Awareness Training on ISO 22716

Good Manufacturing Practices (GMP)

About Qdot

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Qdot managed by a team of experienced professionals, is committed to promote quality & excellence culture in GCC (UAE, QATAR, KSA, Oman, Kuwait, Bahrain)by providing below mentioned services.

Management System Services

- ISO 9001, ISO 14001, ISO 45001, HACCP, ISO 22000, FSSC 22000, BRC GS, Halal, ISO 22716 (GMP),Organic Certification, ISO 27001, ISO 41001, ISO 37001, ISO 50001, ISO 55001, ISO 17020 & ISO 17025 etc

Training Services

- IRCA Approved Lead Auditor
- Awareness & Trainings on ISO Standards

Product Registration

- SABER, SQM, SFDA, CITC, IECEE, ECAS, EQM, RoSH, EESL, SLCP, G-Mark etc

Social Compliance

- SEDEX-SMETA, SA 8000, amfori BSCI, ISO 26001, WRAP, GRLI, ESG, CTPAT etc

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Introduction

- These guidelines are intended to provide guidance regarding Good Manufacturing Practices for cosmetic products.
- These guidelines have been prepared for consideration by the cosmetic industry and take into account the specific needs of this sector.
- These guidelines offer organizational and practical advice on the management of the human, technical and administrative factors affecting product quality
- **Documentation is an integral part of Good Manufacturing Practices**

1. Scope

"Guidelines for the production, control, storage and shipment of cosmetic products"

Note: These guidelines are not applicable to research and development activities and distribution of finished products

- These guidelines cover the **quality aspects of the product**, but as a whole **do not cover safety aspects** for the personnel engaged in the plant, nor do they cover aspects of **protection of the environment**.

- Safety and environmental aspects are inherent responsibilities of the company and could be governed by local legislation and regulation

3. Personnel

"Persons involved in the implementation of the activities described in these guidelines should have **appropriate training** to **produce, control and store products** with a defined quality"

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3.2 Organization

- Organizational structure should be defined
- Adequate staffing levels in the different scope of activity
- The organization chart should show the independence, from the other units of the plant
- Adequate number of properly trained personnel

3.3 Key responsibilities

Management responsibilities

- The organization should be supported by the top management
- The implementation of GMP should be the responsibility of top Management
- Define Access authorization to different areas

Responsibilities of personnel

- know their position
- know their defined responsibilities and activities;
- personal hygiene
- have adequate education training and skills

3.4 Training

Existing Staff

- Training Need Analysis
- Training Plan
- Training Execution

Newly recruited

- Besides basic training on the theory and practice of Good Manufacturing Practices

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3.5 Personnel hygiene and health

- Hygiene programs should be established
- Personnel should be instructed to use hand washing facilities
- wear appropriate clothing and protective garments to avoid contamination of cosmetic products
- Eating, drinking, chewing, smoking or the storage of food, drink or smoking materials or personal medication in the production, control and storage areas should be avoided
- Any unhygienic practice should be forbidden
- **Personnel Health**
- **Visitors and untrained personnel**

4. Premises

4.1 Principle

Premises should be located, designed, constructed and utilized so as:

- to ensure protection of the product;
- to permit efficient cleaning, if necessary, sanitizing and maintenance;
- to minimize the risk of mix-up of products, raw materials and packaging materials
- Design decisions should be based on the type of cosmetic product produced

4. Premises

- Types of area (Separate Areas)
- Space
- Flow
- Floors, Walls, Ceiling , Windows
- Washing & Toilet Facility
- Lighting
- Ventilation
- Pipework, Drain & Duct
- Cleaning and sanitization
- Maintenance
- Consumables
- Pest control

Principle

- Premises must be located to minimize risks of cross-contamination, e.g. **not** located next to a bad surrounding

General

The layout and design should aim to:

- Minimize risks of errors
- Permit effective cleaning
- Permit effective maintenance
- Avoid cross-contamination, build-up of dirt and dust
- Avoid any adverse effect on the quality of products

Design Principles

Keep in mind:

- Material flow
- People flow
- Process flow

Ensure logical flow

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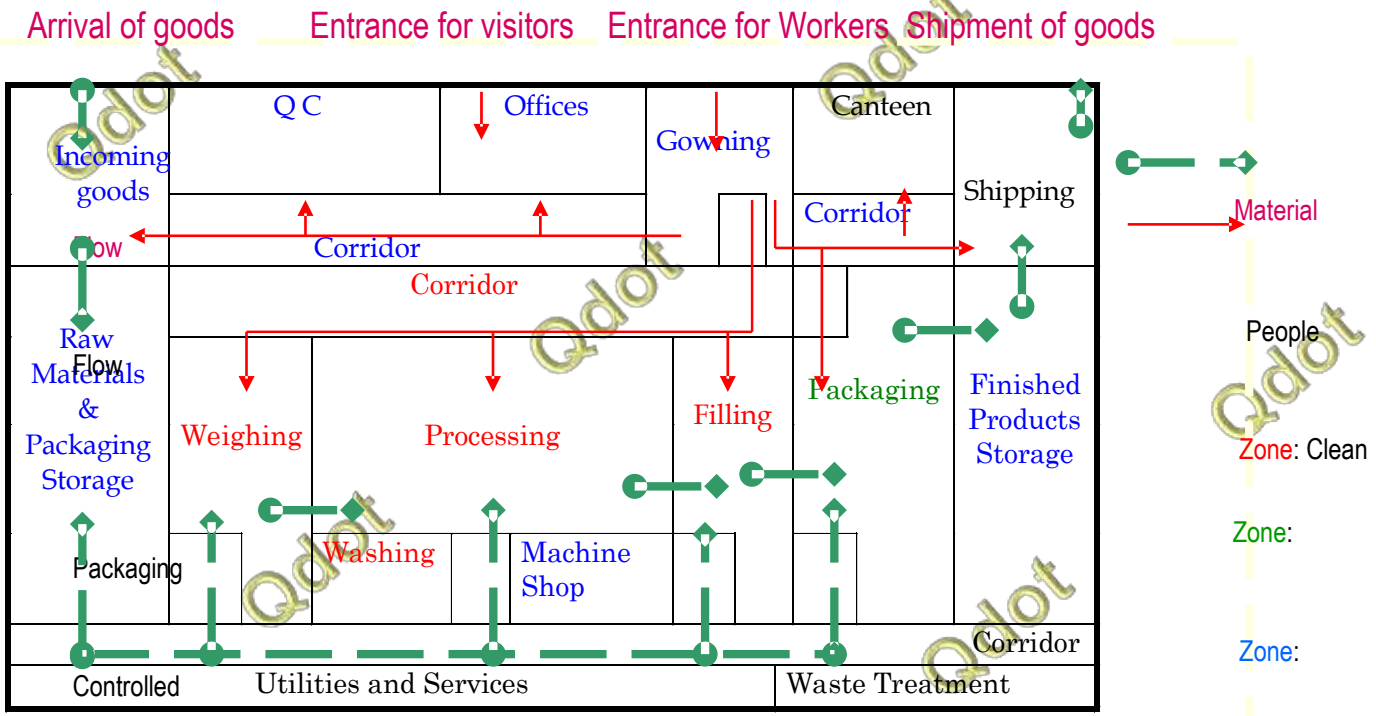
Example of Materials and People Flow



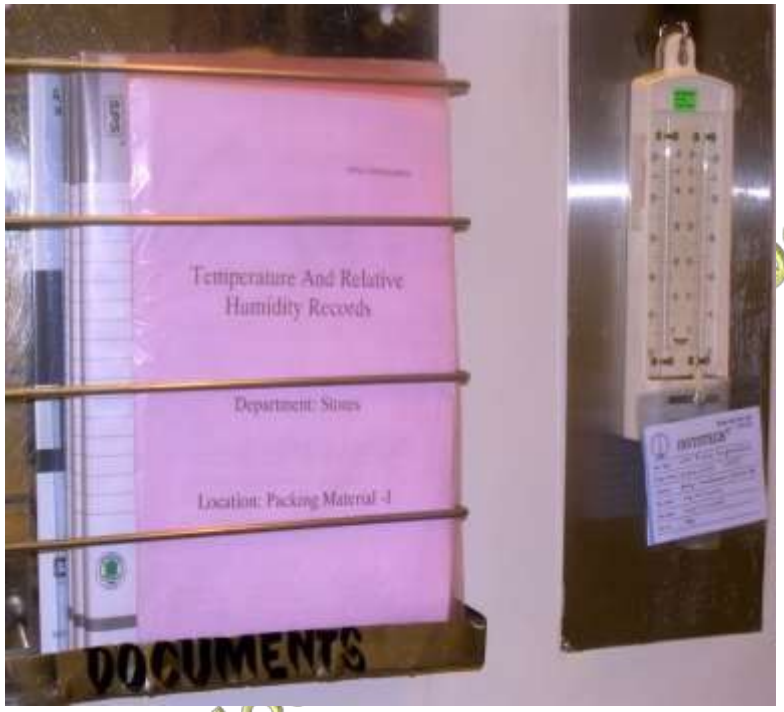
Construction

- Suitable materials
- Electrical supply
- Suitable lighting (especially for visual on-line checks)
- Temperature and relative humidity control
- Appropriate and effective ventilation

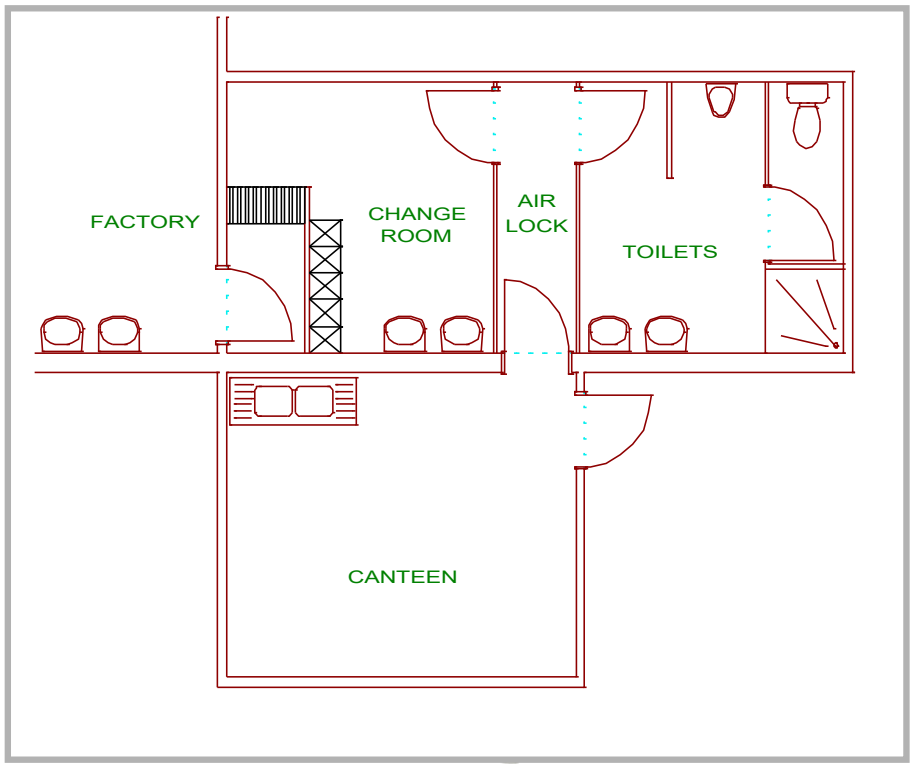
These may affect products during manufacture or storage as well as functioning of equipment

Conditions

- The temperature and relative humidity should be controlled, monitored in accordance with an SOP, and the results recorded. The limits should be appropriate according to the materials stored and product processed



Premises



Premises

- Separate receiving and dispatch bays
  - *Materials and products protected from weather*
- Area to clean incoming materials provided

Premises

Premises

Premises

Premises

General Storage Areas

- Appropriate temperature and relative humidity conditions within defined limits
  - *Provided, controlled, monitored and recorded*
- Good storage conditions: clean, dry and appropriate lights

Packaging Material Storage Areas

Printed packaging materials

- Critical to ensure compliance with correct labelling of products
- Special attention to sampling
- Special attention to safe and secure storage
- Ensure compliance with specifications, prevent mix-ups

Premises

Design of areas for weighing of materials

- Proper air supply
- Dust control measures (including extraction of dust and air)
- Easily cleanable surfaces
- No areas for dust accumulation
- Protection of material, product and operator

Premises

Production Areas

Minimize risk of cross-contamination:

- Dedicated and self-contained facilities for sensitive products

Premises

Finishing of floors, walls and ceilings

Much better

5. Equipment

5.1 Principle

"Equipment should be suitable for the intended purpose and capable of being cleaned and, if necessary, sanitized and maintained"

5. Equipment

- Equipment design
- Installation
- Calibration
- Cleaning and sanitization
- Maintenance
- Consumables
- Authorizations
- Back-up systems

6. Raw Materials and Packaging Materials

6.1 Principle

"Raw materials and packaging materials that are purchased should meet defined acceptance criteria relevant to the quality of finished products"

6. Raw Materials and Packaging Materials

- Purchasing
- Receipt
- Identification and status
- Release
- Storage
- Re-evaluation
- Quality of water used in production

7. Production

7.1 Principle

"At each stage of manufacturing operations and packaging operations, measures should be taken to produce a finished product that meets the defined characteristics"

7.2 Manufacturing operations

- Availability of relevant documents
- Start-up checks
- Assignment of a batch number
- Identification of in-process operations
- In-process control
- Bulk product storage
- Re-stocking raw materials

7.3 Packaging operations

- Availability of relevant documents
- Start-up checks
- Assignment of a batch number
- Packaging line identification
- In-process control
- Re-stocking of packaging materials
- Identification and handling of work-in-process

8 Finished products

8.1 Principle

- Finished products should meet the defined acceptance criteria.
- Storage, shipment and returns should be managed in a manner so as to maintain the quality of finished products.

8. Finished products

- Release
- Storage
- Shipment
- Returns

9. Quality control laboratory

9.1 Principle

"The quality control laboratory is responsible for ensuring that the necessary and relevant controls, within its activity, are carried out for sampling and testing so that materials are released for use and products are released for shipment, only if their quality fulfils the required acceptance criteria"

9. Quality control laboratory

- Test methods
- Acceptance criteria
- Results
- Out-of-specification results
- Reagents, solutions, reference standards, culture media
- Sampling
- Retain sample

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10. Treatment of product that is out of specification

- Rejected finished products, bulk products, raw materials and packaging materials.
- Reprocessed finished products and bulk products

11. Wastes

11.1 Principle

"Wastes should be disposed of in a timely and sanitary manner."

11. Wastes

- Types of waste
- Flow
- Containers
- Disposal

12. Subcontracting

12.1 Principle

"A written contract or agreement should be established, mutually confirmed and controlled between the contract giver and the contract acceptor covering subcontracted activities.."

13. Deviations

- Deviations from the specified requirements should be authorized with sufficient data to support the decision.
- Corrective action should be made to prevent recurrence of the deviation

14. Complaints and recalls

- All complaints that fall within the scope of these guidelines and are communicated to the plant should be reviewed, investigated and followed-up on, as appropriate.
- When a product recall decision is made, appropriate steps should be taken to complete the recall within the scope of these guidelines and to implement corrective action.

15. Change control

- Changes that could affect the quality of product should be approved and performed by authorized personnel on the basis of sufficient data

16. Internal audit

"An internal audit is a tool which is designed to monitor the implementation and the status of these cosmetic Good Manufacturing Practices and, if necessary, to propose corrective actions."

17. Documentation

- Type of Document
- Writing, approval and distribution
- Revision
- Archiving

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