IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Process Validation with Qualification

14-15 June 27
+ 1-2 December 27

A focused course on modern, lifecycle-based process validation and qualification. Learn how to design, qualify, and maintain manufacturing processes in a state of control using science- and risk-based approaches aligned with FDA, EU GMP Annex 15, MHRA, and WHO expectations - supporting compliant, efficient, right-first-time validation.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Ensure your manufacturing processes are validated from end to end using modern, science-based practices that meet today's global regulatory standards. In an era where regulators treat validation as a lifecycle activity rather than a one-time exercise, this course provides comprehensive training on how to design, qualify, and maintain processes in a state of control.

Over two days, participants will learn to integrate process validation and equipment/facility qualification into a unified strategy, aligned with FDA's 2011 Process Validation Guidance, EU GMP Annex 15, UK MHRA expectations, and WHO guidelines. The programme walks through each stage - from initial process design and scale-up (Stage 1), through Installation/Operational/Performance Qualification (IQ/OQ/PQ) and Process Performance Qualification (PPQ) (Stage 2), into ongoing Continued Process Verification (CPV) programs (Stage 3).

Emphasis is placed on a risk- and science-based approach: leveraging tools like Quality by Design (QbD), Design of Experiments (DOE), and Process Analytical Technology (PAT) to build quality into the process, and using data analytics to monitor performance. Participants will also learn how to handle re-validation when changes or transfers occur, and how to document validation activities to satisfy inspectors. This course ensures you can validate processes efficiently and right-first time, supporting both compliance and operational excellence.

Benefits of attending

By attending this course, you will:

- **Implement** Annex 15 / FDA lifecycle validation (Stage 1–3) beyond the obsolete "3-batch" model
- **Demonstrate** sustained state of control using PPQ + CPV + PQR/APR integration
- **Align** IQ/OQ/PQ with PPQ execution, meeting ISPE and PIC/S inspector expectations
- **Apply** ICH Q8/Q9 risk-based validation, defending CQAs, CPPs, and acceptance criteria
- **Design** inspection-ready PPQ protocols with statistical and scientific justification
- **Operationalise** CPV and SPC trending, a growing FDA/MHRA inspection focus
- **Eliminate** data integrity risk using ALCOA+ across validation records and systems
- **Validate** digital tools correctly (spreadsheets, PAT, MES) per GAMP 5 and Annex 11
- **Adapt** validation for modern manufacturing, including PAT, RTRT, and continuous processes
- **Control** change without revalidation overkill, aligning Annex 15 with ICH Q12 principles

Who should attend

This course is ideal for professionals involved in pharmaceutical and biopharmaceutical development, manufacturing, engineering and quality who need to design, execute or assess process validation and qualification activities, including:

- Validation Engineers and Specialists Scientists and development scientists
- Pharmacists involved in product and process development
- Quality Assurance professionals and quality managers
- Quality control managers and senior analysts
- Validation and Qualification Specialists/ Engineers
- Technology transfer and scale-up managers
- Risk management specialists
- Lean and operational excellence specialists
- Operations managers and production engineers
- Late-stage product and process development staff
- Regulatory Affairs Personnel (CMC)

Programme

Day 1

Validation fundamentals and execution

Module 1: Regulatory overview of validation

- EU GMP Annex 15 validation principles
- FDA Process Validation lifecycle (Stage 1/2/3)
- WHO TRS validation expectations (lifecycle approach)
- ICH Q8, Q9, Q10, Q11, Q12 – Overview and Implications
- FDA Vs Annex 15

Module 2: Stage 1 - Process design & risk assessment (practical application)

- QbD linkage: CQAs ↔ CPPs ↔ Control Strategy
- ICH Q9 risk tools: FMEA / risk ranking / worst case
- DOE-based parameter understanding (design space thinking)

Module 3: Stage 2.1 - qualification (IQ/OQ)

- URS → DQ → IQ/OQ traceability
- ISPE baseline approach (risk-based qualification philosophy)
- HVAC & Utilities qualification fundamentals (critical systems)

Exercise 1: Building an equipment qualification strategy

Module 4: Stage 2.2 - PPQ / PQ execution

- PPQ protocol essentials: acceptance criteria + rationale
- Sampling plan: locations, frequency, worst case challenge
- Statistical confidence: variability, capability, trending readiness

Module 5: Stage 3 - OPV / ongoing process verification

- OPV plan: critical metrics, alert/action limits
- SPC trending: control charts, shifts, drifts, signals
- APR/PQR integration: trend to governance escalation

Exercise 2: SWOT analysis of validation strategy

Day 2

Advanced Topics and Maintaining Control

Module 6: Validation documentation & data integrity (ALCOA+)

- Validation Master Plan (VMP): Protocol writing: testable requirements + objective evidence
- Part 11 / Annex 11 considerations (e-records / audit trails)
- GAMP 5 alignment for validation systems support

Exercise 3: Designing an OPV system

Module 7: Advanced validation techniques

- Continuous manufacturing validation concepts
- PAT / RTRT readiness (sensor qualification + model validation)
- Cleaning validation: MACO, worst case, residue strategy

Module 8: Maintaining the validated state & change control

- Requalification vs revalidation triggers (risk-based decision)
- Tech transfer interfaces: gap analysis + comparability evidence
- Controlled change implementation

Module 9: Workshop - Validation Plan Build

- Define CQAs/CPPs + control strategy map
- PPQ design: batches, sampling, acceptance criteria
- CPV dashboard: KPIs, alert/action limits, escalation path

Exercise 4 : Change scenario: assess revalidation requirements

Module 10: Inspection readiness & lessons learned

- Inspector hot-spots: rationale, traceability, execution discipline
- Common findings: weak acceptance criteria, poor deviation handling
- Data integrity failure modes: gaps, backdating, missing raw data

Case Study: Building a sustainable ongoing verification programme

Presenter



Paul Palmer

Paul R Palmer is a Director / Pharmaceutical Consultant and a practicing EU / UK Qualified Person. He has over 35 years experience in the pharmaceutical industry in the development, manufacture and supply of medicinal products and medical devices.

Throughout his career, Paul has intentionally taken on all opportunities as they arose in order to develop a broad range of knowledge with an in-depth detailed understanding of manufacturing, storage, distribution, research, computerised systems, as well as the facilities and services to support each.

People and systems have always been a core focus, how to ensure best use, optimise and enhance efficiency. He has a level of curiosity rarely displayed in people taking on the qualified person role in pharmaceutical manufacturing. Culture, behaviour and psychology are all significant influences on the systems and processes we implement, but are often ignored.

Paul studied psychology as part of his MSc in 1993 and has always enjoyed observing the world around him with a curiosity that is rarely satisfied.

Course dates

14-15 June 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17216*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 19 Apr**
1-2 December 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17533*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 06 Oct**

How to book

Online:
ipi.academy/2053

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

★★★★☆

I really enjoyed this webinar. I will be recommending it to colleagues as a great source of information and introduction to process validation. The material was engaging, and [speakers'] knowledge/experience was communicated very well. I greatly enjoyed the content and presentation style. Topics were split up and presented in a logical order and the exercises were very helpful to reiterate the information that was presented.

Brianna Boehm
Process Validation Technical Writer
Aldevron
May 20 2025

★★★★☆

The webinar is well constructed and the speaker is a very polite and prepared person. I managed to get the initial information needed to start studying and understanding the process validation program, the exercises [were] very helpful.

Alessandra Fanzini
CDMO
REITHERA SRL
May 20 2025

★★★★★

Webinar was excellent, very enjoyable and learned a lot of statistics.

Siobhan Crowe
Operation Manager
Univet Ltd
May 21 2024

★★★★☆

The course was very informative and the speaker explained the content very well. I've also liked that all relevant guidelines have been included in the slides.

Laura Sukacz
Quality Operations Officer
Kent Pharma UK Ltd
Jan 16 2024

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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