IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Process Validation for Medical Devices

22-23 October 2025

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

Process validation is the means of ensuring and providing documentary evidence that processes (within their specified design parameters) are capable of consistently producing a finished product of the required quality.

This course has been designed to focus on process validation for medical devices. Day one will review the Regulatory and Quality Management System (QMS) links to process validation – essentially the need for validation. It will look at the preparation steps to be taken, including initial Risk Assessment, User Requirement Specifications (URS), the format of URS and include a practical review of bad versus good examples.

Day two of the course reviews the Installation Qualification, Operation Qualification and Performance Qualification process (IQ, OQ and PQ) reviewing how this fits with regulatory needs and technical documentation. It will also look at the validation master plan and discuss continuous PQ and when that may be appropriate. Additionally, validation protocol content and execution, covering the recording of findings, managing excursions from required performance, plus other considerations will be reviewed.

Data integrity with an overview of the GAMPv (Good Automated Manufacturing Process) for software will also be included.

This is an excellent opportunity to receive a practical approach to Process Validation for 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 an Independent GMP Consultant and Auditor.

After graduating as a Chemist from university, Mustafa began his 25 year plus career as a Laboratory Supervisor at Bayer, a German Pharmaceutical Company. After 15 years of working as a Quality Assurance Assistant Manager, Laboratory Supervisor, Pharmaceutical Quality Management Systems, and GMP Lead Auditor, he decided to continue his career as a Consultant. He has served the Turkish Atomic Energy Authority (TAEA) as Principal GMP Auditor and Consultant for 6 years. TAEA was audited by the Republic of Turkey Ministry of Health and granted GMP Certificate for 5 Radiopharmaceuticals. This success has won great acclaim from all health authorities and industry.

He has prepared and presented various training courses and workshops to more than 8000 individuals from 150 International and local Pharmaceutical, Medical Device, and Cosmetics companies on GMP, GDP and Pharmaceutical Quality Management Systems. He has taken part in several International Pharmaceutical Facility Establishment projects as GMP Consultant and has also set up various Quality Management Systems for Local Pharmaceutical and Medical Device Companies.

While he was the Vice President of Quality and Technical Operations at a Quality Academia Training and Consultancy firm, he acquired and converted it into a 100 % Turkish Company. As the only IRCA Certificated Pharmaceutical Quality Management Systems and GMP Lead Auditor in Turkey, he currently conducts API, Excipient, Packaging Materials Suppliers and Manufacturers, Third Party Logistics Service Providers, Sterile and Non-Sterile Manufacturing Facilities Audits according to FDA, EMA, PIC /S, TMMDA, MHRA, TGA Health Canada, and WHO regulations and guidelines.

He finished his second university degree in Biopharmaceutical Sciences BSc (Hons) at Atlantic Technological University - Ireland. He is the author of chapter 6 of the book published by PDA named “Good Distribution Practices” and he is preparing his latest book on ‘GMP Audits’ which will be published by Taylor & Francis in 2023.

Course date

22-23 October 2025	**Live online** 09:30-17:15 **UK (London)** (UTC+01) *Course code 15255*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 17 Sep**

How to book

Online:
ipi.academy/2684

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

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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

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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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