IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Practical Risk Management in Clinical Research and Trials

23 April 27
+ 5 October 27

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 now central to regulatory expectations in clinical research. Under ICH GCP E6 (R3) and ICH E8 (R1), sponsors and investigators must implement proportionate, risk-based approaches that protect participant safety, ensure data integrity, and demonstrate effective oversight throughout the clinical trial lifecycle.

Regulators increasingly expect organisations to show how risk is identified, assessed, managed and monitored in practice - not simply documented in theory.

This course provides a practical, inspection-focused guide to implementing risk management within clinical trials and clinical quality systems. It bridges regulatory expectations with real-world tools and processes that can be applied immediately in sponsor, CRO and study site environments.

Benefits of attending

- **Understand** regulatory expectations for risk management under ICH GCP E6 (R3) and ICH E8 (R1)
- **Learn** how to identify and prioritise Critical-to-Quality (CtQ) factors
- **Apply** practical tools for risk identification, assessment and control
- **Integrate** risk management into your Quality Management System (QMS)
- **Link** risk findings to CAPA, oversight and continuous improvement
- **Be** better prepared to explain and defend your risk processes during inspections

Who should attend

This course is designed for professionals involved in clinical research and trial oversight, including:

- Clinical Operations and Study Management
- Quality Assurance and Compliance
- Regulatory Affairs
- Risk and Quality Management Professionals
- Clinical Project Managers
- CRO and Vendor Oversight Personnel
- Clinical Trial Managers and CRAs

It is suitable for those implementing risk-based approaches, updating systems in line with ICH GCP E6 (R3), or preparing for regulatory inspection.

Programme

Introduction to risk management in clinical trials

- Core risk management principles and terminology
- Evolution of risk-based approaches in clinical research
- Why risk management is critical to trial quality and compliance

Regulatory framework and critical-to-quality thinking

- Risk expectations under ICH GCP E6 (R3)
- Proportionate, risk-based approaches in practice
- Critical-to-Quality (CtQ) factors and Quality Tolerance Limits (QTLs)

Risk-based quality management systems

- Integrating risk into clinical processes and governance
- Documentation and evidence inspectors expect
- Applying risk management within a clinical QMS

Risk tools used in clinical trials

- Risk logs, risk matrices and prioritisation techniques
- Failure Mode and Effect Analysis (FMEA) and structured methodologies
- Risk tracking, scoring systems and escalation mechanisms

Managing and monitoring risk in practice

- Linking risk to monitoring strategies and oversight
- Root Cause Analysis and CAPA
- Sponsor and investigator responsibilities under ICH GCP E6 (R3)

Risk-based oversight and continuous improvement

- Risk-based auditing and inspection readiness
- Learning from inspection findings
- Continuous improvement and governance

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

23 April 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17114*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 26 Feb**
5 October 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17387*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 10 Aug**

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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