IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Risk Management in Clinical Research and Trials

24 April 2026
+ 6 October 2026

This essential course will explain the importance of using risk management techniques in clinical trials to comply with the latest focus on inspection in this area.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Effective risk management is now at the heart of running high-quality, compliant clinical trials. With the shift toward proportionate, risk-based approaches in ICH E6 (R3), E6 (R2), and ICH E8(R1), teams are expected not only to identify and evaluate risks early, but also to monitor and respond to them in a structured, transparent way throughout the trial lifecycle.

This interactive one-day course gives you the confidence and skills to apply modern risk management principles in real studies. Through clear explanations, real-world examples, and interactive discussions, we explore what regulators expect, how risk-based quality management works in practice, and how to build a process that supports both participant safety and high-quality data.

The course also introduces the growing role of AI in clinical trial risk management. You'll learn how emerging tools can support early risk detection, help identify unusual data patterns, and strengthen centralised monitoring - while also understanding their limitations and the importance of maintaining strong documentation, oversight, and human judgement.

By the end of the day, you will be equipped to design, implement, and document a practical, proportionate risk management approach that aligns with the latest global expectations and supports successful clinical trial delivery.

Benefits of attending

- **Understand** key risk management tools and when to apply them in pharma, biopharma, projects
- **Learn** how to plan, document, and focus risk-based approaches to meet ICH GCP E6 (R2), E6 (R3), and related regulatory expectations
- **Identify** and share best practices for implementing risk-based tools and approaches in clinical trials including AI
- **Gain** a clear understanding of the risk management objectives outlined in ICH E6 (R3) and ICH E8(R1)

Who should attend

This course is designed for professionals in the pharmaceutical, biotechnology industry who need to understand and apply risk management in clinical research, including:

- Clinical Research Associates (CRAs)
- Clinical Trial Managers (CTMs)
- Quality Assurance professionals
- Regulatory Affairs specialists
- Project Managers
- Data Managers
- Anyone needing to meet regulatory expectations and apply risk-based tools and techniques effectively in their role

Programme

Regulatory frameworks and guidelines

- Overview of regulations and guidance covering risk management in pharma and biopharma
- ICH GCP E6 (R3) risk considerations, including:
  - Proportionate Risk-Based Approach
  - Critical to Quality (CtQ) Factors Identification
  - Defining and applying Quality Tolerance Limits (QTLs)
  - Risk Assessment & Management
  - Sponsor and Investigator Responsibilities
  - How ICH E8(R1) complements E6 (R3) in setting quality expectations

Risk-based quality management systems (QMS)

- What a risk-based QMS means in practice for clinical research
- Core QMS elements that incorporate risk
- What regulatory inspectors expect to see in place for clinical trials

Risk-based processes, tools, and techniques

- Examples of effective risk management processes in clinical research
- Practical tools for risk identification, assessment, and control, including:
  - Root Cause Analysis
  - Risk Breakdown Structure
  - Risk Matrix
  - Risk Prioritisation (scoring systems, heat maps)
  - Risk Log/register and Tracking
  - Failure Mode and Effect Analysis (FMEA)

Clinical trial-specific risk tools

- Pharmaceutical risk-specific tools, including the Risk Assessment Categorisation Tool and how this is being replaced

Presenter

Laura Brown

Dr Laura Brown is an independent pharmaceutical QA, management and training consultant and Senior Lecturer for the MSc in Clinical Research, School of Pharmacy, University of Cardiff. Laura has more than 20 years' experience of quality assurance and managing international clinical trials including risk identification and management. She has worked for several leading companies including GSK, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International and is an international expert on GCP and clinical trial requirements. Laura was chair of the Institute of Clinical Research GCP Forum for six years and writes regularly on clinical research regulatory requirements.

Course dates

24 April 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 16872*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 20 Mar**
6 October 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 16873*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 01 Sep**

How to book

Online:
ipi.academy/2531

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

★★★★☆

There were lots of useful links and information which I can use for further study of the risk management concepts and their application.

Vladilena Daly
Operations and Compliance Manager
CliebntPharma Ltd
Oct 8 2024

★★★★★

Very good

Arna Hrund Arnardottir
Senior Consultant RA
DADA Consultancy BV
Oct 14 2022

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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