IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Clinical Trial Regulatory Requirements

1-2 March 27
+ 23-24 September 27

This course will take you through the key regulatory and guideline requirements for clinical research in Europe, including the new EU Clinical Trial Regulation and a brief review of key FDA requirements.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Clinical trial regulations continue to evolve rapidly, particularly in Europe following the implementation of the EU Clinical Trials Regulation (536/2014) and the introduction of the Clinical Trials Information System (CTIS). These changes affect a wide range of roles involved in the planning, conduct, oversight, and support of clinical trials.

This course provides a structured, high-level overview of the regulatory framework governing clinical trials in Europe, with reference to key US requirements. It focuses on understanding regulatory expectations, roles, and responsibilities rather than hands-on system or submission training.

The programme is designed for professionals who need context, clarity, and confidence when working with regulatory colleagues, CROs, and inspectors.

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
- **Review** key FDA requirements
- **Understand** clinical trial authorisations
- **Assess** the most important legal aspects of clinical trials
- **Ensure** you comply with pharmacovigilance and adverse event reporting

Who should attend

This course is ideal for anyone requiring either an overview or refresher of the current clinical trial regulatory and guideline requirements including the new EU Clinical Trial Regulation. It will be particularly relevant for those working in regulatory, clinical research, clinical operations, project management and quality assurance (GCP auditors); vendor/CRO professionals; study sites; and other professionals in pharmaceutical and biotechnology organisations conducting trials with drugs, biologics or combination products.

It will also be of interest to those departments who liaise/support clinical trial personnel (such as clinical trial supply, pharmacovigilance, quality assurance, document management, legal), regulatory authorities, and any other professionals who want to know more about regulations and guidelines covering clinical trials.

Programme

Day 1

Clinical trial regulatory framework in Europe

- Overview of EU clinical trial legislation and guidance
- Role of EudraLex, ICH guidelines, and national competent authorities
- How EU and international requirements interact

EU Clinical Trials Regulation (536/2014)

- Why the regulation was introduced and what it aims to achieve
- Key structural changes compared with the previous Directive
- Impact on sponsors, CROs, and study teams

Clinical trial transparency

- Transparency obligations under the EU Clinical Trials Regulation
- Public disclosure requirements and lay person summaries
- Common areas of misunderstanding and risk

Clinical trial authorisation – overview

- Purpose of clinical trial authorisation in the EU
- High-level overview of CTA content and structure
- Substantial versus non-substantial modifications

Day 2

Introduction to CTIS

- Purpose of CTIS within the EU regulatory system
- High-level roles and responsibilities
- Common organisational challenges since implementation

Ethics committees and informed consent

- Role of ethics committees in clinical trials
- Key informed consent requirements
- Common ethical challenges in trial conduct

Paediatric clinical trials – overview

- EU paediatric regulation and its objectives
- Paediatric Investigation Plans (PIPs)
- Ethical considerations for trials involving children

Investigational medicinal products (IMP)

- Definition of an IMP under the EU CTR
- Overview of GMP requirements and the QP role
- Labelling and documentation requirements (high level)

Pharmacovigilance and safety reporting

- Key safety terminology and definitions
- Principles of adverse event and SUSAR reporting
- Role of reference safety information (RSI)

US clinical trial regulatory overview

- Purpose and scope of the US IND system
- Key differences between EU and US regulatory approaches
- Practical implications for global trials

Regulatory inspections

- How regulatory inspections are triggered
- What inspectors typically focus on
- Common inspection themes and findings

Recent and emerging developments

- Overview of ICH GCP E6(R3) changes
- Risk-based approaches to trial oversight
- Other emerging regulatory and guidance developments

Presenter



Laura Brown

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 GSK, 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 has written several articles on the requirements of the EU Clinical Trial Regulation, the impact of Brexit on clinical trials and the ICH GCP R2 guideline.

Course dates

1-2 March 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17020*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 04 Jan**
23-24 September 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17313*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 29 Jul**

How to book

Online:
ipi.academy/2280

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★☆

The content of training materials covered all the expected regulatory topics. [Speaker] made a great speech and answered clearly to the questions raised. Workshops sessions were useful to practice.

Marieme Ndeye Gueye
Senior CTA
Chiesi France
Jan 29 2025

★★★★☆

I was hoping to get knowledge on how to manage clinical trial as a legal counsel in a pharmaceutical company. The speaker was clear [and] I lear[n]t a lot but more about regulatory aspect.

Salome Hamon
Junior Legal Counsel
Curium Holding France SAS
Jan 29 2025

★★★★☆

Very insighful training, interactive and lively session with interesting content. small participating group, really appreciated it! [sic]

Dalila Arbadji
Senior Clinical Trial Administrator
Chiesi
Jan 29 2025

★★★★★

Excellent and again would only receive this expected type of learning and understanding with the course by IPI Academy. I know that I will have a comprehensive understanding to use the information learned and apply at my job with IPI Academy webinars. I do not get that elsewhere.

Angela Turner
RA Director

May 25 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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