CERTIFICAZIONE

ISO 15378

Primary packaging materials for medicinal products.
Particular requirements for the application of ISO 9001, with reference to Good Manufacturing Practice (GMP)

TARGET

The service is aimed at all companies that produce primary packaging for medicinal products.

THE CONTEXT

The application of Good Manufacturing Practices (GMP) principles during the production of primary packaging for medicinal products and their controls is of great importance to the safety of patients using packaged drugs. ISO 15378 identifies GMP and specific principles the requirements for a quality management system applicable to the production of primary packaging for medicinal products. ISO 15378 applies to the design, production, quality control, storage and shipment of primary packaging for medicinal products.

THE SERVICE

Certiquality, relying on its extensive experience in the evaluation of management systems in pharmaceutical companies and related sectors such as cosmetics and medical devices, offers primary packaging manufacturers of medicinal products a certification service for compliance with the requirements of the ISO 15378 standard.

The core principles of ISO 15378 are:

- staff (organizational structure, training, hygiene and health);
- the management, cleaning and maintenance of the rooms and of the equipments;
- the acquisition and the control of the raw materials and of the materials of packaging;
- the realization, the packaging and the release of the product;
- the qualification and control of subcontractors;
- non-conforming product management, product rework and recall;
- deviation management and 'change control';
- improvement plans based on data analysis regarding deviations and complaints;
- the documentation (procedures / operating instructions / records) needed for proper operation management.

THE ADVANTAGES

With the ISO 15378 certification, companies have the possibility to:

- Ensure compliance with the Good Manufacturing Practice Principles for Primary Products for Medicinal Products;
- give confidence to customers that production is carried out in accordance with Good Manufacturing Practices;
- to integrate a pre-existing ISO 9001 certification with a more specific sectoral certification.

CERTIFICATION ITER

The main stages of the certification test include:

- Preliminary Verification, performed on request only, allows to evaluate the status of the business management system in relation to what is required by ISO 15378. The gap analysis and gap analysis areas are identified;
- the compliance auditing audit, with the objective of assessing the compliance of the management system with the requirements of ISO 15378, by document analysis and field observations;
- the issuance of the attestation of conformity;
- annual auditing audits and three-year renewal.

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