IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Process Validation with Qualification

22-23 September 2025

Gain a comprehensive understanding of the EU and FDA process validation guidance, learn how to establish a process validation programme, understand the link between QbD and process validation, apply relevant tools for process validation including risk assessment.

Format:
Classroom

CPD:
12 hours for your records

Certificate of completion

Course overview

Attending this invaluable two-day event will give you the tools to fully understand and comply with current EU and FDA process validation guidelines and meet implementation challenges.

In today's pharmaceutical and biopharmaceutical industries, ensuring the reliability and efficiency of manufacturing processes is paramount. The need for rigorous process design, equipment qualification, and validation extends beyond mere compliance; it directly impacts product quality, patient safety, and regulatory adherence.

This comprehensive programme addresses these critical needs by taking a practical and analytical approach to process design, equipment, and utility qualification. It bridges the gap between product specifications and the meticulous verification required for equipment and processes at commercial scale.

Participants will delve into the foundational principles of Good Engineering Practice (GEP), essential for maintaining consistency and reliability throughout the manufacturing lifecycle. The course explores a range of advanced techniques, including Quality Risk Management (QRM), Design of Experiments (DoE), and statistical analysis. These methodologies are pivotal in optimising process qualification, verification, commissioning, and validation to achieve continual improvement and regulatory compliance.

Through expert guidance, attendees will learn how to apply these principles effectively, ensuring robust process design and validation strategies aligned with industry standards and best practices.

Benefits of attending

- **Know** the scope of FDA, EU and other international validation guidelines
- **Establish** a three-stage, science and risk-based, life cycle process validation programme that can be applied to all products internationally, from generic products to novel medicines to ATMPs
- **Clarify** similarities and differences between EU and US regulatory expectations
- **Understand** the importance of a science and risk-based approach to support process validation and qualification
- **Realise** significant business benefits by clarifying the key purposes of validation
- **Reduce** validation documentation by concentrating on product drivers supported by clear qualification steps
- **Unscramble** the real meaning of buzzwords such as qualification, verification and validation
- **Learn** tools and techniques for you to subsequently apply to your products

Who should attend?

Professionals working in development, manufacturing, engineering and quality within the pharmaceutical and biopharmaceutical industry, including:

- Process engineers
- Pharmacists
- Scientists
- Quality assurance professionals
- Quality control managers
- Late-stage product and process development engineers, scientists, pharmacists
- Technology scale-up and transfer managers
- Validation and qualification managers
- Validation and qualification specialists
- Risk management specialists
- Lean management specialists
- Operations managers and engineers

Programme

Day 1

The science and risk-based approach to process validation

ICH Q8/9/10/11/12

Exercise 1 – Key points

Introduction to the FDA process validation guidance

Introduction to the EU process validation guidelines and Annex 15

Exercise 2: Guidances

Process design: FDA PV Stage 1

Exercise 3 : Process design

Quality risk management

Exercise 4: Risk assessment

Day 2

Equipment and utility qualification: FDA PV Stage 2.1

Exercise 5: Equipment qualification

Tools for process validation – part 1

Tools for process validation – part 2

Exercise 6: What techniques/ tools to use at which PV Stage

Process performance qualification / process validation – FDA PV Stage 2.2

Exercise 7: Process validation - number of batches

Continued process verification / ongoing process verification – FDA PV Stage 3

Exercise 8: Ongoing process verification

Case Study: Process improvement

Exercise 9: Continual improvement

Exercise 10: SWOT

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

22-23 September 2025	**Classroom** London *Course code 14938*	GBP **1,499** ~~1,699~~ EUR **2,099** ~~2,379~~ USD **2,407** ~~2,719~~ **Until 18 Aug**

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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