Medical Device Studies: Clinical Evidence

Description: This course has been designed specifically for those who are involved in gathering clinical evidence required for medical devices and in-vitro diagnostic products. Clinical data is required for all medical devices and the emphasis on high quality, appropriate clinical evidence has grown substantially in the last few years. Clinical evidence is key to bringing a device to market and is a very important aspect of post market evidence gathering to meet the legislation. The collection of clinical data to demonstrate safety and performance of a device is pivotal to CE marking a medical device. The collection of post market data is a key aspect of continued safety and performance considerations once the device is on the market.

This course will cover the full range of activities that should be applied during the collection of clinical evidence for both pre and post market studies. It will provide delegates with information on the European regulations for gathering clinical evidence and conducting medical device studies and help them to run studies in Europe and other countries.

Delegates should benefit from the advice and tips on the practicalities of conducting studies within Europe as well as the types of clinical data to collect in order to be compliant.

Benefits of Attending:

- Understand the regulatory requirements and guidance applicable to clinical evidence
- Clarification on Clinical Evaluations (Literature Reviews)
- Understand what is required in terms of clinical data prior to CE marking and post CE mark
- Know what documentation is needed for the pre and post market phases of clinical data collection
- Discover how to conduct a clinical investigation and post market clinical follow-up study
- Plan how to prepare regulatory notifications to the Competent Authorities and obtain other necessary approvals
- Understand the key aspects of pre and post market study setup, management, monitoring and close down
- Discuss how to prepare a paper or presentation for publication and marketing
- Understand the differences between drugs and devices

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