GOOD STORAGE PRACTICES

DEFINITION OF GSP

- The **special measures** that need to be considered in the **storage and distribution** of product, such that the products will be of the **nature and quality intended** when it reaches the consumer

- Specific procedures for :
  ↗ **receiving**
  ↗ **storage**
  ↗ **distribution**
  of materials/cosmetic products

GSP COMPONENTS

1. Premises/warehouse
2. Storage Facilities
3. Personnel
4. Stock management and control
5. Documentation

PREMISES

- General requirement
- Size & storage requirements
- Temperature and humidity control (where required)
- Pest control

GENERAL REQUIREMENTS

- Built for its intended purpose
- Suitable and approved location
- Suitable building materials
- Provide protection
- Provide security from unauthorized persons
- Properly maintained

STORAGE REQUIREMENT

- Segregated areas required (category)
- Dedicated areas required (condition)
- Sampling area

  Wherever possible sampling area for starting materials should be provided to prevent contamination.

STORAGE ENVIRONMENT

- Temperature & humidity control (where required)
- Continuous monitoring of humidity and temperature:
  - Numbers & locations of monitoring points (temperature mapping)
  - Calibrated monitoring equipments
  - Time & frequency of monitoring

STORAGE ENVIRONMENT

- Storage temperature requirement should comply with the labeling requirements.
- Storage condition must not compromise the safety and quality of the product

PEST CONTROL

- Written pest control program

- Outsourcing is recommended
- Use of safe pest control agents
- No risk of contamination to the materials and products
- Proper records

STORAGE FACILITIES

- General facilities:
  - ↗ sufficient lighting
  - ↗ air-conditioning (where required)
- Safety facilities:
  - ↗ personal protective equipments
  - ↗ safety signs
  - ↗ alert/alarm system
  - ↗ fire extinguishers, etc
- Forklifts / trolley
- Computers
- Generators, etc

PERSONNEL

- Qualified personnel with:
  - ↗ experience
  - ↗ good health status
- Sufficient number of personnel
- Appropriate & continuous training programme
- Store organization
  - ➢ department heads
  - ➢ supporting staffs
    - ↗ clerk/store keeper
    - ↗ store attendant
    - ↗ driver/ security guard

TRAINING

- Basic training:

  e.g.: store / warehouse management, inventory , safety, hygiene, good housekeeping (5 S)

- Specific training:

  e.g. computerized stock management

- Documented procedure

- Control System

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

STORAGE & STOCK CONTROL

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

- proper labeling
- scheduled stock check or count

PRODUCT RELEASE

- To follow FIFO or JIT 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

PRODUCT DISPOSAL

Written procedure should be established:

- handling of products before disposal
  - ↗ segregation
  - ↗ labeling
- disposal method should be according to the company and country regulations
- regulatory requirements should be always observed

DOCUMENTATION

- General requirements
- Types of documents
- Control of documents
- Record keeping

DOCUMENTATION OBJECTIVES

Provide clear explanation / instructions:

- Avoids errors and confusions
- As a guideline
- Traceability
- Regulatory requirements

TYPES OF DOCUMENT (1)

1. **Procedures**
   proper instruction/explanation of

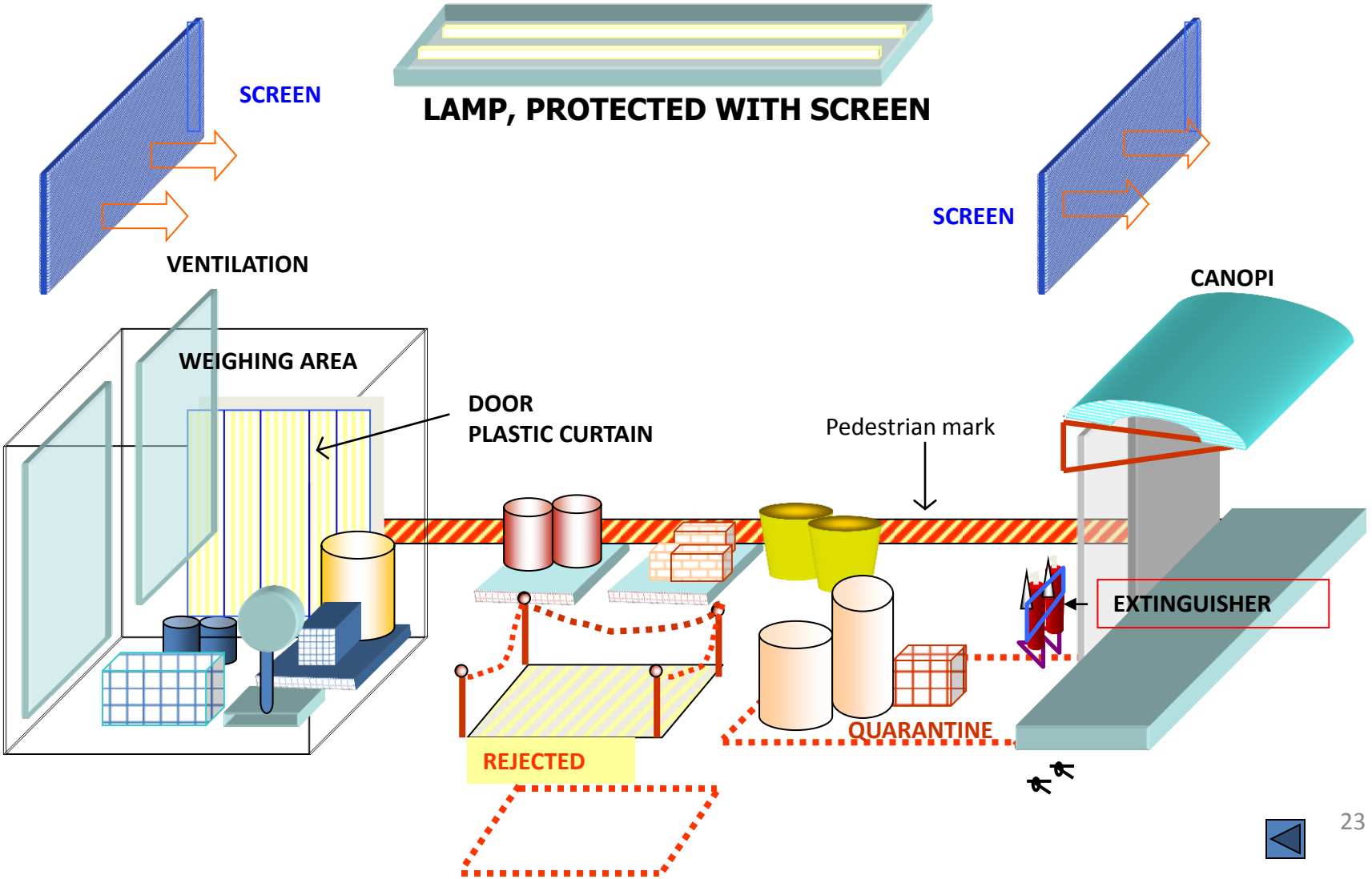
   handling an operation/activity that consist of:
   - explanations
   - flowchart
   - charts/photos

TYPES OF DOCUMENT (2)

2. Record

- written records of the operations or activities
- type of record;
  - ✓ hard copy; stock cards, logbooks
  - ✓ soft copy

WAREHOUSE : AN EXAMPLE



MONITORING POINTS

Numbers and locations of monitoring points (temperature mapping) :

- to ensure a uniform temperature and humidity, at several location in the room a control thermometer and humidity meter is placed and monitor;
- to ensure a uniform temperature and humidity at each location, the room could be provided by roof's ventilation fans to achieve air circulation.

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

PRODUCT COMPLAINT

DEFINITION

- A complaint is when a customer or any other (internal or external party) has reported a product defects, adverse events, or serious adverse events with any of the company's marketed products.
- This is valid regardless of whether:
  - the report is written or verbal
  - there is a returned product attached to the report or not
- The defective product :
  - proved to be harmful under condition of use.
  - lacking in quality, safety, and efficacy.
  - the qualitative and quantitative composition of the product is not as declared.
  - the manufacturing process has not been fulfilled.

PRODUCT COMPLAINT PRINCIPLE

"All complaints and other information concerning potentially defective products must be carefully investigated according to written procedures."

ROLES OF MANUFACTURER

- The manufacturer should be responsible to impose self-regulation upon itself and to remove sub-standard or defective products as fast as possible from the market.

- It would be in the interest of the company to assign responsible person to:

  - investigate product complaints
  - identify & rectify product shortcomings
  - manage product recalls
  - monitor adverse events

COMPLAINT HANDLING PRINCIPLES

1. Complaints should be handled in accordance with a written procedure
2. Carefully reviewed and handled positively
3. Managed by an appointed responsible person
4. Must be given importance
5. Thorough investigation of the cause is essential
6. A major source of information and learning
7. Enable possible production defects to be remedied before they lead to a recall.
8. Necessary actions taken - even a recall decision
9. All complaints should be well documented

RESPONSIBLE PERSON

Within each company a person with adequate knowledge shall be assigned the task of dealing with complaints.

This person must also have the authority to decide the measures to be taken.

COMPLAINT HANDLING PROCEDURE

1. Assigned responsible person
    1. May be authorized person
    2. If not, must advise authorized person of results
    3. Sufficient support staff
    4. Access to records
2. Written procedure describing action to be taken
3. Acknowledge and respond to complainant within a reasonable period
4. Record written and verbal comments
5. Investigate and review to identify the complaint trend
6. Appropriate follow up actions

INVESTIGATION

1. The person in charge of complaints is responsible for initiating the investigation immediately. The person responsible for Quality Control should normally be involved in the investigation.
2. The investigator is responsible for the investigation which has to be carried out immediately. The investigation shall be documented in writing.
3. If a product defect is discovered or suspected in a batch, consideration should be given to determine whether other batches are also affected.
4. The investigation should also cover:
    1. distribution condition
    2. condition under which the product is used

INVESTIGATION RECORDS

Records of Complaint Investigation describe :

1. Name of product
2. Name of active substance, if any
3. Product type
4. Batch number
5. Name of complainant and nature of complaint
6. Records, retention sample investigated, other batches reviewed and staff interviewed
7. Result of investigation: “Justified” or “Not justified”
8. If “justified”, actions taken to prevent reoccurrence
9. Sign-off upon completion

REMEDIAL ACTIONS

1. The person in charge of complaints is responsible for the remedial action decided upon following the outcome of investigation.
2. If it has been decided to make a recall some of the procedures stated in Product Recall Procedure shall be applied.
3. The company management shall discuss possible steps to prevent defects, and take over responsibility for further handling of the cause of the complaint from the person in charge of complaints.

RESPONSES

- Complaints shall always be answered by person(s) assigned by the company.
- Immediate response should be given to the complainant and the manufacturer must be notified of the complaint.
- If the person who complains is informed of the outcome of the investigation over the telephone, the date and information provided shall be noted.

COMPLAINT DECISION

- Complaint justified
  - Actions to prevent reoccurrence
  - Ongoing observation of process
  - Recall product may be required
- Complaint not justified
  - Advise customer of findings
  - Appropriate marketing response

COMPLAINT & DEFECTS CLASSIFICATION

- If complaint is justified, then there has been a failure of the quality system
- Once defect has been identified, company should be dealing with it in an appropriate way, even recall.
- The definition of defects is useful.
- The following system has been found in some countries:
  1. Critical defects
  2. Major defects
  3. minor defects
- While complaints can be classified as:
  1. Medical (e.g unexpected adverse reactions)
  2. Technical (e.g quality,packaging or labeling defects)
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CRITICAL DEFECTS

Those defects which can be life threatening and require company to take immediate action by all reasonable means, whether in or out of business hours

Examples :

- Product labeled with incorrect name or incorrect formula
- Counterfeit or deliberately tampered-with product

MAJOR DEFECT

A defect, which is a non conforming product, obvious to the consumer, it may not be hazardous.

Example:

- Microbiological contamination of products with some risk for users
- sub standard products
- lack of information in use or warning which represents a significant hazard to the users .

MINOR DEFECT

A defect ,which has no important effect upon the use of the cosmetic product and does not otherwise produce a hazard.

Example :

- Lacking in labeling , packaging.

DOCUMENTATION

Documentation of complaint investigation :

1. Each individual complaint and attached documents shall be filed.
2. A final report shall be prepared and documented.
3. In the event of product recall (product safety) the authority should be notified

PRODUCT RECALL

DEFINITION (1)

- **Product recall :**
  is a process taken by the responsible person who placed the product on the market, to remove or withdraw a particular cosmetic product from all links of distribution.

- The removal or withdrawal may be due to critical quality defects discovered or serious adverse cosmetics reactions reported which might cause health risks to users during and after distribution of the product

DEFINITION (2)

- Safety Alert :
  Advice regarding a specific situation of a product, which is not conforming with the safety specification. When there is a risk of significant hazard to consumers of a product which has been distributed on the market ,the manufacturer should disseminate the safety alert through mass communication media available including newspaper, radio and television

DEFINITION (3)

- Withdrawal:
  Removal of product from sale or use for reasons not connected with quality and safety such as change of packaging etc. as a marketing strategy

- Recall for Product Correction:
  the removal of product for rework.

REASONS FOR RECALL

Voluntary recall :

- Customer complaint
- Detection of quality and safety failure after release
- Result from the ongoing stability testing
- Result of an inspection
- Tampering
- Adverse event reporting

Mandatory recall :

- Directed by the national regulatory authorities

RECALL PRINCIPLE

There should be a system to recall products known or suspected to be defective from the market promptly and effectively.

CLASSES OF RECALL

- Unless the relevant authorities have already specified the degree and level of a particular product recall, the class and level will be decided by the product recall committee based on the risks involved .
- The product recall committee shall comprise of personnel who are responsible for the execution and coordination of recall. The persons responsible should handle all aspects of the recalls with the appropriate class of urgency.
- In cases of product recall initiated by the manufacturer, the product recall committee must inform the relevant authorities immediately of this decision when necessary.

RECALL CLASSIFICATION

NO	CLASSIFICATION	SITUATION	EMBARGO
A	Class I Recall	Products with major health risks	It should be under an embargo within 7 days
B	Class II Recall	Products with minor / unlikely health risks or sub standard	It should be under an embargo within one month

The class of product recall is classified according to the seriousness of quality defects and adverse events of the products.

LEVEL OF RECALL

NO	LEVEL OF RECALL
A	Up to all consumers (end users)
B	Up to all points of sales (e.g. pharmacies, beauty centers, beauty saloons, beauty outlets)
C	Up to all sub distributors (wholesalers, grocers).
D	Up to all importers and main distributors.

The level of the product recall depends on :

- the nature of the problem,
- the extent of the product's distribution and,
- the degree of hazard involved.

NOTIFICATION OF RECALL

- A sample of the recall notice must exist.
- Recall notices must be mailed in envelopes or faxed which can be clearly recognised as such.
- The notification of recall should include:
  - The name of the product, and pack size
  - The product batch number
  - The nature of the defect
  - The action to be taken
  - The urgency of the action (with reasons, indication of health risk, as appropriate)

RECALL NOTICES DISSEMINATION

LEVEL A : TO ALL CONSUMERS

- This level of recall will apply to Class I recall and carried out in the comparatively rare instances when it is necessary to try to stop all use of a product and to recover stock that has reached the end user.
- *When there is imminent danger the public are warned by a media release which is meant to urgently alert the public by radio, television and the press.*

RECALL NOTICES DISSEMINATION

LEVEL B : TO ALL POINTS OF SALES

- This level of recall will apply to Class II recall.
- All wholesalers will be identified and asked to provide contacts by telephone to obtain a list of all points of sale. These points can be established through a distribution record.
- *Recall notices will be mailed or faxed to all points of sales. At the same time representatives from the company will be sent to these points of sale to retrieve the stocks.*

RECALL NOTICES DISSEMINATION

LEVEL C : TO WHOLESALERS & STOCKISTS

- This level of recall will apply to Class II recall where consumers are not at any risk from administering the products.
- *The wholesalers and stockists will be contacted by the company representatives so that arrangement can be made to retrieve all stocks concerned from the wholesalers and stockists.*

RESPONSIBILITY

- The General Manager (the highest person in management) has the ultimate responsibility to direct the prompt removal of defective/recalled products from the market.
- The Quality Control Manager is responsible for the assignment of a Qualified Recall Team and determining the recall strategy.
- The Recall Team is responsible to carry out all recall activities under the supervision of Recall Team Leader.
- The Recall Team Leader is responsible for execution and coordination of all recall activities and to evaluate the effectiveness of the recall in a suitable interval.

PRODUCT RECALL MANAGEMENT

Organizing the return of the recalled product :

- Producer should settle a centre to collect and store all returned stocks of the recalled product;
- All needed data, quantity, and nature of product shall be noted down by this centre as records;
- Depending on the class of product recall, the producer should manage the most effective and appropriate mode of transportation of recalled products;
- All stocks of the recalled products will be stored separately in a different section of the warehouse to prevent any mix-up.
- The producer has to prepare a progress report of the recall including the reconciliation between the delivered and recovered quantities

FATE OF PRODUCT RECALL

- All available records and information on the returned stocks will be collected for evaluation purpose;
- A report of the affected stocks will be presented to the Product Recall Committee and the fate of the product shall be determined.
- The recalled product may be reworked if it meets appropriate standards and specifications e.g. mislabelling …, etc;
- The recalled product shall be destroyed if the conditions under which the cosmetics product casts doubt on its safety, identity and quality;
- Upon approval from the relevant authorities, proper destruction with appropriate precautionary measures will be taken to ensure total elimination of affected stock;
- Detail destruction process, the date and quantity shall be recorded.

THE FINAL RECALL REPORT

- **Final Recall Report**, a written evaluation summarizing the circumstances leading to the recall, corrective actions taken and the disposition of the recalled product, will be prepared by the Recall Team once the recall is considered closed.

- Report consists of:
  - Fate of the products
  - Reconciliation result
  - Disposal report/certificate if any
  - Copy of alert notification or any other form of notification

DOCUMENTATION

- Quality Control department is responsible to keep in a Recall File :
  - effectiveness checklist,
  - the Recalled Product Record,
  - the Progress Report,
  - the Recall Report, and
  - all other pertinent correspondence.
- The recall files will be retained for at least one year after the expiration date of the recall lot.