IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Process Validation for Medical Devices

10-11 June 27
+ 2-3 December 27

This course focuses on the Regulatory and Quality Management System links to Process Validation for medical devices, and reviews the Installation Qualification, Operation Qualification and Performance Qualification Processes and how these fit with regulatory needs and technical documentation.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Overview

Gain the knowledge and practical expertise required to successfully implement process validation within the medical device industry. This comprehensive training provides a thorough understanding of regulatory expectations, validation methodologies, and industry best practices, while equipping participants with the practical skills to plan, execute, document, maintain, and continuously improve process validation activities throughout the product lifecycle.

Through interactive workshops, real-world case studies, and scenario-based exercises, participants will gain hands-on experience in applying key validation principles, including risk assessment, User Requirement Specifications (URS), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), validation planning and documentation, data integrity, and software validation considerations. The course also explores Validation Master Plans, continuous process verification, and managing deviations during validation execution.

By bridging regulatory requirements with practical implementation, this training enables participants to confidently apply process validation principles, enhance product quality, ensure regulatory compliance, and support the delivery of safe and effective medical devices.

Benefits of Attending

- **Gain** a clear understanding of how Process Validation fits into the Quality Management System
- **Understand** the regulatory drivers for Process Validation
- **Know** the scope of FDA, EU and UK guidelines
- **Realise** significant business benefits by clarifying the key purposes of validation
- **Receive** a practical demonstration of document format and content expectations

Who Should Attend

- Validation specialists new to the medical device industry
- Quality and Regulatory specialists wanting to understand where Process Validation fits into compliance needs
- Process engineers
- Validation and Qualification managers
- Operations managers

Programme

Day 1

Why is Process Validaton Needed?

- Regulatory need - USFDA, EU, UK
- Quality need - fitting into the QMS
- Links for Design and Development
- Validation Policy, Validation Master Plan, Validation SOP
- Process Mapping Study

Where to Start?

- Risk assessment
- Direct, Indirect, or no impact to product quality
- Level of validation required

User Requirement Specification (URS)

- Review internal procedure.
- Format
- Approval
- Critical Process Parameters
- Critical Quality Attributes

Group Exercise - Review of an Existing URS

- Critique of format
- Critique of content

Workshop: URS

- Breakout groups to review and suggest improvement in the selection of URS

Day 2

Factory Acceptance Test

- Definition and example

Site Acceptance Test

Facility Qualification

- HVAC
- Water
- Steam
- Compressed Gas

Computerized System Validation

- Electronic Signatures and Electronic Records
- IT Cyber Security
- Disaster Recovery & Business Continuity
- GAMP5

Cleaning Validation

- Prerequisites and example

Personnel Qualification

- Training
- Education

Analytical Method Validation

- Prerequisites and example

Supplier Assessment

- Supplier Audit & Qualification

Instalation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)

- Regulatory need? How will this fit with Technical documentation?
- Risk-based commissioning and qualification
- Quality Need? What drives this from the QMS?
- Links for Design and Development
- Validation Master Plan
- Continuous PQ – What and when?

Validation Protocols

- Review internal procedure
- Example of good practice with links to conformity assessment requirements
- Sampling plan requirements

Valdiation Protocol Execution

- Recording of findings
- Managing excursions from required performance
- Data Integrity
- Considerations
- Approval

Change Control, Revalidation & Requalification

- Risk-based change control
- When to requalify, how to revalidate?

Group Exercise: Review of Exisiting Validation Plan & Report

- Critique of format
- Critique of content

Workshop: Validation Plan & Report

- Breakout groups to review and suggest imporvement in Validation Protocol

Presenter



Mustafa Edik

Mustafa Edik is a leading pharmaceutical, biotechnoloy, medical device quality and GXP expert with over 28 years of hands-on leadership in GMP, GDP, GCP, GLP, and broader GxP compliance across the pharmaceutical, biotechnology, and medical device industries.

As Turkey's first IRCA-certificated Lead Auditor for GMP and Pharmaceutical Quality Management Systems (PQMS), he brings unmatched credibility and depth to audits, compliance strategies, and regulatory readiness. Holding a BSc in Chemistry, and a BSc (Hons) in Biopharmaceutical Sciences & Engineering from Atlantic Technological University (Ireland), and an Executive MBA, Mustafa combines strong scientific foundations with strategic business acumen.

His career highlights include senior roles at Bayer Türkiye, where he progressed from Quality Control Lab Supervisor to Deputy QA Manager, and GMP Lead Auditor to Global GMP Lead Auditor, managing complex quality operations and audits in a multinational environment. He has personally led more than 4,200 hours of GxP audits across over 200 facilities worldwide.

Today, as Founder and Lead Consultant at Quality Academia Eğitim & Danışmanlık, Mustafa delivers high-impact consulting, training, and project management services to local and global clients. His expertise spans across:

- GMP/GDP audits and supplier qualification
- Validation, qualification, and quality risk management (ICH Q9)
- Root cause analysis, CAPA, OOS/OOT, change control, and data integrity
- Sterile/non-sterile manufacturing, process improvement, and cost-of-quality optimisation
- Clinical trials (GCP & ICH E6), pharmacovigilance, and third-party manufacturing
- Regulatory alignment with FDA, EMA, PIC/S, MHRA, TGA, TMMDA, WHO, and ICH standards

Mustafa has trained over 9,000 professionals in GxP topics and designed certified auditor programs for Turkish authorities including Turkish MOH and Ministry of Agriculture and Foresty. He served as Principal GMP Consultant & Auditor at the Turkish Atomic Energy Authority, supporting successful TMMDA GMP approvals for 5 radiopharmaceutical products. As the first Turkish consultant selected by the Developing Countries Vaccine Manufacturers Network (DCVMN), he has led teams of 100+ engineers, auditors, and quality specialists while managing dozens of international projects.

A prolific author, Mustafa's works include:

- “Sorularla GMP Dokümantasyonu” – a practical guide to GMP documentation
- “GMP Audits in Pharmaceutical and Biotechnology Industries” (Taylor & Francis / CRC Press, June 2024) – a comprehensive reference on effective GMP auditing practices

Recognised internationally for his practical, risk-based approach and knowledge transfer focus, Mustafa Edik is dedicated to elevating pharmaceutical quality standards, helping companies achieve compliance excellence, reduce risks, and drive operational efficiency.

Course dates

10-11 June 27	**Live online** 09:30-17:15 **UK (London)** (UTC+01) *Course code 17217*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 15 Apr**
2-3 December 27	**Live online** 09:30-17:15 **UK (London)** (UTC+00) *Course code 17550*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 07 Oct**

How to book

Online:
ipi.academy/2684

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

★★★★☆

Overall, satisfied. Although a lot of the course was very high level - a better understanding of process validations and requirements was achieved.

Gerard Curran
Quality Engineer
FIRE1
Jun 4 2026

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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