

MED DEVICES mission is to provide a complete business service aimed at assuring the product conformity. We help worldwide exporters to gain global market access. Our extensive experience & structured way of working assures that no stone is left unturned to make your product a global success.

MDQMS (EN ISO 13485: 2003)

An ISO 13485 is the international standard recognized for medical device regulations around the world and it specifies requirements for a quality management system exclusively for medical device manufacturers. ISO 13485:2003 contains requirements essential for organizations operating at any tier in the medical devices and pharmaceutical supply chain. The primary objective of the standard is to facilitate harmonized medical device regulatory requirements and as a result, it includes some particular requirements for manufacture, installation and servicing such as added requirements on record-control, sterilization and risk management.

The medical device industry is affected by a complex array of regulatory systems, national and international standards and other requirements. We provide services that help manufacturers understand what they need to do to place compliant devices on markets throughout the world. Whatever devices you produce, as a medical device manufacturer you have a responsibility to consistently deliver devices that are safe and effective. ISO 13485: 2003 is based on ISO 9001. In particular, the requirements for customer satisfaction and continual improvement have been modified to make them more appropriate for regulatory purposes. Organizations can register to ISO 13485 as a standalone or in conjunction with an ISO 9001 or other registration.

Benefits of ISO 13485

- Promotes harmonization of regulatory requirements for manufacturers of medical devices on an international scale.
- It incorporates many of the quality management principles and delivers the benefits of an ISO 9001 based quality management system.
- A number of countries have incorporated ISO 13485 into their regulatory systems. Compliance with ISO 13485 can be used in support of regulatory compliance.
- Creates a competitive advantage
- Ensures a consistent and effective approach to business management
- Reduces risk factors via the use of risk management techniques
- Engages top management involvement
- Provides a robust framework for assuring product consistency

CE Marking

The CE Mark is the gateway for the companies who want to export to Europe. It is mandatory for a wide range of products sold within or exported to the European market. The European community has implemented a system to protect the health of consumers and user of manufactured products. CE Mark assures the user of a product that it conforms to the requirements of relevant directive of European Union and harmonized European standard.

CE Marking is the manufacturer's claim that the product meets the essential requirements of all relevant European Directives. CE Marking compliance is a legal requirement in the European Union member states and the European Economic Area countries. Other countries are like to adopt the directives in the future. The CE marking does not apply to: cosmetics, chemicals, pharmaceuticals, foodstuffs.

CE marking on a product.....

- Indicates to governments that the product can be legally sold within the European Union (EU) and the European Free Trade Area (EFTA).
- Ensures the product can move freely throughout the European Single Market

- Indicates to customers that the product meets designated minimum safety standards and therefore has a minimum level of quality
- Promotes public health and safety
- Enhances product credibility
- Leads to improved sales and greater customer satisfaction

MED DEVICES provides CE Marking as per following European directives

- Medical Device Directive
- In-Vitro Diagnostic Device Directive
- Active Implantable Medical Device Directive

USFDA Consulting

The FDA registration is required for all companies that manufacture, process, pack or store food or beverages that may be consumed in the United States. Companies located outside the U.S. must designate a U.S. Agent for FDA communications.

For medical devices classified as Class II and III, a 510k clearance is necessary in order to market the product in the U.S. The Clearance requires compliance to the CFR, Part 820 Quality System Regulations (QSRs), Good Manufacturing Practices (GMP) and the other applicable CFRs for the product type and indications for use.

MED DEVICES provides training and assist in the filing the 510k clearance application , and the implementation of a quality management system in compliance with the QSRs and the applicable CFRs.

