





Presented by Management Forum

# **Mastering Computer System Validation**

**24-25 November 2025** + 17-18 June 2026, 10-11 December 2026

This course covers the key concepts of computer systems validation and provides practical guidance on how to comply with the regulations applicable to the pharmaceutical industry.



**Format:** Live online



**CPD:** 12 hours for your

records



Certificate of completion

# **Course overview**

Ensure your computerised systems are fully compliant, reliable, and designed for long-term success. Mastering Computer System Validation provides a deep dive into the critical discipline that underpins trust in digital pharmaceutical operations. This course moves beyond simple testing to show how a well-structured validation lifecycle proves that your systems perform as intended, every time. You will learn how to establish and maintain systems that generate accurate data, maintain robust audit trails, and secure electronic records for the lifetime of your products.

Regulatory expectations have evolved, and so must your approach. In an era of increasing scrutiny, inadequate validation can lead not only to data integrity breaches but also to costly compliance failures and regulatory findings. Through this course, you will understand how to interpret and apply the principles of EU Annex 11, FDA 21 CFR Part 11, and GAMP®5 with confidence and clarity.

This training transforms CSV from a checkbox exercise into a strategic enabler. You'll explore how validation supports operational excellence, business continuity, and digital transformation initiatives from traditional on-premise systems to modern AI driven and cloud-based platforms. Real world case studies and interactive exercises ensure the lessons translate directly to your workplace.

By the end of the course, you will have mastered a practical, risk-based framework for computerised system validation that aligns with both regulatory requirements and business objectives. Most importantly, you'll gain the assurance and authority to lead validation activities that withstand inspection, safeguard data integrity, and inspire confidence across your organisation.

# Benefits of attending

- Gain a comprehensive overview of computer system validation (CSV)
- **Enhance** your understanding of the key terms used in CSV
- Recognise how Good Practices apply to computerised systems
- Understand the different approaches which might be employed
- Learn how to manage the risk associated with data integrity
- Master Regulatory Frameworks Gain expert-level understanding of EU Annex 11, FDA 21 CFR Part 11, and GAMP 5 principles
- Practical Risk-Based Approach Learn to streamline validation without compromising compliance
- Inspection Readiness Develop documentation and strategies that satisfy inspectors globally
- Future-Proof Skills Understand CSV in the context of AI, SaaS, and data integrity challenges
- Real-World Application Apply your knowledge to authentic case studies from pharmaceutical operations

# Who should attend

- Quality management specialists
- Pharmaceutical validation professionals
- Pharmaceutical project managers
- Computer system engineering specialists



# **Programme**



### Terminology

- Key terms
- Common acronyms

### Overview of computer system validation (CSV)

- Introduction to CSV
- Why is it so important?
- Regulatory requirements
- FDA's 21 CFR Part 11
- Other regulatory guidelines
- International regulations (EudraLex Volume 4 Annex 11,ICH, WHO)
- The GAMP framework

#### Where to start

- How to manage electronic data
- Risk-based approach to CSV
- Audit readiness
- Exercise: data integrity

#### Types of computer system

- Business system
- Standalone control systems
- Equipment control systems
- Infrastructure

### The six elements

- Hardware
- Infrastructure
- Software
- Data
- Documentation
- Records
- Exercise: creating an infrastructure map

### Validation documentation

- Inventory
- SOPs and protocols....
- Records
- Training
- Change control

### **Industry standards**

- cGMP
- GAMP®5
- Validation
- Eudralex
- CFR
- PIC/s
- Exercise: risk management

#### Q&A



### Introduction and recap of day 1

## **Practical application**

- A risk-based approach
- The V model
- Software
- Hardware
- Exercise: putting them together

### Validation in phases

- Concept
- Project
- Operation
- Retirement
- Exercise: Supplier involvement

#### Validation planning

- Risk-based decisions
- Supplier assessment
- Activities
- Deliverables
- Responsibilities
- Exercise scaling effort

### Protocols and testing

- Test relationships
- Structure
- Requirements
- Managing change
- Exercise: summary report

# System validation

- Software validation
- Installation qualification
- Operational qualification
- Performance qualification
- Exercise: what comprises validation

### **Data migration**

- Upgrades
- New systems
- Planning and testing
- Automation vs manual
- Exercise: the process

# Wrap up and Q&A

# **Presenters**



### Paul Palmer

24-25 Nov 2025 17-18 Jun 2026 10-11 Dec 2026

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.



Aneta Jell

24-25 Nov 2025

Aneta Jell is a seasoned Quality Assurance professional with over 20 years of experience across manufacturing, contract operations, and quality leadership in the pharmaceutical industry. Currently serving as Quality and training manager at PaulPalmer limited she oversees global contract manufacturing quality, ensuring GxP compliance, regulatory alignment, and supply chain integrity. Her expertise spans GMP, ISO 9001, ISO 17025, and

QMS administration, with proven strength in audits, CAPA, deviations, and technical agreements. A qualified QMS lead auditor with bilingual proficiency in English and Slovak.

Aneta is recognised for driving continuous improvement, fostering compliance culture, and

leading high-performing quality and HSE teams.

# **Course dates**

24-25 November 2025 Live online

09:30-17:30 **UK (London)** (UTC+00)

Course code 15091

GBP 1,499

EUR 2,099 USD 2,399

17-18 June 2026 Live online

09:30-17:30 **UK (London)** (UTC+01)

Course code 15924

GBP **1,299** <del>1,499</del>

EUR 1,819 2,099

USD 2,087 2,399

Until 13 May

10-11 December 2026 Live online

09:30-17:30 **UK (London)** (UTC+00)

Course code 16228

GBP **1,299** <del>1,499</del>

EUR 1,819 2,099

USD 2,087 2,399

Until 05 Nov

# How to book



# Online:

ipi.academy/2628

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**

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

# \*\*\*\*

All good. Very experienced and knowledgeable speaker, explained every aspect in detail and made simpler.



**Pramod Patil** 

Validation Specialist MeiraGTx Jul 9 2025

# \*\*\*

The session was highly interactive, and the speaker was very open to questions, providing detailed explanations and insights. Their willingness to dive deep into the topics made the session both engaging and informative.



**Jayamol Thomas** 

Quality Manager Moonlake Jul 9 2025

# \*\*\*

Overall, the course was really good, the speakers were of a very high standard and knew their stuff super well. This really shone through their examples and diverse experience in pharmaceuticals.



Yasmeen Scotto

OA Validation Associate Catalent Micron Technologies Limited Mar 19 2024



Overall the course was good.



**Ervin Javier Obnial** 

Validation Specialist ViroCell Biologics Jul 24 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:







**ALEKSANDRA BEER** Email:

**YESIM NURKO** Email:

Harry ALTAMONT Tel: +44 (0)20 7749 4749 Tel: +44 (0)20 7749 4749 Tel: +44 (0)20 7749 4749 Email:

inhouse@ipiacademy.com inhouse@ipiacademy.com inhouse@ipiacademy.com



IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the

10-12 Rivington Street London EC2A 3DU

ipi.academy

**Tel:** +44 (0)20 7749 4749 Email: info@ipiacademy.com