

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

Trish Parry - FICR, CSci

Trish is an independent training and clinical research consultant. She has extensive experience in global monitoring and international clinical project management as a result of working in multi-national pharmaceutical companies and clinical research organisations. She has set up and maintained the European Clinical Quality and Training Department in a large US company and she is an experienced trainer in clinical research and GCP.

Trish is author of Statistics in Clinical Research (The Institute of Clinical Research 2004) and is on the Editorial Board of the Institute of Clinical Research's Journal, CRFocus. She is one of the founders of the Institute of Clinical Research Trainers Forum.

She is a Chartered Scientist and fellow of the Institute of Clinical Research.

Course Fee: £650 +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)118 384 2040 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