Clinical Trial Regulatory Requirements

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Clinical Trial Regulatory Requirements

Benefits of attending:

- Decipher the framework of clinical trial regulations and guidelines in Europe
- Gain an update on the new EU Clinical Trial Regulation 536/2014
- Understand key FDA requirements
- Understand clinical trial authorisations: regulatory and ethical approval
- Assess the most important legal aspects of clinical trials
- Ensure you comply with pharmacovigilance and adverse event reporting

Expert trainer:

Dr Laura Brown
Independent QA expert and training consultant in the pharmaceutical industry and Course Director of the MSc in Clinical Research, Cardiff University

‘Very interesting course, good speaker – she was very knowledgeable.’
Chantal Mutsaers, Phara Plus Life Science Services

‘Content interesting and covered a lot of topics, presentation was varied, and speaker was clear and interesting to listen to.’
Vikesh Lad, MHRA
## Programme

### Day one

- **Introduction, welcome and objectives**
- **Understand the current framework of clinical trial regulations in Europe**
  - Pharmaceutical clinical trial legislation – EudraLex 10 contents explained
  - ICH and its importance
  - Key FDA requirements which differ from EU requirements,
  - The impact of Brexit
- **Overview of the current EU clinical trials requirements**
  - The key requirements of the EU Clinical Trials Directive
  - Case study – main issues of the Clinical Trials Directive and why this will be replaced with the Clinical Trial Regulation
  - The new EU Clinical Trial Regulation
  - Update on the new Clinical Trial Regulation, implementing acts, EU portal and database and new documentation
  - What key changes will be introduced?
  - Implementation and compliance
- **Clinical trial regulatory authorisation and amendments**
  - How to apply for the EudraCT number
  - Current requirements for an EU clinical trial application (CTA) and how this will change with the new Clinical Trial Regulation
  - Substantial amendments and non-substantial amendments
  - US regulatory requirements for clinical trials – US IND
- **Ethics Committee (EC) submissions and approval**
  - Roles and responsibilities: sponsor and investigators
  - Completing EC applications
  - Informed consent requirement

### Day two

- **Running clinical trials in children: the paediatric plan and ethical considerations**
  - The EU regulation on paediatric medicines and the paediatric committee
  - Ethical considerations for clinical trials in children guideline
- **Brief overview of legal aspects of clinical trials**
  - Data protection – GDPR
  - Enforcement and sanctions
  - Liability
  - Contracts
- **Investigational medicinal product**
  - GMP requirements and the role of the Qualified Person
  - Labelling requirements
  - Discuss: what inspectors expect for compliance
- **Pharmacovigilance and adverse event reporting**
  - Safety reporting definitions and requirements
  - What are the reporting requirements for SUSARs, adverse events and adverse reactions?
- **Awareness of other recent EU and FDA developments in clinical trial requirements**
  - Clinical trial transparency requirements in the EU – recent EMA policy on publication of clinical data
  - Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products
  - EU medical device regulations
  - New EU requirements for trial master files including electronic TMFs
  - New FDA and EU risk-based monitoring guidance
  - FDA guidance on electronic informed consent
  - ICH update
- **Brief considerations for preparing for regulatory inspection**
  - How to prepare for inspection
  - What questions inspectors may ask

## Key topics to be covered include:

- The current requirements of the EU Clinical Trials Directive
- The impact of Brexit
- Clinical trial authorisations
- Complexities for running paediatric trials
- Requirements for managing investigational medicinal products
- Legal aspects of clinical trials
- Requirements of pharmacovigilance
- ICH update
- Regulatory inspections

### Expert trainer

Dr Laura Brown is an independent QA and training consultant and director of the MSc in Clinical Research at Cardiff University’s School of Pharmacy. Laura has many years’ experience in the pharmaceutical industry, working for companies including Glaxo Wellcome, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International. She has worked as a clinical research manager, audit director and as head of a training department and is an international expert on regulatory requirements in clinical research. She was Chair of the Institute of Clinical Research GCP Forum for six years and writes regularly on clinical research regulatory requirements. She is a member of the editorial board of SCRIP Clinical Research Journal and author of SCRIP’s latest GCP guide and a practical guide to the Clinical Trials Directive. She has also written several articles on the requirements of the new EU Clinical Trial Regulation, the impact of Brexit on clinical trials and the ICH GCP R2 guideline.

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