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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 and the Active Implantable 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 as part of post-market surveillance to support continuing compliance.

Course Benefits

- 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

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

- Prepare a clinical evaluation in accordance with MED DEV and GHTF Guidance Documents:
  - Establish design and intended use equivalence with competitor and pre existing designs
  - Identify data available from the clinical literature
  - Supply 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
- Determine whether or not a clinical investigation is required for their device
- Maintain and update clinical evaluation documentation throughout post-market product lifecycle

Intended Audience

- MDD and AIMD R&D Engineers and Scientists
- Clinical and Regulatory Affairs Professionals

Prerequisites	• Familiarity with own device clinical safety and performance issues • Awareness of: □ Essential Requirements (Annex I) and Clinical Evaluation (Annex X) of 93/42/EEC or Essential Requirements (Annex 1) and Clinical Evaluation (Annex 7) of 90/385/EEC □ MED DEV 2.7.1 or GHTF guidance document SG5/N2R8 □ MED DEV 2.12-2 or GHTF guidance document SG5/N4:2010
Further Information	This can be delivered as an on-site training session tailored to your company's requirements.