

CERTIFICAZIONE ISO 22716

Cosmetics - Good Practice
Manufacturing (GMP)



TARGET

The service is aimed at all companies that:

- produce and pack cosmetics with their own brand name;
- produce and pack cosmetics on behalf of third parties.

CONTEXT

The EC Regulation no. Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 provides for the safety of cosmetic products placed on the market to ensure that products are manufactured in accordance with GMP Good Manufacturing Practices ISO 22716 is the first international document that sets the principles for the application of Good Manufacturing Practices in

companies that produce cosmetics and is the harmonized standard for the application of the provisions of Article 8 of Regulation No. 1223/2009. ISO 22716 applies to the production, control, storage and shipping processes of cosmetic products. It does not, however, apply to product research and development and product distribution.

ISO 22716 rules in particular:

- Staff (organizational structure, training, hygiene and health);
- The management, cleaning and maintenance of the premises and of the equipments;
- The acquisition and control of raw materials and packaging materials;
- The realization, the packaging and the release of the product;
- Qualification and control of subcontractors;
- Non-conforming product management, product rework and recall;
- The management of deviations and the 'change control';
- The management of the improvement by carrying out corrective and preventive actions based on the analysis of deviations and complaints;
- The documentation (procedures / operating instructions / recordings) necessary for a proper management of the production, control and shipping processes of the cosmetic product.

SERVICE

Certiquality, using its extensive experience in evaluating management systems in cosmetics companies and related pharmaceutical and medical devices companies, provides cosmetic manufacturers with ISO 22716 compliance certification services.

The Certiquality service can be performed in two different ways:

- CERTIFICATION ACCREDITED BY ACCREDIA UNDER ISO 22716
- INSPECTION FOR SUPPLIERS ON THE APPLICATION OF GMPs

A) ACCREDITED CERTIFICATION UNDER ISO 22716

The main stages of the certification test include:

- Preliminary verification, carried out on request only, allows to evaluate the status of the business management system in relation to what is required by ISO 22716. The areas of improvement and strength analysis (gap analysis) are identified;
- the compliance auditing audit, with the aim of assessing the compliance of the management system with the requirements of ISO 22716, by document analysis and field observations;
- the issuance of the attestation of conformity;
- annual auditing audits and three-year renewal.

For companies already certified according to ISO 9001 with Certiquality, certification for compliance certification and subsequent periodic audits can be carried out in conjunction with planned activities such as surveillance and renewals.

ADVANTAGES

With certification accredited by Accredia, ISO 22716, companies have the possibility to:

- Ensure compliance with the rules on Good Manufacturing Practices for Cosmetic Products;
- give confidence to interested parties (customers, distributors, importers, and consumers) that production is carried out in accordance with Good Manufacturing Practices;
- Integrate a certification according to ISO 9001 for Quality Management Systems with a more specific sectoral certification.

B) INSPECTION FOR SUPPLIERS ON THE APPLICATION OF GMPs

Every time a cosmetic Manufacturer entrusts to third parties, production must ensure that this is done under Good Manufacturing Practice (GMP).

Consider, in fact, that Article 11 of European Regulation no. 1223/2009 provides for the provision of a Product Information File (PIF), the contents of which must include a description of the manufacturing method and a declaration of compliance with the Practice of Good Manufacturing.

In order to fully comply with the binding requirements, the Manufacturer must therefore qualify the supplier, define the contractual arrangements binding the production of cosmetics under GMP and carry out the relevant controls (inspections at production sites).

Certiquality is able to carry out, on behalf of the Manufacturer, inspections at the supplier's production sites to verify compliance with the harmonized standard UNI EN ISO 22716 and any additional requirements specified by the customer (Manufacturer).

The inspection service is divided into the following phases:

- designing the activity with the buyer with the provision of any check-lists;
- document analysis;
- audit in field;
- issuing the final report.

TRAINING

Field activities can be integrated with a classroom activity, which can also be carried out at the company's website and concerning:

- the ISO 22716 standard and the ISO 9001 standard applied to the cosmetic sector;
- Internal Auditor Qualification for a Good Manufacturing Practice System (GMP).