

Medical Device Trials

This one-day course is ideal to provide evidence for regulatory inspectors that sponsor, CRO and investigator site personnel to ensure they have been appropriately trained in the ISO 14155 requirements for conducting clinical investigations of medical devices.

What Is The Course About?

This course will introduce, explain and discuss fundamental concepts and current issues relating to compliance, human subject protection, research development and clinical investigation in the current regulatory environment for medical device clinical trials. Knowledge of ISO 14155 is essential to everyone working on medical device clinical trials and for those who work with clinical trial professionals. Regulatory inspectors now look for evidence that professionals working on clinical trials have received regular training in ISO 14155 and also understand how to comply with ISO 14155 requirements.

By The End Of This Course, You Will Be:

- familiar with the most important areas of ISO 14155
 - understand the most important principles of ISO 14155
 - ensure that informed consent procedures are properly implemented for device trials
 - understand the requirements for Ethics Committees and Institutional Review Boards and how to obtain approvals
 - understand the responsibilities of the Sponsor and Investigators
 - able to ensure successful preparation for ISO 14155 inspection and audit
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The Trainer

Dr Laura Brown

Laura is an independent training consultant and Director of the MSc in Clinical Research at Cardiff University. Laura has more than 18 years experience in the pharmaceutical industry. She has worked for several companies as a Clinical Research Manager, Audit Director and as Head of a Training Department.

Laura is an international expert on monitoring and Clinical Research issues. She was Chairman on the Institute of Clinical Research GCP Forum for six years, and writes regularly on clinical research and GCP.

She is a member of the Editorial Board of the Good Clinical Practice Journal and is author of SCRIP's latest GCP guide, and a practical guide to the Clinical Trial Directive.

Course Fee: £599 +vat

If you book on the course more than 9 weeks in advance, a 10% discount will be applied.

Location: The Regency Hotel, 100 Queens Gate, South Kensington, London, SW7 5AG

For more information about this or any of our other courses or services, please call us on +44 (0)118 975 4512 or visit our website www.rostrumtrainingsolutions.com

Programme

Medical Device Trials

Introduction & Objectives

Overview Of Device Terminology And Regulations

- An introductory overview of the regulations guiding research of medical device development
- Device classifications
- The competent authority and the Notified Bodies
- ISO 14155 and Revision of ISO 14155-1:2003 and ISO 14155-2:2003
- Medicinal device clinical trials and regulatory approvals

Study Set Up Planning And Preparation To Comply With ISO 14155

Informed Consent Procedures

- Ensuring that informed consent procedures are properly implemented
- Special requirements for consenting vulnerable subjects

Ethics Committees Review

- Composition, procedures and records to comply with ISO 14155

Understand The ISO 14155 Responsibilities Of The Sponsor Including The Monitor And Investigators

- Understanding the key roles and responsibilities of the sponsor, monitor and investigator
- Pharmacovigilance requirements for medical devices

Essential ISO 14155 Documentation To Avoid Non-Compliance

- The Clinical Investigation Plan (CIP)
- Investigator's brochure
- Case report forms
- Essential clinical investigation documents to comply with ISO 14155

Audit And Inspection To Comply With ISO 14155

- How to prepare for an audit and/or regulatory inspection
- The latest inspection policies and findings
- What questions inspectors ask and tips on how to answer these