Clinical Evaluation

Recent amendments made to the Medical Device Directive (MDD 93/42/EEC) state that every medical device affixing CE Logo, regardless of its classification, must have a clinical evaluation report in its Technical File / Design Dossier.

The Directive's specific focus on implantable or class III medical devices gives the false impression that clinical investigation does not apply to other Medical devices. This has lead to the current situation where clinical trials are rarely done in the pre-market steps of medical devices development.

Clinical investigation is rarely conducted because of the investment in time, human resources and costs. In addition, clinical investigation is sometimes perceived as risky or harmful.

With the implementation of Directive 2007/47/EC, clinical evaluation has become a central element of regulatory compliance under the Medical Device Directive and Active Implantable Medical Device Directive.

Manufacturers of innovative technologies face the greatest impact, as they must present complete and sufficient clinical evaluation files to ensure timely assessment and favorable review of their products.

Benefits of Conducting Clinical Evaluation

- **Regulatory conformance**: Conforming to the regulatory framework is necessary and should be done in order to get Notified Body approval for Technical file followed by CE Certification. Choosing to perform a clinical investigation is the best answer to conform to the new requirements of the Medical Device Directive MDD 93/42/EEC.

- **Early detection and resolution of safety issues**: Over 25% of safety alerts are due to manufacturing defects. This high proportion demonstrates the importance of an early detection of potential safety issues. Early assessment gives the manufacturer time to take corrective action and to provide potential damages to the company's reputation.

- **Manufacturer Image**: An early clinical investigation most often results in a positive image and greater usage of the product throughout the healthcare system. A well-designed clinical investigation based on a robust methodology gives a chance to publish a scientific article in a peer-reviewed journal.

Types of Clinical Evaluation

There are three types of clinical evaluation: 1) basic literature review, 2) advanced literature review, and 3) clinical evaluation. The route you take will be based on your product classification and product type.

Methodology and guidelines when performing an Investigation

The most important part lies in the methodology used. Any evaluation must be conducted following a strict design as the choice of the study design and methodology conditions, the success of the clinical study.

Appoint I 3 Consulting for Better navigation and Results

Working Early with I 3 Consulting for smooth and error free submission to Notified Bodies. Our project manager's work with clients to ensure clinical investigation was adequate to generate relevant data in any of the above said methods.

Our systematic approach includes support in protocol generation, documentation and Coordination with Notified Bodies and Client.

I 3 Consulting provide clients with a detailed checklist of required information for submission for an EC type or design examination with the added benefit of shortening the overall review time.

Additional Documents

The European Commission issued two new MEDDEV guidance document in Dec 2010 related to Clinical investigation, while a new version of a related ISO STANDARS RLAESED IN February 2011

(1) MEDDEV 2.7/4 **(2)** MEDDEV 2.7/3 **(3)** ISO 14155:2011

Get a Customized Proposal

Complete our Quote Request Form for a detailed proposal. For more urgent requests, feel free to use our Website Skype link or direct dialing numbers to USA & India.