Clinical evaluation for Medical devices

Course Description

BSI's Clinical Evaluation for Medical Devices one day course is designed to support manufacturers by confirming the information necessary to demonstrate clinical safety and performance of their product in accordance with the requirements of the European Medical Devices Directive.

On completion of training, manufacturers will be able to determine if a clinical trial is required, prepare a clinical evaluation report including literature review and determine requirements for post-market clinical follow-up and post-market surveillance to support continuing compliance.

Benefits to Your Business

- Avoid frequent pitfalls of clinical regulatory submissions
- Provide robust documentation in support of the clinical safety and performance of your device
- Ensure continuing compliance throughout device lifecycle.

Learning Objectives

On completion of this training, participants will be able to:

- Determine whether or not a clinical investigation is required for their device
- Prepare a clinical evaluation in accordance with MED DEV 2.7.1 and GHTF Guidance Documents:
  - Implement risk evaluation pre/post review
  - Establish design and intended use equivalence with competitor and pre existing designs
  - Identify data available from the clinical literature
  - Supply and prepare documentation relating to clinical investigations that meets Notified Body requirements (if clinical investigation was deemed necessary and completed)
  - Demonstrate that there is sufficient clinical data to meet the safety and performance requirements of the device
  - Identify residual clinical risks and determine whether post-market clinical follow-up is required
- Maintain and update clinical evaluation documentation throughout post-market product lifecycle.

Intended Audience

- Medical Device R&D Engineers and Scientists
- Clinical and Regulatory Affairs Professionals.

Course Duration

One day

Prerequisites

- Familiarity with own device clinical safety and performance issues
- Awareness of:
  - Essential Requirements (Annex I) and Clinical Evaluation (Annex X) of the European Medical Device Directive or Essential Requirements (Annex 1) and Clinical Evaluation (Annex 7) of the European Active Implantable Medical Device Directive
  - MED DEV 2.7.1 or GHTF guidance document SG5/N2R8.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

Book this course online by visiting bsigroup.com/en-IL or call us today on +39 02 66 79 09 210

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.