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INFOMATICS

UNDERSTANDING ISO 22716:2007 COSMETIC GMP

GOOD MANUFACTURING PRACTICES

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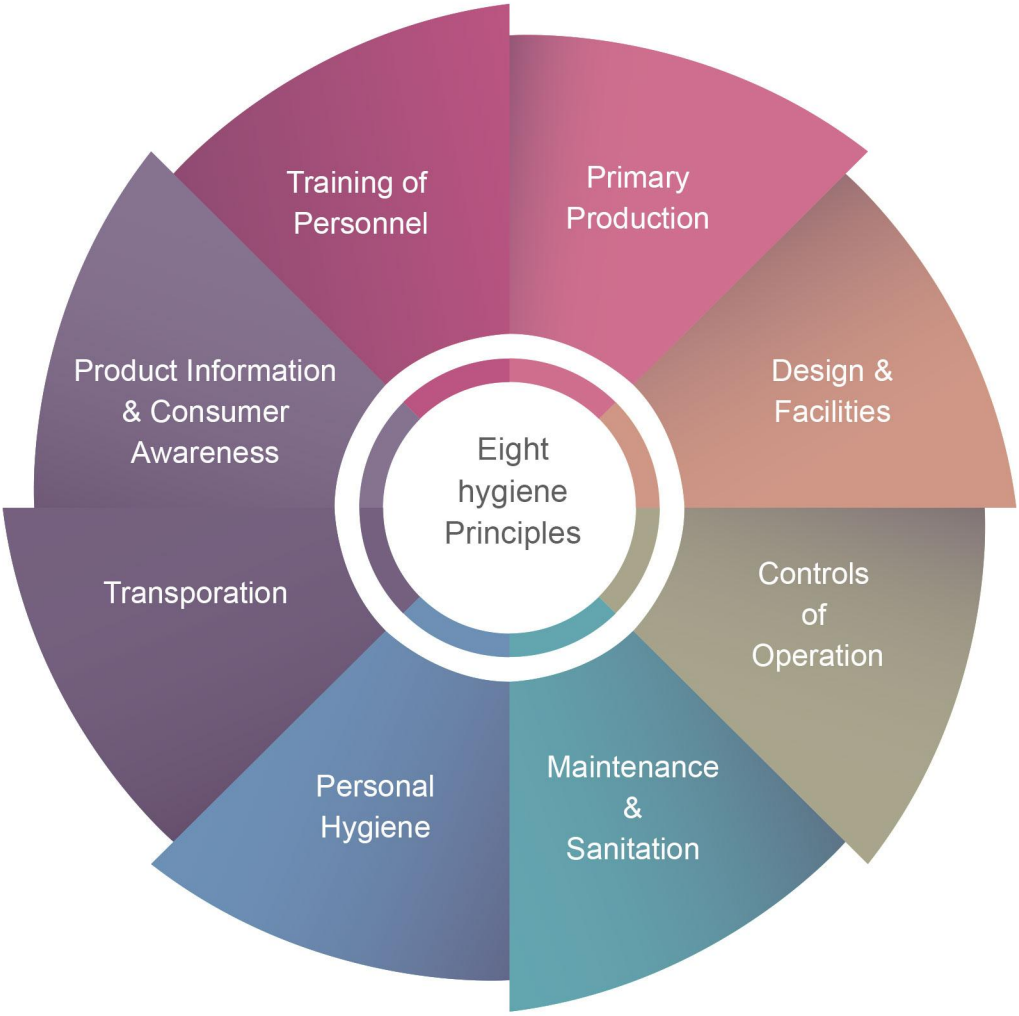
WHAT IS ISO 22716?

- One of the pillars of the EU cosmetics Regulation, ISO 22716:2007 gives guidelines for the production, control, storage and shipment of cosmetic products.
- To ensure Consumer Safety, cosmetic products placed on the EU market should be produced according to good manufacturing practice (GMP)
- The objective of the GMP is to define the activities which lead to the final product cor responding to the expected specifications, and therefore product safety

- Cosmetics Good Manufacturing Practices are a set of hands-on advice, operational rules and organizational guidelines especially focused on human, technical and administrative factors affecting product quality.
- ISO 22716 is the standard describing the Cosmetics Good Manufacturing Practices. It has been written in collaboration with cosmetics industry professionals and promotes best-in-class methods.
- Scope of ISO 22716 is not only limited to production activities but also includes control, storage and expedition.



Benefits of ISO 22716 - Cosmetics Good Manufacturing Practices.

Implementation of theGMP program provides the following benefits to your organization:

- Validates conformity of the Management System with the new legal requirements
- Develops sustainable respect amongst customers, employees, stockholders, regulators and competitors towards your organization, for a demonstrable commitment to GMP.
- Reduces operating costs, as rework and penalties, due to non-compliance, are minimized/eliminated.
- Enhances operating efficiencies with improved quality standards.
- Provides leverage to access European and Global Markets.
- Inspire consumers' confidence.
- Increases competitive market appeal.
- Standardized Quality improves product consistency and acceptance in the market.
- Risk-free status enhances reliability of product and trust in your organization.

We partner with your organization to implement ISO 22716 Good Manufacturing Practices

The highly experienced quality management professionals at Lakshy help you to design and implement ISO 22716 Good Manufacturing Practices.Our dedicated approach to your success and a host of comprehensive services are all aimed towards helping your organization achieve ISO 22716 Good Manufacturing Practicescertification.

We partner with you through the process of becoming ISO compliant by:

- Conducting an initial gap analysis.
- Helping you establish policies and objectives.
- Identifying documentation requirements.
- Coordinating document preparation, reviews, approvals, and issuance.
- Managing implementation schedules, training, follow-up actions.
- Aidingyour selectionof a Registrar with the appropriate industry experience.
- Achieving successful accreditation.

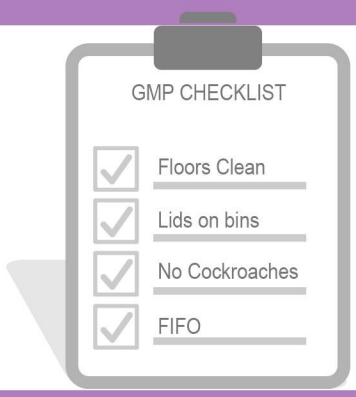
In addition to consulting (onsite and online), we provide the following trainings:

- ISO 22716 Overview Training
- ISO 22716 Good Manufacturing Practices Training
- ISO 22716 Internal Auditor training
- ISO 22716 Implementation training

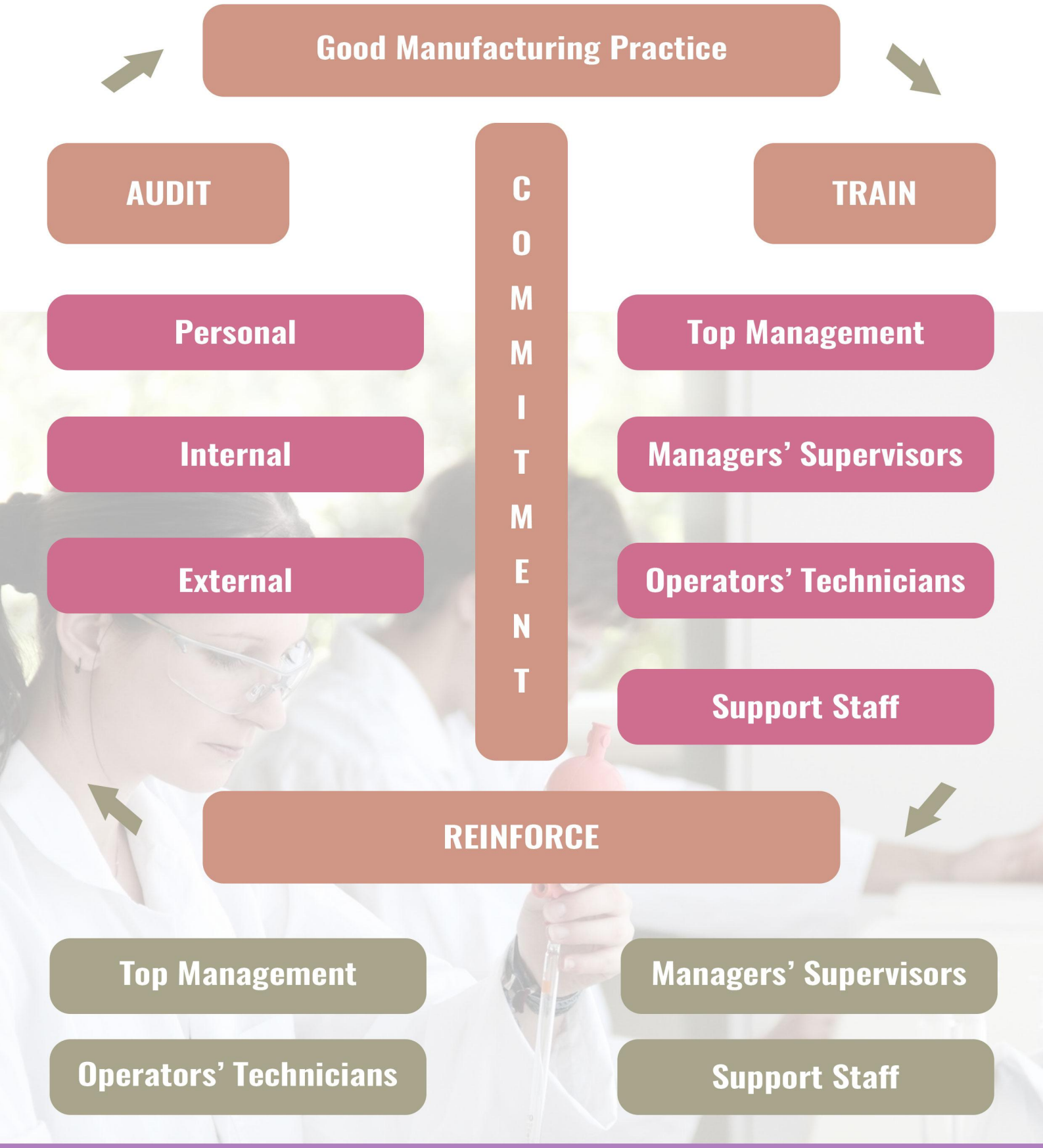
Focus areas of ISO 22716 Good Manufacturing Practices.

ISO 22716 provides guidance in broadly 5 areas of your business:

- Personnel
- Premises and equipment
- Production
- Quality control
- Quality systems



Good Manufacturing Practice



FDA Good Manufacturing Practice (GMP) Process

Control our design/ developement

Control our raw materials & suppliers

Control our production process

Control our sub contractors/ acquisition

Manage crisis alert and responses

Steps To Establishing An Effective GMP

1. Committed focus on GMP by the Top Management, for a top-down approach.
2. Define responsibilities for GMPawareness trainingandmonitoring of Hygiene and Health.
3. Monitor the upkeep of the Premises, Lighting, Ventilation and Sanitation, with stringent checks on daily cleaning and the regular maintenance and calibrations of equipment's.
4. Only use Approved Suppliers for the procurement of Raw Material and packaging Material.
5. Implement a proper Storage System with systematic Identification and Labelling of Raw Material.
6. Apply strict control measures at each stage of manufacturing and packaging operations.
7. Storage, shipment and returns should be managed with a view to sustain the quality of finished products.
8. Optimize the output of the Quality Control laboratory to confirm that products comply with acceptance criteria.
9. Quality Processes for monitoring, measurement, corrective action & prevention.
10. Establish internal audit program and training, for conducting an initial audit to evaluate conformity to GMP requirements.
11. Final Certification Audit.

Documentation

Examples

Quality Manual
Quality Policy Statement

Processes, e.g.,train personnel

Sample testing & Equipment Calibration Step-by-Step

Maintenance Test & Training Records

- A policy documents the intent and goal of the organisation to conform to ISO 22716 Requirements.
- Quality manual describes the approaches to achieve quality data. It includes quality policy.
- A process describes how various quality requirements can be achieved.
- Standard operating procedures or working procedures are step by step instructions on how to exactly perform a specific task.
- Records are generated on day by day basis.
- All records should be well controlled.

With a team of highly qualified consultants and trainers, having vast industrial experience, we partner with organizations across the world to implement and achieve ISO 22716 Good Manufacturing Practices.

Our consulting approach is highly professional, time bound and effective, resulting in ease of implementation, and adds value to the business processes of the client.

Contact us at info@iso-consultants.com to get your organization ISO 22716 Good Manufacturing Practices Accredited.