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26 JUNE 2025

Welcome to CTFA's Cosmetic Good Manufacturing Practice (cGMP) Training 2025

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Housekeeping Rules for the Hybrid Training Session

Welcome and thank you for joining us for today's hybrid training session. Please take note of the following housekeeping rules to ensure a smooth and respectful experience for all attendees:

Microphones: Kindly keep your microphone muted unless you are speaking, if you are joining virtually.

Cameras: If you are joining virtually, please keep your video turned off unless you are speaking. You are welcome to switch on your camera when asking a question or contributing to the discussion.

Questions & Participation:Questions will be addressed by the trainers during the Q&A session at the end of each topic.
Virtual attendees can use the chat function or the 'raise-hand' icon to participate.
In-person attendees will be given the opportunity to raise questions verbally.
If using the 'raise-hand' icon, kindly lower it once your question has been addressed.

Breaks: A comfort break is included in the agenda. Virtual participants are encouraged to remain logged in during this time.

Recording: Recording of the session by attendees is not permitted. Please note that the session will be recorded for internal purposes only and will not be shared.
A PDF copy of the presentation will be distributed after the session.

Technical Support:For virtual attendees, if you experience any technical issues, please contact Samantha at **samantha@ctfa.co.za**.

Post-Training Support: Should you require any additional support or notes after the session, feel free to contact Samantha via email.

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PROGRAM

08:45 - 09:00	Welcome
09:00 - 10:00	Training Session 1
10:15 - 11:15	Training Session 2
11:15 - 12:00	BREAK
12:00 - 13:00	Training Session 3
13:15 - 14:30	Training Session 4

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Session 1 - Overview

What does Cosmetic Good Manufacturing Practices entail?

ISO/SANS 22716:2011 Cosmetic GMP – content

Responsibilities and Company structure

Internal Training program

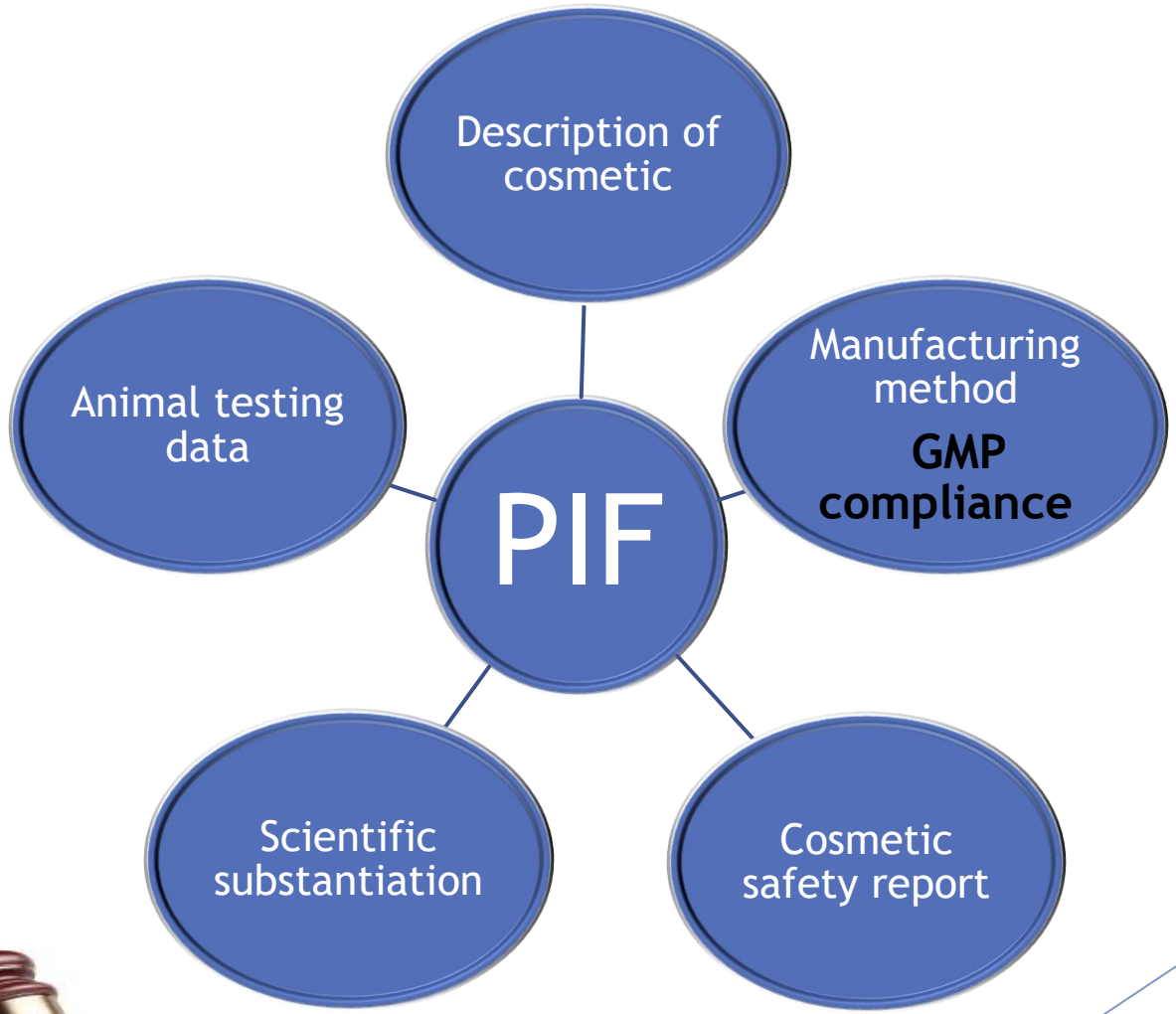
Premises design

Equipment design

Product Manufacture Process

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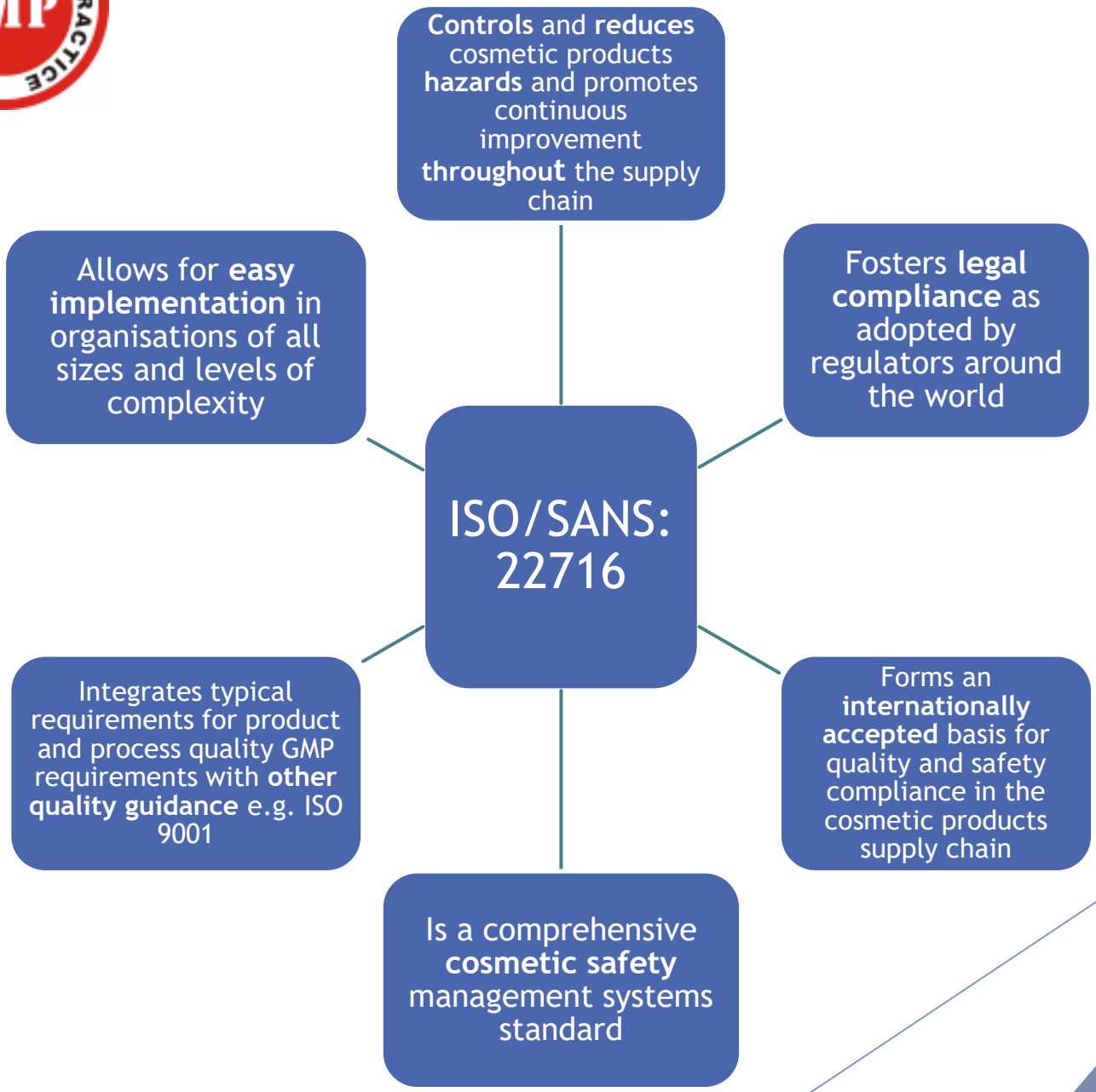
NDoH - Regulations relating to labelling, advertising and composition of Cosmetics R. 1469, 22 December 2017





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Relevance of ISO/SANS 22716:2011



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cGMP

<u>Objective</u>:
To define activities to obtain a product that meets defined characteristics



GMP constitutes the practical development of quality assurance throughout the plant's activities



Based on sound scientific judgement and risk assessment



Documentation is an integral part of GMP

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Contents of ISO/SANS 22716:2011



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Responsibilities

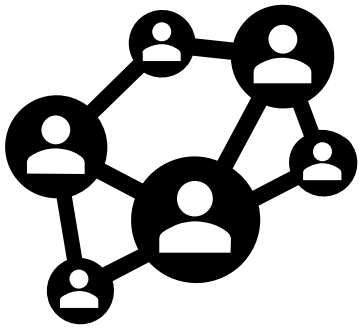
Person involved in implementation of GMP activities should have appropriate training to produce, control and store products with a defined quality

Organisational structure – adequate staffing levels depending on the diversity of production

Quality assurance and quality control - independent units from other business structures

Top management support essential

Participation and commitment of all departments and at all levels within the company



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Responsibilities



Individual job description for:

Head of Manufacturing/Operations

Head of Quality

Head of Quality:

Clear references to responsibilities and authority of quality issues such as:

Release product

Move product to different quality status

Deviation control and investigation

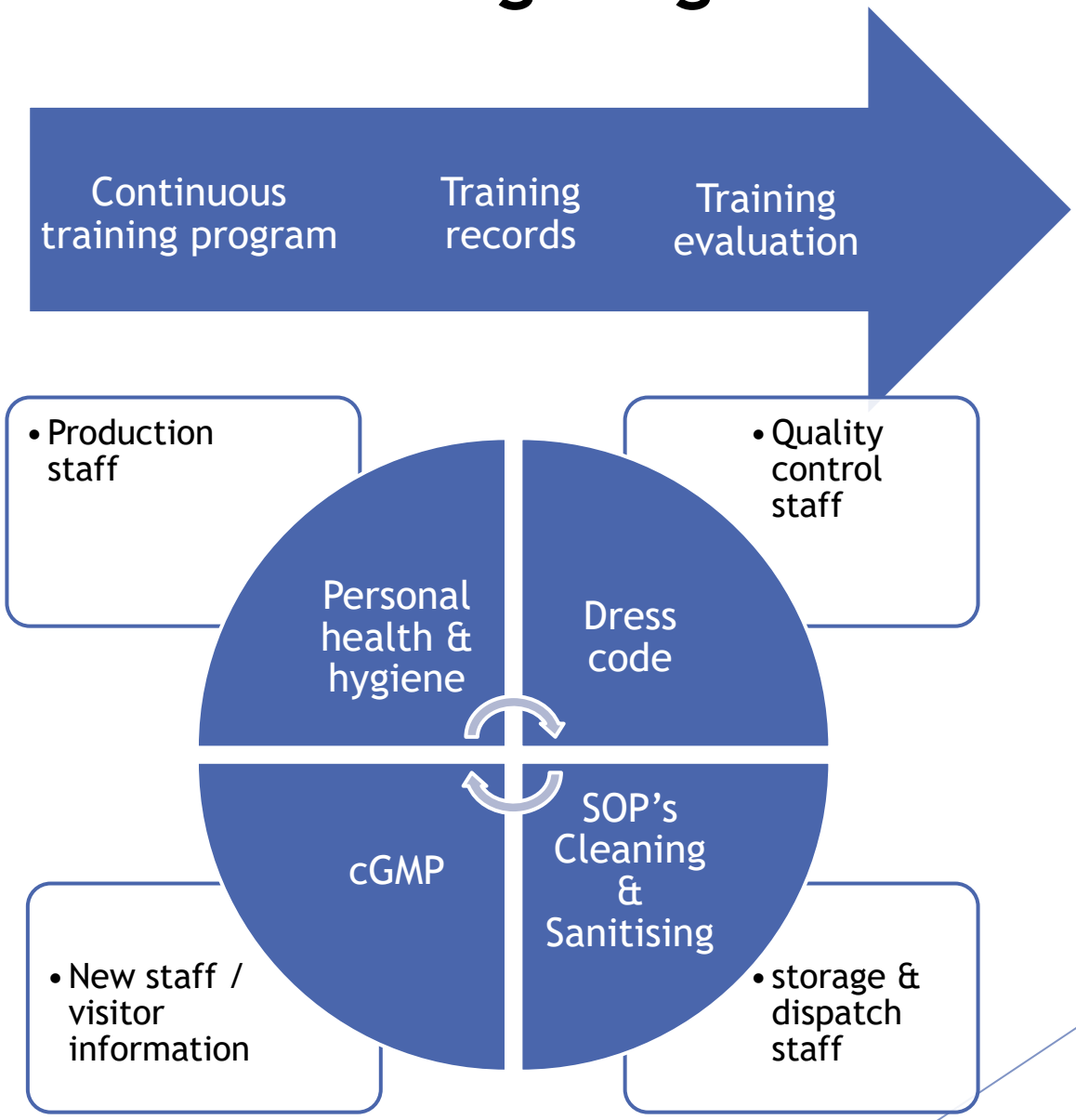
Change control

Internal audit

etc.

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Training Program



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Training Program



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Premises

Location design, construction & utilisation should:

- Ensure protection of product
- Allow efficient cleaning and sanitising (smooth and resistant surfaces, curved edges, screened / non -opening windows)
- Separate and defined areas for receipt and storage of raw material, packaging, production, packing, storage, quality control, dispatch
- Allow flow of material and people that minimises mix-ups, contamination and mistakes
- Separate washing and toilet facilities for personnel
- Ventilation
- Adequate and safe lighting
- Maintenance
- Pipework, drains and ducts – drip and condensation free, allow cleaning

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Premises

Manufacturing areas must be accessible to authorised personnel only

Special badge for the area

List of which areas open to whom

Entire facility requires a clear access control policy

Rooms for sensitive products or materials need to have special access controls in place

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Cleaning and Sanitisation

- Premises should be maintained in a clean condition.
- No wooden cleaning equipment, natural fibre brushes
- Essential to protect product from contamination
- Cleaning and sanitising agents should be specified and effective (HOW?)
- These must be clearly labelled and stored safely and their preparation and use instructions should be provided
- Cleaning and sanitising programme specific to each area – doc., identify
- For equipment assigned for continuous production or production of successive batches of same product - cleaning and sanitising at appropriate intervals. (DETERMINE INTERNALLY)

Pest Control

- Premises' design and construction - restrict access to pests
- Pest control programme should be in place
- Registered contractor must be used
- Type of pest controls to be used, bait numbering and locations, report at each inspection is required

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COMFORT BREAK

Session 2 - Overview

What does Cosmetic Good Manufacturing Practices entail?

ISO/SANS 22716:2011 Cosmetic GMP – content

Responsibilities and Company structure

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Premises design

Equipment design

Product Manufacture Process

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Equipment



SHOULD BE SUITABLE FOR INTENDED PURPOSE



SHOULD BE CAPABLE OF BEING CLEANED AND SANITISED AND MAINTAINED



DESIGNED TO PREVENT CONTAMINATION, DUST, MOISTURE, ETC.



TRANSFER HOSES AND ACCESSORIES NOT IN USE SHOULD BE CLEANED AND SANITISED AND KEPT DRY AND PROTECTED FROM DUST ETC.



STAINLESS STEEL MATERIAL



SHOULD BE LABELLED AND IDENTIFIED IN REGISTER AND CLEANING AND SANITISING LOGS

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Equipment: Calibration

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- Calibration done regularly, records kept
- Calibration done regularly using traceable and certified standards
- Calibration labels on instruments and equipment
- Calibration out of specification identify instrument or equipment as such, remove and investigate impact on product quality and appropriate steps to be taken

Equipment: Maintenance

Preventative maintenance programme should be in place to prevent unexpected downtime

Maintenance staff should be trained on GMP

Maintenance tools should be safely stored and not left unattended

Back-up systems should be available

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Product Manufacture Process



Product development



Product stability testing



Raw ingredient and packaging purchase, receipt and storage



Manufacturing operation



Packaging operation



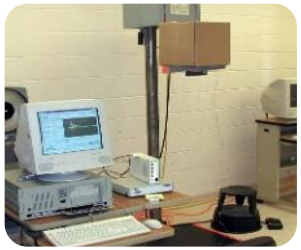
Finished product storage, shipment , returns

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Product Manufacture Process



Product development



Product stability testing



Raw ingredient and Packaging purchase, receipt and storage



Manufacturing operation



Packaging operation



Finished product Storage, Shipment , Returns

- Ingredient TDS / MSDS
- Safety, approval, efficacy of ingredients
- Bulk/ Finished product specification

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Product Manufacture Process



Product development



Product stability testing



Raw ingredient and Packaging purchase, receipt and storage

- Receiving checks
- QC sampling testing
- Approval/rejection



Manufacturing operation



Packaging operation



Finished product Storage, Shipment , Returns

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Raw material and Packaging material: Purchasing

Vendor or sub-contractor qualification programme is required
Supplier must be evaluated and approved through questionnaire and audits
Acceptance criteria, actions in case of defect or modifications, transport conditions must be established
Once approved supplier cannot change on financial terms but needs to go through similar qualification programme as set for earlier supplier (change control procedure (SOP))
Written and controlled quality approved list of suppliers and vendors is required
Re-assessment from time-to-time based on risk-assessment e.g. questionnaire or audit

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Raw material and Packaging material: Receipt and Storage

Receiving department checklist to verify physical quality has not been compromised e.g. damaged container, temperature and humidity, mix-ups and contaminations

Document check – purchase order = delivery document = product

Labelling of material = description/trade name, code number, date received, supplier name, batch number, expiry date

Material should be identified as accepted/rejected/quarantined - electronic or physical labelling system

Quality control department responsible for testing and release of material for use for production



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Raw material and Packaging material: Receipt and Storage

When can a Certificate of Analysis be used for approval of a raw material?

If there are established technical requirements,

If there is experience and knowledge of the supplier,

If there has been a supplier audit,

If supplier's test method has been agreed to.



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Raw material and Packaging material: Receipt and Storage

- Storage Conditions must be defined, controlled and monitored
- Materials must be sealed and stored off the floor on plastic pallets
- If repacked, labelling requirements must be adhered to
- Quarantined or rejected material should be stored in a demarcated area and identified and controlled through a system
- Stock rotation – practice FIFO (or FEFO)
- Periodic inventory checks should be performed to ensure stock reliability vs an electronic system
- Re-evaluation should be periodically carried out to re-evaluate the suitability of use of material



Raw material: Water



- Water treatment system to supply defined quality of water
- Quality control testing and monitoring of process parameter e.g. pH, conductivity, micro
- Sanitisation of system is necessary to prevent filters, pipes, storage tanks etc. from contamination
- Water stagnation should be avoided
- System should be made of material that will not impact the quality of water, e.g. leaching or contamination prone material

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RECAP

What does Cosmetic Good Manufacturing Practices entail?

ISO/SANS 22716:2011 Cosmetic GMP – content

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LUNCH BREAK



Session 3 - Overview

Product manufacturing process

Quality Control laboratory

Sub-contracting processes

Deviations in results

Product complaints / recalls

Internal audits

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Product Manufacture Process



Product development



Product stability testing



Raw ingredient and packaging purchase, receipt and storage



Manufacturing operation



Packaging operation



Finished product storage, shipment , returns

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Product Manufacture Process



Product development



Product stability testing



Raw ingredient and Packaging purchase, receipt and storage

WEIGHING PROCESS



Manufacturing operation



Packaging operation

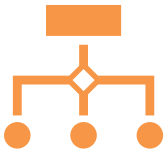


Finished product Storage, Shipment , Returns

- Equipment
- Batch sheet/ packing order
- Manufacturing/ packaging procedure
- Quality Assurance
- Quality Control
- Approval/rejection / deviation

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Production: Manufacturing Process



Requirements

Manufacturing documentation

Suitable equipment

Product Formulation

Batch sheet (with batch no. assigned)

Manufacturing procedure – sign off

Cleaning and sanitising instructions - sign off

Labelling

Start-up check sheet - sign off



Weighing of raw materials

Cleaning and sanitisation Instructions - sign off

Labelling and sealing

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Production: Manufacturing Operations

Identification of in-process operations – equipment used must be labelled

In-process control – clearly defined, acceptance criteria, appropriate action

Bulk product storage - suitable containers, defined area, appropriate conditions

- define storage duration
- re-evaluation before packaging

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Product Manufacture Process

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Product development



Product stability testing



Raw ingredient and Packaging purchase, receipt and storage



Manufacturing operation



Packaging operation

- Equipment
- Batch sheet/ packing order
- Manufacturing/ packaging procedure
- Quality Assurance
- Quality Control



Finished product Storage, Shipment , Returns

BULK STORAGE RE-EVALUATION

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Production: Packaging Operations



Requirements:

- packaging documentation
- suitable equipment
- packing order (list of packaging materials and quantities) with batch no. assigned
- packaging procedure (filling, closing, labelling, coding)
- cleaning and sanitising instructions for sign off
- Start-up checks for sign off

Assignment of batch number – each unit of finished product (traceability)

Packaging line identification – product and batch number being packaged

In-process control – clearly defined, acceptance criteria, appropriate action

Re-stocking of packaging

Identification and handling of work-in-process materials

Product Manufacture Process



Product development



Product stability testing



Raw ingredient and Packaging purchase, receipt and storage



Manufacturing operation



Packaging operation



Finished product Storage, Shipment , Returns

- Quality Assurance
- Quality Control testing

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Finished Product: Storage

Meet defined acceptance criteria

Storage, shipment and returns managed to maintain quality of finished product

Release of product – test methods, comply with specifications, quality control personnel

Storage – defined area, appropriate conditions for an appropriate length of time, permit organised storage (release area/quarantine area/ rejection area)

Identification – code, batch no, storage conditions, quantity

FIFO practice

Periodic inventory checks – inventory accuracy, acceptance criteria met, discrepancies must be investigated

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Finished Product: Shipment and Returns







Measures in place to ensure shipment of defined finished product

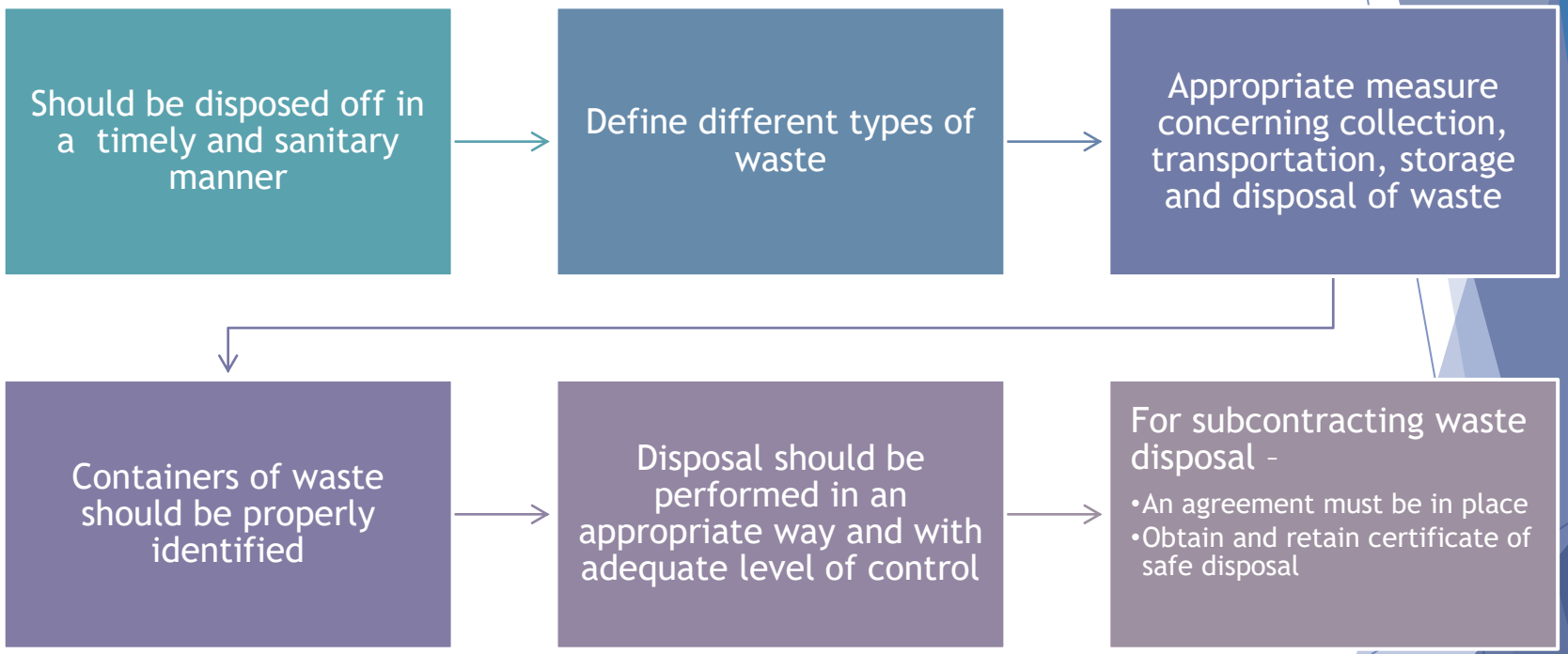
Precautions to maintain product quality

Returns

- Identified and stored in defined area
- Evaluated against defined criteria to determine disposition
- Release instruction given before returning to market
- Measures in place to avoid inadvertent redistribution of unreleased product

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Waste: Handling and Disposal



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COMFORT BREAK

Session 4 - Overview

Product manufacturing process

Quality Control laboratory

Sub-contracting processes

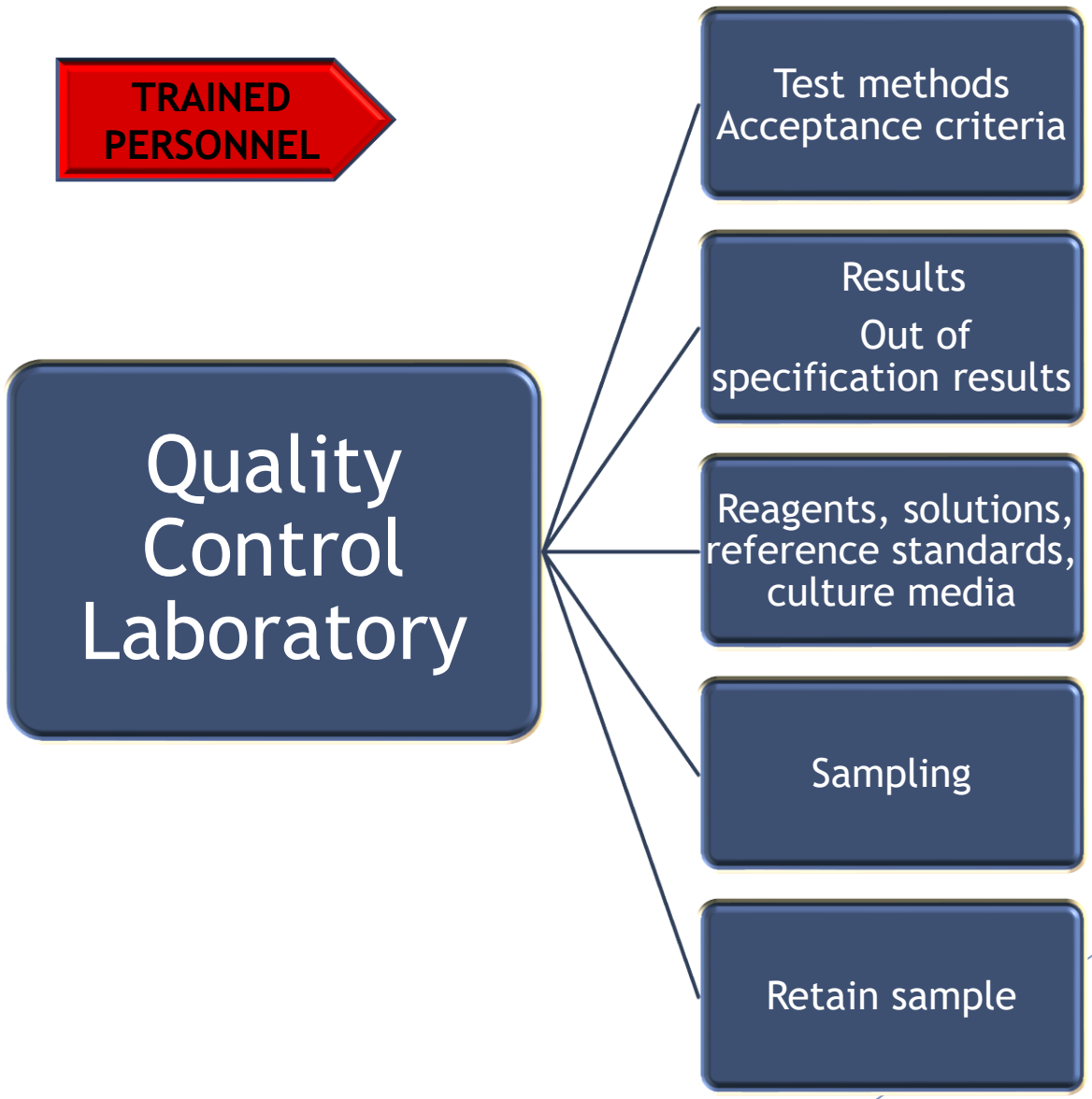
Deviations in results

Product complaints / recalls

Internal audits

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Quality Control Laboratory



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Quality Control Laboratory

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Plays a central role in GMP process

Quality control personnel must be trained

Equipment and instrumentation must be appropriate and accurate

Test methods, acceptance criteria for raw materials, packaging, bulk product and finished product must be defined

Results must be recorded, reviewed (approval/rejection/pending)

Out of specification results -

- reviewed by authorised personnel
- investigated and possible retesting
- decision(deviation/rejection/ pending)

Quality Control Laboratory

Reagents, solutions, reference standards, culture media – identified

Reagents, solutions, reference standards, culture media

- Identify: name strength/concentration/ signed/opening date/ storage conditions/ safety
- precautions when handling

Sampling should be performed by authorised and trained personnel

Sampling should be defined in terms of method, equipment, amount, precautions to avoid deterioration or contamination, identification, frequency

Identification: name, code, batch number, date of sampling, container number from which sample was taken, sampling point if applicable

Retain sample – raw material, bulk product, finished product in appropriate manner and designated area

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Raw ingredients/ Packaging/ Product: Out-of-specification

Rejected raw materials, packaging materials, bulk product, finished product

Decision to destroy or to re-process should be approved by responsible person in quality department

Method of reprocessing should be **defined** and approved in a SOP

Controls should be performed and results should be reviewed by authorized personnel to verify conformity

Actual re-processing steps need to be tracked and traced in the batch manufacturing records.

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Documentation

Documentation is an integral part of GMP

Document system must be established, designed, installed and maintained according to the particular company's organisational structure and product types e.g. electronic system or hard copy

SOP is required for development, control , distribution and review of all documents

To protect company

Define activities as per GMP	History of activities	Prevent risk of mis-interpretations	Prevent loss of information	Prevent confusion or error inherent to verbal communication

Documentation

Include procedures, instructions, specifications, protocols, reports, test methods and records of activities

Handwritten data should be legible with permanent ink, signed and dated, correction must be legible

- Correction pen disallowed



Practical examples of GMP documentation are:

- Log books for equipment, temperature and pressure charts
- ➢ Calibration certificates for scales, thermometers and pressure gauges
- ➢ Incoming raw material and packaging material documentation
- ➢ Batch processing documents = manufacturing and packaging records
- ➢ Test reports, deviation forms, corrective and preventive action forms, rejection forms, re-work forms

Documentation

Legible and comprehensive

Approved, signed and dated

Prepared, updated , withdrawn, distributed , classified

Referenced

Accessible

Removed when out-dated



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Documentation



- Original document must be archived and controlled copy should be used
- Duration of archive as per applicable legislation and regulations
- Secure storage of original document
- Storage can be hard-copies or electronic
- Back-up data should be stored at separate secure location at regular intervals

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Subcontracting



A written contract should be in place which is mutually confirmed and controlled by both parties

Subcontracting activities include: Manufacturing, packaging, analysis, cleaning and sanitisation or premises, pest control, equipment and premises maintenance, shipment

The contractor should be assessed and should have the means to honour the contract, comply with GMP guidelines and can perform operations as agreed.

Periodic audits should be carried out to verify that controls are still in place

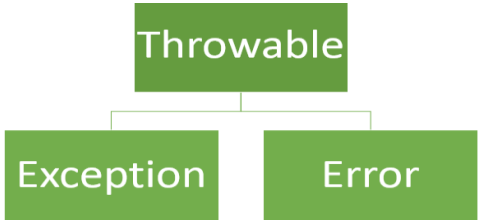
Information on the acceptable operations should be provided to the contractor

Any changes that may affect the quality of the services or products should be shared prior to implementation of the contract

Contract should be clear about respective duties and responsibilities of both parties

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Deviations



A deviation consist of temporarily setting aside specified requirements due to unforeseen circumstance.

It should be temporary and decision to do this must be authorised with sufficient data to justify its need

Deviations from specified requirements should be authorised with sufficient data to support the decision

Corrective action should be taken to prevent recurrence of the deviation or out-of-specification product

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Product complaints

All complaints should be centralised, logged with details, reviewed, investigated and followed-up

Investigation and follow-up should include:

steps to prevent recurrence of the defect

checking other batches of the same product for defect

Review of complaints should be done periodically to check for trends or recurrence of a defect

This is part of the post-marketing surveillance requirement in the Draft regulations

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Product Recalls

A recall procedure should be in place and re-visited regularly

Personnel should be trained on how to handle a product recall and only an authorised person should co-ordinate the recall process

Operation should be initiated promptly and in a timely manner

Appropriate authorities should be notified of recalls which could impact **consumer safety**

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Product Recalls

Recalled product should be identified and stored separately in a secure area while waiting a decision

Product recall process and procedure should be periodically evaluated

Change control – changes that could affect product quality should be approved and performed by authorised personnel on the basis of sufficient data

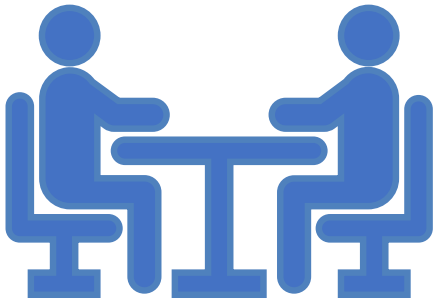
Internal Audit



- Monitor the implementation and status of cGMP and to propose corrective action where required.
- Competent personnel required to carry our independent and detailed internal audit regularly or on demand
- Observations should be recorded, evaluated and shared with management
- Where corrective actions are required a follow-up audit should be carried out and the findings closed

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QUESTION & ANSWER SESSION



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Thank you!