ISO 22716 COSMETICS - GOOD MANUFACTURING PRACTICES

WHO IS CONCERNED?

- Any business organisation which:
- Produces or manufactures cosmetic products under its own trademark;
- Produces or manufactures cosmetic products for third parties.

FRAMEWORK

EU Regulation (EC) no. 1223/2009 of the European Parliament and of the Council of 30 November 2009 provides that, to ensure their safety, cosmetic products placed on the market must be produced according to Good Manufacturing Practices (GMP).
The ISO 22716 standard is the first international document laying down the principles for the application of Good Manufacturing Practices by companies that produce cosmetics and is the harmonised standard pursuant to Article 8 of Regulation (EC) no. 1223/2009. ISO 22716 which applies to production, control, storage and shipment of cosmetic products. It does not apply, however, to research and development activities or to the distribution of finished products.

ISO 22716 specifically governs the following areas:

- Personnel (organisational structure, professional training, hygiene and health);
- Management, cleaning and maintenance of premises and equipment;
- Purchasing and control of raw materials and packaging materials;
- Production, packaging and release of finished products;
- Qualifications and monitoring of subcontractors;
- Management of non-conforming products, re-evaluations and product recalls;
- Management of deviations and change control;
- Management of improvements following the implementation of corrective and preventive actions, based on deviations and complaints data analysis;
- Necessary documentation (procedures / operating instructions / records) for proper management of the production, control and delivery processes of cosmetic products.

OUR SERVICES

Benefiting from a long experience in assessing company management systems in the cosmetics industry and its related sectors such as pharmaceutical products and medical devices, Certiquality provides cosmetics manufacturers with certification services against the requirements of the ISO 22716 standard.

Our services can be performed in two different ways:

- CERTIFICATION AGAINST THE ISO 22716 STANDARD
- VERIFICATION OF GMP APPLICATION BY SUPPLIERS

A) CERTIFICATION AGAINST THE ISO 22716 STANDARD

The main stages of the certification process are:

- ✓ An optional preliminary audit to assess the condition of the company's management system against the requirements of the ISO 22716 standard. A gap analysis will identify the system's strengths and potential areas for improvement;
- ✓ A certification audit, with the aim of assessing the compliance of the management system to the requirements of ISO 22716, through a documentary analysis and on-site findings;
- ✓ Issuance of the certificate of conformity;
- ✓ Annual surveillance audits and triennial re-assessment audits.
- ✓ For companies already ISO 9001-certified by Certiquality, the certification and subsequent periodic audits can be carried out in conjunction with planned surveillance and re-assessment activities.

YOUR BENEFITS

Certification against ISO 22716 provides your company with the following abilities:

- ✓ Ensure compliance with applicable regulatory requirements concerning GMP for cosmetics;
- ✓ Make interested parties (customers, distributors, importers, and consumers) confident that your production is carried out in accordance with GMP;
- ✓ Integrate a specific sectoral certification within an ISO 9001 quality management system certification.

B) VERIFICATION OF GMP APPLICATION BY SUPPLIERS

Whenever a manufacturer of a cosmetic product delegates its production to a third party, such manufacturer must ensure that Good Manufacturing Practices are followed.
Article 11 of EU Regulation (EC) no. 1223/2009 provides that, for each cosmetic product placed on the market, a product information file must be made available, the contents of which must include a description of the manufacturing method of and a statement on compliance with GMP.
The manufacturer, in order to fully comply with regulatory requirements, must therefore assess the subcontractor, define the contractual agreements that will ensure that its production of cosmetics follows GMP and make the necessary checks (inspections of manufacturing sites).
Certiquality can perform, on behalf of the manufacturer, inspections at the manufacturing sites of the supplier in order to verify conformity with the harmonised standard UNI EN ISO 22716 and to any additional specific requirements defined by the contract giver (manufacturer).
Our inspection services are divided into the following phases:

- ✓ Planning activities with the manufacturer, to include the preparation of any necessary check-lists;
- ✓ Documentary analysis;
- ✓ On-site audit;
- ✓ Issuing of the final report.

PROFESSIONAL TRAINING

Certiquality complements its audit activities with a training programme of classroom courses on company premises as well as distance learning, on the following topics:

- ✓ Standards ISO 22716 and ISO 9000 for the cosmetics industry;
- ✓ Internal auditor qualification for GMP systems.

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