ISO 13485
MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

WHO IS CONCERNED?

These services are intended for any company:

manufacturing or placing on the market medical devices, in-vitro diagnostic devices and active implantable devices;

designing, manufacturing or testing devices or components or sub-assemblies of such devices for the benefit of third parties;

designing, developing or providing services related to medical devices, such as for example sterilization, distribution, installation and maintenance of medical devices, surface finishing or packaging.

FRAMEWORK

EU Directives separately govern three categories of medical devices: active implantable medical devices (EU Directive 90/385/EEC), medical devices in general (EU Directive 93/42/EEC) and in-vitro diagnostic medical devices (EU Directive 98/79/EEC).
Each of the three directives provides that, in order for a manufacturer to place a medical device on the market, it develop and implement a comprehensive quality assurance system or production quality system according to the risk class of such product The ISO 13485 standard specifies the requirements for a quality management system that can be used by an organization in the design, development, production, installation and maintenance of medical devices, as well as in the design, development and the provision of related services.

OUR SERVICES

Benefiting from its long experience as a notified body for CE certification of medical devices, Certiquality provides companies in the medical devices business with certification services for quality management systems against the ISO 13485 standard.
Recognised to be a harmonised standard within the meaning of the EU Directives governing the placing on the market of medical devices, ISO 13485 may be used by manufacturers as a reference for the implementation of quality management systems which meet the regulatory procedures governing the design, production and placing on the market of medical devices.
Certification of a quality management system against ISO 13485 can be conducted simultaneously with the CE certification of a medical device, as this standard embodies the system requirements which complement the technical requirements at product level.
Companies producing medical devices may also easily integrate an ISO 13485-compliant quality management system with the additional requirements set forth in standard ISO 9001 regarding:

- Customer and customer satisfaction;
- Continual improvement of organisational performance and processes.

YOUR BENEFITS

The benefits resulting from certification against ISO 13485 can be found in the following abilities:

- ✓ to demonstrate the ability to supply medical devices and provide related services that meet customer requirements and comply with the applicable regulatory requirements;
- ✓ to facilitate any qualification process with a manufacturer wishing to outsource, partially or totally, the production activities of a medical device.

CERTIFICATION PROCESS

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 13485 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 13485, through a documentary analysis and on-site findings;
- ✓ Issuance of the certificate of conformity;
- ✓ Annual surveillance audits and triennial renewal audits.

ISO 13485 audits can be combined with audits against the ISO 9001 standard or the requirements of EU Directive 93/42/EEC.

PROFESSIONAL TRAINING

Certiquality can integrate classroom training to its activities, which can also be dispensed on your company's premises. Courses cover such various topics as:

- ✓ EU Directive 93/42/EEC;
- ✓ Risk Management in the Manufacture of Medical Devices According to Standard ISO 14971;
- ✓ ISO 13485 (Medical Devices – Quality Management Systems);
- ✓ Clinical Evaluation of Medical Devices.

CONTACT US dispositivimedici@certiquality.it – 02.80691734

www.certiquality.it