IPI Academy

MANAGEMENT forum



Presented by
Management Forum

ICH Q9(R1) Quality Risk Management (QRM)

24 June 27
+ 3 December 27

A full-day masterclass that shows GMP teams how to put ICH Q9(R1) into practice. Learn how to turn Quality Risk Management from a compliance exercise into a practical, data-driven approach that strengthens product availability, contamination control, and regulatory readiness.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

This full-day masterclass goes beyond the fundamentals of ICH Q9(R1) and focuses on how to operationalise the revised guideline in real-world GMP environments. Participants will learn how to transform QRM from a compliance activity into a strategic, data-driven decision-making framework that strengthens product availability, contamination control, and organisational resilience.

The course blends practical exercises, scenario-based workshops, and interactive simulations to help teams apply the new principles of subjectivity reduction, uncertainty management, proportionality, and lifecycle-integrated risk thinking.

This programme is ideal for organisations seeking to modernise their QRM systems, align with evolving regulatory expectations, and prepare for the digital future of risk management.

Benefits of attending

- **Translate** ICH Q9(R1) principles into operational QRM frameworks
- **Build** risk systems that support supply continuity and contamination control
- **Apply** proportionality to ensure QRM effort matches true risk impact
- **Identify** and mitigate cognitive bias in risk assessments
- **Quantify** uncertainty and incorporate it into decision making
- **Use** structured techniques to uncover hidden hazards

Who should attend

This course is designed for a cross-functional pharmaceutical audience - anyone involved in making, reviewing, or approving risk-based decisions in GMP operations. Attendees include:

- Quality Assurance and Quality Control personnel
- Risk owners and decision makers
- Manufacturing & operations leaders
- Process development & validation specialists
- Engineering and Technical Support
- Regulatory Affairs professionals
- Supply Chain and technical operations managers
- Validation, Process Development, and Engineering roles
- Regulatory affairs teams
- Consultants, Auditors, and Service Providers
- Digital transformation and data analytics roles

Programme

Module 1: The new QRM landscape

- Why Q9(R1) matters now
- Regulatory signals and inspection trends
- The shift from compliance to strategic risk management

Module 2: Bias, uncertainty & decision quality

- Deep dive into subjectivity drivers
- Tools to reduce bias in cross-functional teams
- Practical uncertainty scoring models

Module 3: Advanced hazard identification

- Systems thinking approaches
- Failure pattern recognition
- Hazard identification for contamination control
- **Simulation:** Hidden hazards in a sterile manufacturing scenario

Module 4: Proportionality & right sizing

- When to use high formality vs low formality QRM
- Scaling tools for product availability risks
- **Case Study:** Choosing the right level of formality

Module 5: Digital QRM & AI enabled risk systems

- Data driven risk review
- Digital maturity models for QRM
- AI use cases in hazard detection and trending
- **Interactive Exercise:** Designing a digital QRM dashboard

Module 6: Building a future ready QRM programme

- Integrating QRM across the lifecycle
- Strengthening contamination control strategy
- Preparing for next generation regulatory expectations
- Group discussion & action planning

Case Study - Risk scoring & risk based decision making

Presenters



Farah Nadeem

Farah Nadeem is an Operations Manager at Paul R. Palmer Limited/ Pharmaceutical Consultant and a Trainee Qualified Person. Farah is a Pharmacist and recognised QA expert and has over 20 years of experience in the Pharmaceutical industry in the development, manufacture and supply of medicinal products.

Throughout her career, she has held various quality assurance roles and actively pursued new opportunities to expand her knowledge and expertise. As a result, she has gained a comprehensive understanding of manufacturing, storage, and distribution processes, as well as the facilities and services that support them. Involved in documentation management: writes, reviews, and audits SOPs and QMS implementations. Assists companies in meeting regulatory requirements.

In her current role as a QA Operations Manager for a Pharmaceutical Consultant Company, Farah Nadeem provides various solutions, including assistance in obtaining the first MIA(IMP) and MIA licenses, as well as preparation and hosting for regulatory inspections. Her work involves collaborating with Paul Palmer to offer services such as QP declarations for API manufacturers, regulatory inspection hosting, commercial and clinical batch release, compliance audits, and coaching and training in GxP.



Aneta Jell

Aneta Jell is a seasoned Quality Assurance professional with over 20 years of experience across manufacturing, contract operations, and quality leadership in the pharmaceutical industry. Currently serving as Quality and training manager at PaulPalmer limited she oversees global contract manufacturing quality, ensuring GxP compliance, regulatory alignment, and supply chain integrity. Her expertise spans GMP, ISO 9001, ISO 17025, and QMS administration, with proven strength in audits, CAPA, deviations, and technical agreements. A qualified QMS lead auditor with bilingual proficiency in English and Slovak, Aneta is recognised for driving continuous improvement, fostering compliance culture, and leading high-performing quality and HSE teams.

Course dates

24 June 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17261*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 29 Apr**
3 December 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 17557*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 08 Oct**

How to book

Online:
ipi.academy/2707

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

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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