



**Compliance & Validation Services**  
Presents a 2-Day Online Training Course on:

# Pharmaceutical Process Validation

**2 & 3 November 2021**  
**Live Online Training Course**



November 2021						
Su	Mo	Tu	We	Th	Fr	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

- Latest regulatory guidance (USFDA, EMA/EU, PIC/S) & ICH Q8, 9, 10, 11, 12 and the 3 Stage approach to validation
- Effective process development & understanding
  - Identifying Critical Quality Attributes, establishing Critical Process Parameters and their relationships, including Design Space
  - Quality by Design (QbD)
- Tools for Process Validation
  - Quality Risk Management
  - Use of Statistics
- Process Validation approaches for:
  - Small & large molecule API/Drug Substance manufacture
  - Pharmaceutical Drug Product manufacture, including fill/finish
  - Pharmaceutical Packaging
- Maintaining the Validated State
  - Continued/Ongoing Process Verification
  - Statistical process control
  - Quality Systems, e.g. effective change control

## Course Summary: Pharmaceutical Process Validation - 2 & 3 November 2021 - Live Online Training Course

This pharmaceutical validation training course provides attendees with a detailed appreciation of the full life cycle related to pharmaceutical and biopharmaceutical process validation. The course covers process validation for pharmaceutical and biopharmaceutical Active Pharmaceutical Ingredients (API's), a variety of pharmaceutical product formulations and primary/secondary packing.

The course includes areas such as: the concept of Operating Space, Design Space and Knowledge Space and how this relates to real life; typical process design considerations; the importance of correctly identifying critical quality attributes and the control parameters that influence / affect them (using risk assessment tools to help); quality by design and design of experiments; equipment / process control philosophy and maintaining process development traceability from laboratory through to pilot / scale-up studies and eventual production scale.

A typical approach to the validation of secondary packing operations is included, together with an overview of key regulations, guidelines and standards, including the latest FDA process validation guide and ICH Q8. Validation documentation requirements, sampling requirements (acceptable quality levels), management of deviations and Continued Process Verification, including critical GMP supporting systems, are also covered by this course. The course will be presented by individuals who have extensive and recent 'hands-on' knowledge and experience of the subject.

### Presenters



**Mike James, Compliance & Validation Services Limited:** Mike has over 25 years' experience in the pharmaceutical industry, working in a variety of compliance and validation roles. His experience includes preparation and delivery of national/client-based validation training courses, hands-on validation work, validation project management and regulatory compliance consultancy. Previously, Mike spent four years as the Site Validation Manager for GlaxoSmithKline (GSK) at Speke, where he was responsible for all site validation activities, including the development and maintenance of the Site Validation Programme. Before moving to the pharmaceutical industry he spent 15 years as an industry chemist. x



**Bruce Davis** has over 25 years experience with the pharmaceutical industry having previously worked for AstraZeneca. He is an engineer by profession & has put in place many development and manufacturing facilities, in EU, the Americas and Asia. He is strong supporter of the benefits brought from science and risk based approaches, supporting Quality by Design and the latest 3 Stage Process Validation. He started his own business in 2008, running training and consultancy both externally and in-house for pharmaceutical companies. He likes to make his courses engaging and relevant and is passionate about the importance of linking science and technology to practical manufacturing and engineering, to support patient needs.



**Peter Whyment:** Peter has worked in the Biopharmaceutical Manufacturing Industry for over 30 years and has a wealth of knowledge/expertise in the area of process validation. During his time in industry he has worked in Quality Control Laboratories, Analytical Development and as a senior scientist in a Manufacturing, Science & Technology function, Peter has overseen the successful technical transfer or commercial manufacturing of several biotechnology processes, including Insulin and growth hormone products.

### Who Should Attend

Individuals to benefit from attending this course include anyone involved directly or indirectly in process validation activities. The course is ideally suited to people who are new to process validation roles, or those who wish to expand their knowledge base, or those whose job roles require them to have a greater understanding of process validation. This will involve personnel from production, quality assurance, validation, technical support and engineering departments.

On leaving the course attendees will: have a broad and detailed understanding of the activities involved in pharmaceutical process validation; be able to apply and share their new knowledge; improve their individual effectiveness; and look back on a valuable experience.

### Online System & Course Fees

We use the industry leading GotoWebinar®, LogMeIn, Inc. platform for our online training courses. It's intuitive and simple to use, however we do recommend that you check your system's compatibility using the 'CHECK SYTEM COMPATIBILITY' link provided below (we use 'standard webinar'). To find out more about how our online training process works, from booking through to the end of the course, please click on the 'HOW IT WORKS' link provided below.

[CHECK SYSTEM COMPATIBILITY](#)

Course fees are **£1,120.00 (GBP)** per attendee.  
(See Page 4 for further details on fees/bookings)

[HOW IT WORKS](#)



## DAY 1 (Tuesday 2 November 2021)

## Day 2 (Wednesday 3 November 2021)

**Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam**

### Introduction *[Mike James]*

- Fundamental reasons for undertaking process validation and for getting it right
- Overview of regulations and a summary of documentation requirements

### A science and risk based, lifecycle approach to Product Development and Manufacture – Validation Stage 1 *[Bruce Davis]*

- The link between Process Validation and a lifecycle approach to Product Development and Manufacture
- Introduction to Quality by Design (QbD) (ICH Q8 and Q11)
- QbD terminology:
  - Quality Target Product Profile (QTPP)
  - Critical Quality Attribute (CQA)
  - Critical Process Parameter (CPP)
  - Critical Material Attributes (CMA)
  - Design Space
  - Control Strategy
  - Continual Improvement
- Examples/workshops
- ICH Q12 draft
- Application to legacy products

### Systems Supporting a Science and Risk based approach *[Bruce Davis]*

- Quality Risk Management (ICH Q9)
  - Risk tools, using real life examples
- Pharmaceutical Quality System (ICH Q10) – Applicable to the product lifecycle
  - Process & Product Quality Monitoring
  - Corrective & Preventative Action (CAPA)
  - Change Management
  - Management Review

### Tools Supporting QbD *[Bruce Davis]*

- Process Analytical Technology (PAT)
- Design of Experiments (DoE)
- Process Analysers
- Multivariate data analysis
- Process Modelling
- Process Control

**Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam**

### Statistics For Process Validation *[Bruce Davis]:*

- Tools used and application throughout the lifecycle of process validation.

### Process Performance Qualifications, US & The different EU approaches to Process Validation – Validation Stage 2.2 *[Bruce Davis]:*

- Relationship to development phase (process design objectives)
- Establishing the number of batches required
  - Risk and statistical basis
  - Bracketing, Matrix, and Family Approaches
- Establishing acceptance criteria
- Testing / sampling matrix – covering CQAs
- Traditional Process Validation
- Continuous Process Verification
- Hybrid approach

### Continued/ Ongoing Process Verification – Validation Stage 3 *[Bruce Davis]*

- CPV plan
- Product Quality and Process Performance Monitoring System
- Statistical Process Control tools
- Link to APQR

### API Process Validation, Small Molecules *[Mike James]*

- Regulatory perspective
- Determining impurity profiles and identifying risks
- Simplifying manufacturing routes
- Identifying / defining critical process parameters
- Typical PV approaches to multistage synthesis of APIs/Workshop

### Process Validation - Biopharmaceutical API Manufacturing *[Industry Expert]*

- Real-life case studies
  - Process definition
  - Critical process control parameters
  - Sequence of events involved in a complex project
  - Process validation testing strategy
  - Resolving issues

### Packaging Validation *[Mike James]*

- Annex 15 – What is its impact?
- Key considerations relating to packing process robustness
- What are the GMP risks relating to poor operations/materials
- Key packaging attributes and related control parameter
- Equipment qualification focus versus process validation focus
- Typical validation approaches, including grouping of products in relation to pack/line set-up.

**Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam**

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**How to book on this course:**

- The simplest and quickest way is to book online. Please visit/return to our web-site, find the online course you are interested in and follow the simple instructions (link included below), or
- Print out this page, complete the form below by hand and return by fax, email or post.

**CLICK HERE TO BOOK ONLINE**

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Tel: +44 (0)1625 500833 or +44 (0)1270 760882

 E-mail: [info@candvs.com](mailto:info@candvs.com)
**Alternative Booking Form (\*\* indicates required fields)**
**Booking Terms & Conditions**

<b>*Booking Contact Name:</b>		
<b>*Booking Contact E-mail Address:</b>		
<b>*Booking Contact Telephone Number:</b>		
<b>*Company Name &amp; Address:</b>		
<b>*Billing Address</b> <i>(Only complete if different to Company Address)</i>		
<b>*Attendee Information:</b>	<b>Attendee Name(s):</b>	<b>Attendee Email Address:</b>
<b>Company VAT Number (or Sales Tax Number) – *EU Countries Only</b>		
<b>*Method of payment, e.g. card or invoice payment</b>	NOTE: For card payments by telephone, please ensure you have entered your telephone number above and we will contact you. Alternatively, call +44 (0)1625 500833 to make your payment.	
<b>Payment Reference (if available)</b>	NOTE: For invoice payments we will need a valid purchase order number to fully confirm the booking.	
<b>* Total Fees Due</b> <b>£1,120 [GBP]</b> per attendee	NOTE: If your finance centre or attendees are based in the United Kingdom (UK), or attendees are booking as private individuals (non-company), the course fee will be subject to an additional 20% UK VAT charge ( <b>£1,344</b> per attendee including UK VAT). For EU Countries where finance centres and attendees are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule. For non-EU countries and non-EU attendees, VAT is not applicable.	

**Booking Confirmation**

Bookings will only be confirmed upon payment by credit card, or in the case of invoice payment (bank transfer), upon receipt of a valid purchase reference number.

**Cancellation by Attendees**

Cancellation refunds will depend on how long before the course start date the cancellation is received. The following refund structure will apply:

- More than 7 days will qualify for a refund of the course fee paid after the deduction of actual expenses incurred by CVS in connection with the course that the attendee has registered for and there shall be no future liability on the part of either party.
- No refund will be given for cancellations received with less than 7 days' notice.
- Substitutions for registered attendees from the same company will be accepted without notice, but for administration purposes, we kindly ask you to let us know as soon as you can.

**Cancellation by CVS**

CVS does not issue refunds for attendees unless:

- We have cancelled a course.
- We have changed the time or date of a course.

If we do cancel or reschedule an event, CVS is not responsible for any costs incurred by attendees. Only the course fee will be refunded.

Please be assured that we are not in the habit of cancelling events. We only cancel events in exceptional circumstances.

**Speaker/Presenter Changes**

We reserve the right to change a speaker without notice.

**Course Attendees**

If you click 'yes' to 'include my name/company' on the attendees list', when completing the online booking form, your name and company will be included on the list and distributed to all the participants.

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**Course Fee & VAT Liability**

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**Liability**

CVS reserve the right to cancel or reschedule any course and/or change presenters.

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