Implementation & Documentation Requirements for ISO 22716:2007 Certification

ISO 22716 is an international standard that gives guidance for the production, control, storage and shipment of cosmetic products. It deals with all aspects of the supply chain of cosmetic products. The guidelines cover the quality and safety of the product, and they affect manufacturers, as well as suppliers, retailers, brand holders and retailers of cosmetic products. It does not, however, cover safety aspects for the personnel engaged in the plant, or the protection of the environment.

With ISO 22716 implementation using MyEasyISO software platform, not only do you receive a guideline for your business' path, you also commit to ensuring the safety, quality and excellence of your product.

In accordance with the ISO 22716 guide, the manufacturing system of your company will be audited and inspected on the following areas:

- Complaint and recalls
- Contracting/ subcontracting
- Documentation and records
- Internal audits and Laboratory quality controls
- Material management
- Packaging and labelling
- Personnel, HR & Training
- Premises, buildings or facilities maintenance
- Production and in-process controls
- Storage and distribution

Below you´ll find all the documentation that it is needed to meet ISO 22716:2007, Cosmetics GMP & how MyEasyISO can make this compliance simple, easy, employee friendly, effective and always audit ready :

Section		Requirement		Required documentation	
				Description	MyEasyISO Module
3	Personnel	3.3.2	Responsibilities of personnel	Job Descriptions	HR
		3.4	Training	Personnel and Training	HR
				Initial Orientation Program	HR
		3.5.1	Personnel Hygiene and Health	Gowning, Hand Washing and Conduct	HR
		3.5.2		Response Plan for Incidents Involving Biohazards	Emergency Preparedness
		3.6	Visitors and Untrained Personnel	Initial Orientation Program	HR
4	Premises	4.10	Premises Cleaning and Sanitation	Premises Cleaning and Sanitation	Inspection
		4.11	Maintenance	Premises Maintenance Program	Maintenance
		4.13	Pest Control	Pest Control	Maintenance
5	Equipment	5.3	Installation	Equipment Installation Qualification	Inspection
		5.4	Calibration	Control of Measuring and Test Instruments	Calibration
		5.6	Equipment Cleaning and Sanitation	Equipment Cleaning and Sanitation	Inspection
		5.6	Maintenance	Equipment Maintenance	Maintenance
				Equipment Technical Data Sheet	Maintenance
				Equipment Maintenance Checklist	Maintenance
				Equipment Maintenance Request	Maintenance
				Equipment Maintenance Work Order	Maintenance
				Equipment Maintenance Record	Maintenance
6	Raw Materials and Packaging	6.2	Purchasing	Purchasing and Assessment of Suppliers	Purchase
				Supplier Audits	Purchase
				Supplier Corrective Action Request (SCAR)	Purchase
				Performance Evaluation of Suppliers of Significant Materials and Services	Purchase
		6.3	Receipt	Incoming Inspection	Quality
				Raw materials specifications	Operations
		6.4	Identification and Status	Identification & Traceability of Raw Materials, Manufactured, and Packaged	Quality

Section		Requirement		Required documentation	
				Description	MyEasyISO Module
7	Production	7.2.1 7.2.3 7.2.4 7.2.5 7.2.6 7.2.7	Manufacturing operations: Availability of relevant documents	Production and Process Control of Chemical Process	Operations
				Production and Process Control of Machining Process	Operations
				Product Specifications	Operations
				Product Bill of Materials (BOM)	
				Production Work Order	Operations
				Work Instructions for the use of specific equipment (boiler, reactors, filters, drillers,	Documented Information
				In-Process Inspection (for chemical and machining	Quality
		7.2.2	Start-up Checks	Production Line Clearance Procedure	Documented Information
		7.3.1 7.3.3 7.3.4 7.3.5	Packaging Operations	Production and Process Control of Packaging Process	Documented Information
				Packaging Product Specifications	Documented Information
				Packaging Product Bill of Materials	
				Packaging Work Order	Purchase
7	Production	7.3.1	Packaging Operations (continued)	Work Instruction for the use of specific equipment (as sealers)	Documented Information
		7.3.2	Start-up checks	Packaging Line Clearance Procedure	Documented Information
		7.3.6	In process Control	Packaging In-Process Inspection	Documented Information
8	Finished Product	8.1 8.2 8.3	Finished Products	Final product specification	Quality
				Final Inspection	Quality
				Product Release	Quality
		8.4	Shipment	Shipping Procedure	Documented Information
		8.5	Returns	Customer Returns	Documented Information

Section			Requirement	Required documentation	
				Description	MyEasyISO Module
9	Quality Control Laboratory	9.2	Test Methods	Analysis Procedures (for those not included in the EU Pharmacopoeia)	Quality
		9.3	Acceptance criteria	Raw material, in process or final product specifications, establishing the acceptance	Quality
		9.4	Results	Raw material, in process or final testing results forms (indicating the acceptance criteria)	Quality
		9.5	Out-of-Specification Results	OOS Procedure	Non-conformity
		9.6	Reagents, solutions, reference standards, culture media	Receipt and Storage of Chemicals	Documented Information
				Preparation and Standardization of Solutions	
				Cleaning and washing of laboratory glassware	
				Laboratory Basic Safety Rules	Documented Information
		9.7	Sampling	Sampling Procedure	
		9.8	Retain Sample	Retains	
10	OOS product	10.1	Rejected finished products, bulk products, raw materials and packaging materials	Control of Non-Conforming Product	Non Conformity
				Non-Conforming Event Procedure	
				Root Cause Analysis (RCA) Procedure	
		10.2	Reprocessed finished products and bulk products	Rework Procedure	
11	Wastes		Wastes	Handling, Storage, Treatment and Disposal of Wastes	Waste Management
12	Subcontracting			Subcontractor management & Control	Purchase
	Deviations	13.1 13.2	Deviations	Deviation Procedure	Non Conformity
14	Complaints & Recalls	14.2	Product Complaints	Customer Complaints Management	Customer Compliant
		14.3	Product Recalls	Recall Procedure	Non Conformity
15	Change Control		Change Control	Creating and Changing Specifications	Change Management
				Risk Assessment Procedure	Internal Audit

Section			Requirement	Required documentation	
				Description	MyEasyISO Module
16	Internal Audits		Internal Audits	Corrective and Preventive Action System Procedure	Non Conformity
				Internal Audits Procedure	Internal Audit
17	Documentation		Documentation	Document Control and Data Control Procedure	Documented Information
				Signature Authority for Controlled Documents	
				Document Retention Storage and Disposition	
				Good Documentation Practices