained based on company maintenance schedule

GOOD HOUSEKEEPING PRACTICES



GOOD HOUSEKEEPING PRINCIPLES

A well-planned, well-executed and controlled cleaning and sanitation programme for rooms, machines and equipment is very important to achieve a hygienic standard.

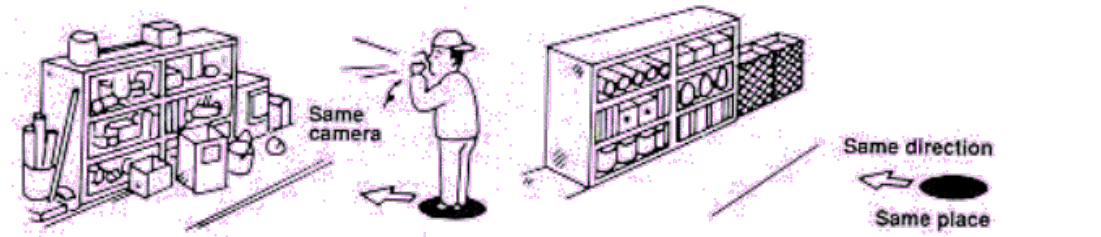
Cleaning and sanitation alone will not assure a hygienic standard in production. Process hygiene as well as personal hygiene are important factors.

Buildings / facilities should be so constructed that clean and unclean processes and products do not mix.

The cleaning program must be performed regularly, dependent on the demand for cleaning in the specific areas. The requirements for cleaning have to be defined before establishing the cleaning program.

GOOD HOUSEKEEPING ADVANTAGES

- A Clean Workplace is High in QUALITY;
- A Clean Workplace is High in PRODUCTIVITY;
- A Clean Workplace Keeps COSTS Down;
- A Clean Workplace Saves TIME;
- A Clean Workplace Ensures EFFICIENT Delivery;
- A Clean Workplace Provides HEALTHY environment;
- A Clean Workplace is SAFE for people to work in;
- A Clean Workplace is High in MORALE.



Before cleaning program **After cleaning program**

5 S: WORKPLACE ORGANIZATION

SEIRI (CLEARING UP):
Remove what is not needed and keep what is needed

SEITON (ORGANIZING):
Place things in a such way that they can be easily reached whenever they are needed

SEISO (CLEANING):
Keep things clean and polished; no trash an dirt in workplace

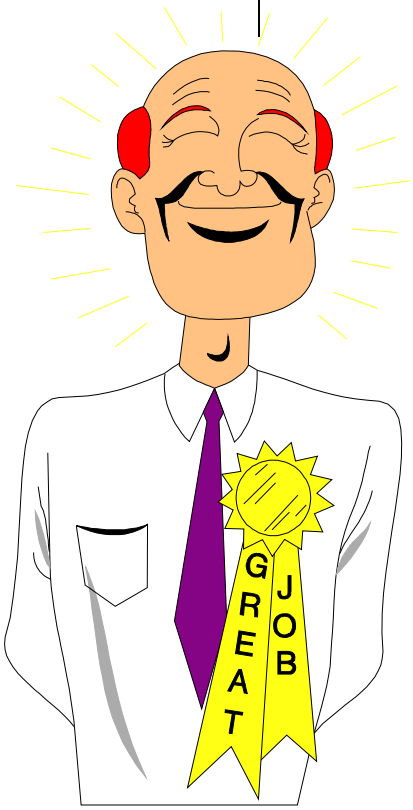
SEKETSU (STANDARDIZING):
Maintain cleanliness after cleaning-perpetual cleaning

SHITSUKE (SELF DICIPLINE):
Commitment, a typical teaching and attitude towards any undertaking to inspire pride and adherence to standards established for the four components

5 S: WORKPLACE ORGANIZATION

Benefit of 5S implementation :

- reduce inventory,
- efficient on workplace usage,
- reducing time for searching material and finished goods,
- keep workplace clean and tidy,
- improve working condition,
- reduce work accident,
- increase discipline,
- follow procedure etc.

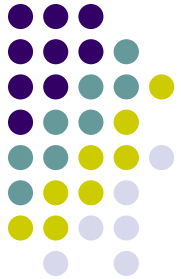


GOOD STORAGE PRACTICES

REQUIREMENT OF GSP

To ensure that when the end product reaches the consumer, it is of good quality and safe to use.

MATERIAL REQUIREMENTS (1)



- All incoming materials should be quarantined immediately after receipt until they are released for use in production
- Raw materials should be stored under appropriate condition.
- Storage condition should be controlled, monitored and recorded

MATERIAL BASIC REQUIREMENTS (2)

- Storage of materials should be orderly to avoid mix up and cross contamination
- Ensure that there is an effective system in controlling stocks
- Ensure that consumption of starting materials follows :
  - ✓ FIFO ~ First-In-First-Out, or
  - ✓ EEFO ~ Earliest Expiry, First Out.

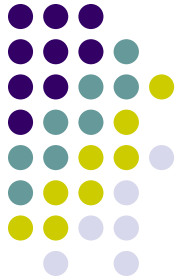
MATERIAL BASIC REQUIREMENTS (3)

- Personnel in charge of raw material purchase should have sufficient knowledge of the materials, products and suppliers of the materials
- Raw materials should be purchased from qualified suppliers. Raw materials should have approved specification and deliveries are accompanied with a certificate of analysis.
- it is suggested to purchase raw materials directly from manufacturers or appointed distributors .

MATERIAL VERIFICATIONS

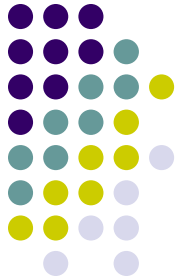
- Starting materials should be checked and verified for their conformity to specifications and be traceable to the p roduct.
- Samples of raw materials should be physically checked for conformity to specifications prior to release for use. Raw materials should be clearly labeled .
- All materials received should be clean and checked for appropriate protective packing to ensure no leakage, perfo ration or exposure to environment.
- Deliveries of raw materials that do not comply with specification should be segregated and disposed according to standard operating procedures

STOCK MANAGEMENT & CONTROL



- receiving & identity inspection
- storage & stock control
- product release, repackaging & transportation
- product disposal

RECEIVING & INSPECTION (1)



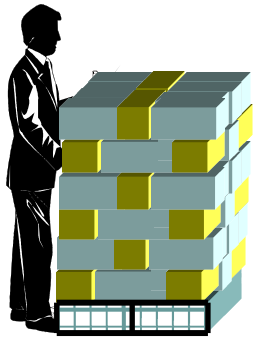
All deliveries should be checked:

- ✓ containers are not damaged
- ✓ quantity of deliveries
- ✓ labels
- ✓ suppliers name & address

RECEIVING & INSPECTION (2)

- product information
- product name, batch no
- manufacturing/expiry date,
- storage requirements:
  - Stack on pallets
  - Use standard pallets

    wooden pallets should be free from pest
  - Interlocking pattern of the box for stability



STORAGE & STOCK CONTROL

- systematic storage system
  - ↗ sufficient passage way for easy movement
  - ↗ inspection / checking
  - ↗ apply stock card

- proper labeling
- scheduled stock check or co

Identification labels

PRODUCT RELEASE

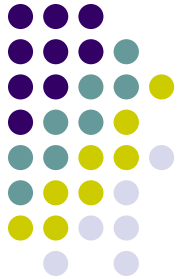
- To follow FIFO / FEFO system
- Recheck before delivery
- Monitor goods condition during transport and at delivery

RETURNED GOODS

Available written procedure:

- segregation of returned goods
- labeling of returned goods
- investigations & evaluations on:
  quality and safety

REJECTED/DAMAGED GOODS



Apply written procedure:

- segregation of returned goods
- labeling of returned goods
- investigations & evaluations on:
  - ✓ quality, and
  - ✓ safety
- disposal of goods

THANK YOU
for your attention