IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Clinical Trial Regulatory Requirements

15-16 September 2025

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

Are you up to date with the regulatory requirements for clinical research in the EU and key requirements in the US?

Do you understand the impact of the new requirements of the EU Clinical Trials Regulation?

This course will take you through the key regulatory and guideline requirements for clinical research in Europe, including the EU Clinical Trial Regulation, ICH GCP R3 update, a brief review of key FDA requirements and update of other recent changes.

This interactive programme will highlight the most important of these key requirements and changes and how these are likely to impact on trials now and in the future for pharmaceutical and biotechnology companies and study sites.

Key topics to be covered include:

- The EU Clinical trials Regulation (536/2014) and update
- The New Clinical Trial Information System (CIS)
- Clinical trial authorisation
- Complexities for running paediatric trials
- Requirements for managing investigational medicinal products
- Legal aspects of clinical trials
- Requirements for pharmacovigilance
- ICH GCP R3 update
- Regulatory inspections

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

Overview of the framework of clinical trial regulations in Europe

- Background to the history of clinical trial legislation
- Pharmaceutical clinical trial legislation – EudraLex 10
- ICH and its importance
- Key FDA requirements that differ from EU requirements

EU clinical trials regulation

- Update since the implementation of the EU Clinical Trials Regulation and implementation texts
- Clinical Trial Transparency
- The key changes of the Clinical Trials Regulation
- The new Clinical Trials Information System (CTIS) experience

Clinical trials regulatory authorisation

- EU clinical trial application (CTA) for submission in the EU
- Notices and requests for information requirements
- Substantial changes/modification and non-substantial changes
- Ongoing and end of study reports including the lay person summary
- US regulatory requirements for clinical trials – US IND

Day 2

CTIS (Clinical Trial Information System)

- Overview of CTIS
- Roles and responsibilities
- CTIS training

Ethics Committee (EC) approval

- EC applications as part of the Clinical Trials National Approval
- Informed consent requirements
- Ethical considerations for running trials including countries outside of traditional countries

Running clinical trials in children: the paediatric plan and ethical considerations

- The EU regulation on paediatric medicines and the paediatric committees
- Ethical considerations for clinical trials in children guideline

Brief overview of legal aspects of clinical trials

- Data protection – GDPR
- Enforcement and sanctions
- Liability and insurance
- Contracts

Investigational medicinal product under the clinical trials regulation

- 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?
- RSI (reference safety information)

Awareness of other recent EU, FDA and international developments in clinical trial requirements including:

- ICH GCP R3
- EMA Inspections: Questions and Answers on Good Clinical Practice (GCP)
- Accelerating Clinical Trials in the EU
- Clinical trial transparency requirements in the EU
- Guidance on real world data
- EU medical device regulations
- Requirements for trial master files including electronic TMFs
- FDA and EU risk-based monitoring guidance
- FDA guidance on electronic informed consent
- FDA to increase racial and ethnic diversity in Clinical Trials

Regulatory inspection

- How to prepare for inspection
- What questions do inspectors ask? Tips on how to answer these.

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 date

15-16 September 2025 **Live online**
09:30-17:00 **UK (London)** (UTC+01)
Course code 14915

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 11 Aug

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 **15% 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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