IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Risk Management for Clinical Research

7 October 2025

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

Risk management is becoming increasingly important in clinical trials, as well as in ensuring compliance with regulatory expectations. Numerous pharmaceutical guidelines now cover risk management in clinical trials, including ICH GCP R2 and R3, and the FDA's Risk-Based Monitoring of Clinical Investigations: Questions and Answers guidance.

During this one-day course you will learn how to apply a risk-based approach when managing your clinical trials lifecycle. We will review the principles of risk management and how to apply them within a clinical trial setting according to ICH GCP R2 and R3.

The ICH E6(R3) Good Clinical Practice (GCP) guideline, includes significant updates to integrate risk-based approaches to clinical trial design, conduct and a proportionate Risk-Based Approach. Under ICH E6(R3), risk considerations are central to ensuring data integrity, participant safety, and regulatory compliance.

This essential course will explain the importance of using risk management techniques in clinical development to comply with the latest focus on inspection in this area. It will show you how risk management can improve the quality of your clinical research projects and demonstrate the importance of using risk analysis and risk management techniques in clinical trials. You will learn how to identify, evaluate and implement specific risk-based techniques for risk management, including a quality management framework.

The course will enable you to develop quality risk management principles applicable to clinical trials, pharma, biopharma and device development, as well as to identify and share best practices for risk management tools and approaches.

Benefits of attending

- **Understand** risk management tools and when and how the tools are used in pharmaceutical, biopharmaceutical and medical device projects
- **Learn** how to plan risk-based approaches, how to document and where to focus to meet regulatory requirements and expectations to meet ICH GCP R2 and R3
- **Develop** and apply risk management principles and tools to your development projects
- **Identify** and share best practices for implementing risk-based tools and principles
- **Gain** a clear understanding of the objectives outlined in ICH Guidance ICH E6 R3 and E8 concerning risk management in clinical trials

Who should attend?

Anyone who is needs to understand risk management working in the pharmaceutical industry, including:

- Clinical research associates (CRAs)
- Clinical trial managers (CTMs)
- Quality assurance professionals
- Regulatory affairs specialists
- Project managers
- Data managers
- Those needing to understand the regulatory expectations, associated guidance and be able to apply different tools and techniques in their role.

Programme

A brief overview of risk management

- Why risk management is important in clinical trials
- Definitions of key risk management terminology
- Brief overview of regulations and guidelines which cover risk management applied to the pharma and biopharma industry industry including key risk considerations emphasised in ICH E6 R3:
  - Proportionate Risk-Based Approach
  - Critical to Quality (CtQ) Factors
  - Risk Assessment & Management
  - Sponsor and Investigator Responsibilities

Risk-based quality management system (QMS) – what does this really mean? How does it look?

- What are the elements of a QMS which include risk
- What does a regulatory inspector expect to be in place for clinical trials?
- Group discussion on using a clinical QMS, including risk

Risk-based processes/tools and techniques

- Examples of risk management processes
- Risk based tools for clinical trials including:
  - Root cause analysis
  - Risk breakdown structure
  - Risk log
  - Risk prioritisation techniques (scoring systems, heat maps, etc.)
  - Failure mode and effect analysis
  - Risk Matrix
  - Examples of pharmaceutical risk specific tools for clinical trials including Risk Assessment Categorisation Tool
- Identification of Critical to Quality Factors
  - How to determine what is critically important to the successful completion of the trial.
- Quality Tolerance Limits
  - What are the QTLs and how to define them
- Applying corrective and preventative actions (CAPA)

Brief review of risk-based approaches to auditing

- Example of best practice guide – RQA (Research Quality Association)

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 date

7 October 2025

Live online
09:30-17:00 **UK (London)** (UTC+01)
Course code 14983

GBP **649** ~~749~~
EUR **909** ~~1,049~~
USD **1,043** ~~1,199~~
Until 02 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 **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

★★★★☆

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.

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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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