IPI Academy

MANAGEMENT forum

Presented by
Management Forum

ICH Q9(R1) Quality Risk Management (QRM)

25 September 2024

ICH Q9(R1) Quality Risk Management has recently been updated by the regulators. This training course will bring participants right up-to-date with the latest Q9(R1) requirements. It will explain the changes and give context as to how these impact pharmaceutical products and processes. It will cover a range of product types and situations.

Format:
Live online

Certificate of completion

Overview

ICH Q9R1 Quality Risk Management has recently been updated by the regulators.

This update has been triggered by regulators seeing evidence of inadequacies in quality risk management processes, such as unjustified assumptions, unsystematic approaches, formality not commensurate to the risk, high levels of subjectivity, and that these can impact product availability.

This training course will bring participants right up-to-date with the latest Q9R1 requirements. It will explain the changes and give context as to how these impact pharmaceutical products and processes. It will cover a range of product types and situations.

This is an ideal opportunity to get up to speed with the recent changes and discuss the implications with an expert in this field.

Benefits of Attending

- **Keep** up to date with the changes
- **Understand** the implications on products and processes
- **Discuss** new terms such as subjectivity, uncertainty, importance and complexity
- **Stay abreast** of the latest thinking on Quality Risk Management (QRM)

Who Should Attend

Anyone from the pharmaceutical industry or related academia who wants to ensure they are up-to-date with the latest thinking on QRM, including:

- Manufacturing, production management, and technical support functions
- Development scientists
- Engineers
- Regulatory departments
- Quality Assurance
- Supporting companies such as equipment suppliers and consultants

Programme

Welcome and Introduction

Background to Q9(R1) Regulatory Update

Summary of the Main Steps for a QRM Approach from 'Initiation to Review'

Explanation of the Main Changes and How this will Impact Development and Manufacturing Processes

Introduction of New Terms Such as Formaility, Risk-Based Deciision-Making, Subjectivity, and What They Mean

Examples of Good and Poor Practices in the Use of QRM for a Range of Pharmaceuticals

The Importance of QRM and Product Availability Risks

How Risks may Change Across the Product Lifecycle with Examples

Q&A and Key Take-Aways

Presenter

Bruce Davis

Bruce Davis runs his own training/consultancy company for science and risk based approaches to Engineering and Process Validation (PV), Quality by Design (QbD), Technology Transfer (TT), Quality Risk Management and other related topics. He has run many training events for companies both in the UK and internationally. He is past Chair of ISPE International Board of Directors. He led, co-lead or contributed to a number of their guidances for PV, QbD & TT and most recently has co-written one chapter on TT for ATMPs (i.e personalised medicines) . He is a professional engineer with many years' experience in the pharmaceutical industry and a wide international knowledge. He previously worked at AstraZeneca, where his responsibilities included managing international engineering and leading changes to qualification practices. He is an established trainer and likes to engage with participants, to try to ensure the training experience is related to their particular requirements, and to bring in the importance of science and risk based thinking.

Course date

25 September 2024	**Live online** 13:30-17:00 **UK (London)** (UTC+01) *Course code 14277*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 21 Aug**

How to book

Online:
ipi.academy/2707

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

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

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ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy