Medical Device Regulatory Solutions

global regulatory consultants

- CE Marking
- ISO 13485
- U.S FDA 510k
- U.S FDA Registration
- 21 CFR 820

I 3 CONSULTING

CE Marking

Of Electro Mechanical, Software, Biocompatible, In vitro Diagnostic and Implantable Medical Devices

We offer complete solutions for CE Marking your devices by offering the following services

- Technical Consultancy
- Documentation (Technical File Preparation)
- Product Testing
- GAPS Analysis/ Review of Technical File
- Notified Body Audit and Certification.

ISO 13485:2003 (EN ISO 13485:2012)

Regulatory authorities in most major markets like European Union, United States, Canada, Japan, and Taiwan require, or strongly prefer, that manufacturers marketing medical devices in their countries have a third-party audited and certified Medical Device Quality Management System in place. An ISO 13485:2012 compliant system expedites access into those countries that require it. I 3 Consulting is uniquely qualified to provide expert advice on compliance, scientific, and technical matters. Additionally, I 3 Consulting help clients through:

- Identification of deficiencies and gaps in compliance and provision of remediation plans
- Implementation Support
- Trainings & Internal Audits
- Certification audit by leading CB's

510k Clearance

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE).

I 3 Consulting help clients through:

1 Technical and Scientific Consultancy

2 Review and 510k Submission with the help of US Agent.

3 Organize testing in reputed accredited Laboratories.

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US Agent Services

Under the Code of Federal Regulation 807.40(b) the Food and Drug Administration requires a foreign establishment to designate a United States Agent to act as their official correspondent.

We have a proven track record assisting companies in registrations and listings. As United States Agent for your company, we can ensure compliance with the new regulation, which became effective February 11, 2002.

Establishment Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended to use in the United States (U.S.) are required to register annually with the FDA. I 3 Consulting also help clients in solving obstacles like

- Warning Letter Response
- FDA 483 Observations
- FDA 483 Responses

FDA QSR 21 CFR 820

FDA 21 CFR Part 820, also known as the Quality System Regulation QSR which outlines Current Good Manufacturing Practice CGMP regulations that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished medical devices intended for human use and sale in the United States of America.

I 3 Consulting help clients to implement CFR 820.

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