

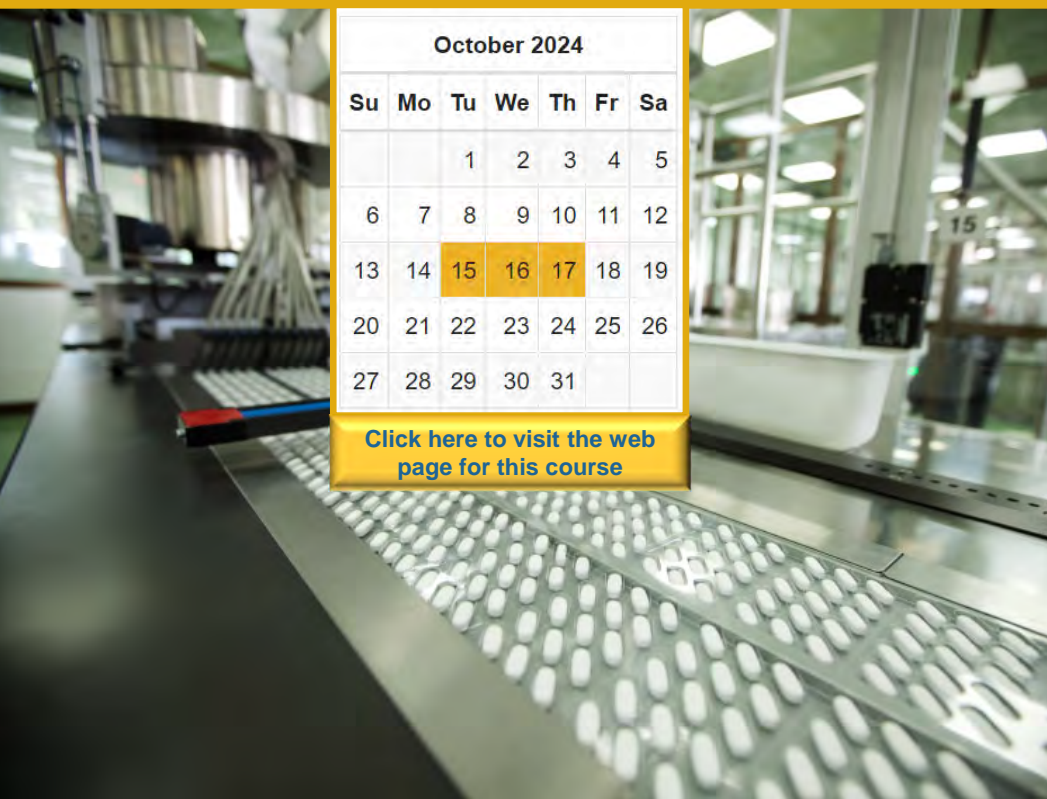


**Compliance & Validation Services**

**Presents a 3-Day In-Person Training Course on:**

# **Pharmaceutical Process Validation**

**Hotel Scandic Copenhagen, Denmark  
15, 16 & 17 October 2024**



October 2024						
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	31		

[Click here to visit the web page for this course](#)

- Latest regulatory guidance (USFDA, EMA/EU, PIC/S) & ICH Q8, Q9, Q10, Q11, Q12 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
    - Equipment Qualification
    - Packaging Process Validation for a range of primary packaging types/formats
    - Secondary and tertiary packaging are also covered
  - Continued / Ongoing Process Verification
  - Statistical process control

## Course Summary - Pharmaceutical Process Validation - 15, 16 & 17 October 2024 - Hotel Scandic Copenhagen

This pharmaceutical validation training course provides delegates 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 packing operations/processes (covers different types of primary packaging) is included, together with an overview of key regulations, guidelines and standards, including the FDA process validation guide and ICH Q8. Validation documentation requirements, sampling requirements, acceptable quality levels, management of deviations and Continued Process Verification, together with critical GMP supporting systems are also covered by this course.

Delegates will be provided with a 3-slide per page printed binder upon arrival on Day 1 and PDF versions of the slides will be sent out by email to each delegate after the course. Day-time meals and refreshments, together with a drinks reception and course dinner, held on the evening of Day 1 (Tuesday 15 October 2024), are included in the overall package

### 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 delegates 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.

### Venue & Course Fees

**Hotel Scandic Copenhagen:** Modern, centrally located hotel with great views of the Lakes and Copenhagen's skyline. The hotel facilities include a gym, bar and restaurant.

Address: Vester Søgade 6, 1601 Copenhagen V, Denmark

Tel: +45 33 14 35 35

Email: copenhagen@scandichotels.com

[Click here to view Hotel's location \(Google Maps\)](#)

[Click here to visit the Hotel's website](#)



Course fees are **£2,500.00 (GBP)** per delegate. Accommodation is **NOT** included. (See Page 4 for further details on fees/bookings)



Day 1 (Tuesday 15 October 2024)	Day 2 (Wednesday 16 October 2024)	Day 3 (Thursday 17 October 2024)
<b>Start: 09:00 CET</b>	<b>Start: 09:00 CET</b>	<b>Start: 09:00 CET</b>
<b>Introduction [Mike James]</b> <ul style="list-style-type: none"> <li>Fundamental reasons for undertaking process validation and for getting it right</li> <li>Examples of what can happen if you get things wrong</li> </ul>	<b>Statistics For Process Validation [Bruce Davis]:</b> <ul style="list-style-type: none"> <li>Tools used and application throughout the lifecycle of process validation.</li> </ul>	<b>Introduction to Qualification and Validation of Pharmaceutical Packaging [Mike James]</b> <ul style="list-style-type: none"> <li>Scope and key concepts</li> <li>Critical aspects</li> <li>Development of the packaging system URS</li> </ul>
<b>A science and risk based, lifecycle approach to Product Development and Manufacture – Validation Stage 1 [Bruce Davis]</b> <ul style="list-style-type: none"> <li>The link between Process Validation and a lifecycle approach to Product Development and Manufacture</li> <li>Introduction to Quality by Design (QbD) (ICH Q8 and Q11)</li> <li>QbD terminology:               <ul style="list-style-type: none"> <li>Quality Target Product Profile (QTPP)</li> <li>Critical Quality Attribute (CQA)</li> <li>Critical Process Parameter (CPP)</li> <li>Critical Material Attributes (CMA)</li> <li>Design Space</li> <li>Control Strategy</li> <li>Continual Improvement</li> </ul> </li> <li>Examples/workshops</li> <li>ICH Q12</li> <li>Application to legacy products</li> </ul>	<b>Process Performance Qualifications, US &amp; The different EU approaches to Process Validation – Validation Stage 2.2 [Bruce Davis]:</b> <ul style="list-style-type: none"> <li>Relationship to development phase (process design objectives)</li> <li>Establishing the number of batches required               <ul style="list-style-type: none"> <li>Risk and statistical basis</li> <li>Bracketing, Matrix, and Family Approaches</li> </ul> </li> <li>Establishing acceptance criteria</li> <li>Testing / sampling matrix – covering CQAs</li> <li>Traditional Process Validation</li> <li>Continuous Process Verification</li> <li>Hybrid approach</li> </ul>	<b>Process Validation - Biopharmaceutical API Manufacturing [Peter Whyment]</b> <ul style="list-style-type: none"> <li>Real-life case studies               <ul style="list-style-type: none"> <li>Process definition</li> <li>Critical process control parameters</li> <li>Sequence of events involved in a complex project</li> <li>Process validation testing strategy</li> <li>Resolving issues</li> </ul> </li> </ul>
<b>Systems Supporting a Science and Risk based approach [Bruce Davis]</b> <ul style="list-style-type: none"> <li>Quality Risk Management (ICH Q9)               <ul style="list-style-type: none"> <li>Risk tools, using real life examples</li> </ul> </li> <li>Pharmaceutical Quality System (ICH Q10) – Applicable to the product lifecycle               <ul style="list-style-type: none"> <li>Process &amp; Product Quality Monitoring</li> <li>Corrective &amp; Preventative Action (CAPA)</li> <li>Change Management</li> <li>Management Review</li> </ul> </li> </ul>	<b>Continued/Ongoing Process Verification (Stage 3) [Bruce Davis]</b> <ul style="list-style-type: none"> <li>CPV plan</li> <li>Product Quality and Process Performance Monitoring System</li> <li>Statistical Process Control tools</li> <li>Link to Annual Product Quality Review (APQR)</li> </ul>	<b>Packaging Equipment Qualification Overview [Mike James]</b> <ul style="list-style-type: none"> <li>Impact assessments and risk assessments to determine the scope and depth of testing</li> <li>Typical testing carried out at Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ)</li> <li>Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)</li> <li>What testing can we carryout at these stages and what tests can we leverage into the IQ and OQ to avoid repetition</li> </ul>
<b>Tools Supporting QbD [Bruce Davis]</b> <ul style="list-style-type: none"> <li>Process Analytical Technology (PAT)</li> <li>Design of Experiments (DoE)</li> <li>Process Analysers</li> <li>Multivariate data analysis</li> <li>Process Modelling</li> <li>Process Control</li> </ul>	<b>API Process Validation, Small Molecules [Mike James]</b> <ul style="list-style-type: none"> <li>Regulatory perspective</li> <li>Determining impurity profiles and identifying risks</li> <li>Simplifying manufacturing routes</li> <li>Identifying / defining critical process parameters</li> <li>Typical PV approaches to multistage synthesis of APIs</li> </ul>	<b>Packaging Process Validation [Mike James]</b> <ul style="list-style-type: none"> <li>Lengths and numbers of batches required               <ul style="list-style-type: none"> <li>Can we use a matrix approach?</li> </ul> </li> <li>Documentation requirements and acceptance criteria</li> <li>Sampling and testing requirements – Monitoring of CQAs and CMAs</li> <li>Controlling/monitoring of CPPS</li> <li>Ensuring personnel variables</li> <li>Reporting</li> <li>Ongoing process verification</li> </ul>
		<b>Sampling [Mike James]</b> <ul style="list-style-type: none"> <li>Sampling by variables and by attributes</li> <li>Sampling standards</li> <li>Tables and Plans (covering Lot Tolerance Percentage Defect (LTPD) levels and Acceptable Quality Limits (AQL)</li> <li>Example sampling plans</li> </ul>



## How to book on this course:

- The simplest and quickest way is to book online. Please use the link below to visit the specific web page for this course
- Print out this page, complete the form below by hand and return by fax, email or post.

[CLICK HERE TO BOOK ONLINE](#)

Fax: +44 (0)1625 800833

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>*Delegate Information:</b> <i>Please let us know if any delegate has any special dietary requirements by emailing the information to <a href="mailto:info@candvs.com">info@candvs.com</a>, or by using the space below.</i>	<b>Delegate Name(s):</b>	<b>Delegate 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>£2,500 [GBP]</b> per delegate	NOTE: If your finance centre or delegates are based in the United Kingdom (UK), or delegates are booking as private individuals (non-company), the course fee will be subject to an additional 20% UK VAT charge ( <b>£3,000</b> per delegate including UK VAT). For EU Countries where finance centres and delegates are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule. For non-EU countries and non-EU delegates, 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 Delegates

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

- More than 28 days will incur a cancellation fee of £200 GBP per registration and qualify for a refund of the remaining course fees
- Between 28 days and 14 days notice will qualify for a 75% refund
- Between 14 days and 7 days notice will qualify for a 50% refund
- No refund will be given for cancellations received with less than 7 days notice
- Substitutions for registered delegates 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 delegates 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 delegates. 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 Fee & VAT Liability

For the majority of participating countries, VAT will be ZERO rated. However, for companies whose finance centre is based in the United Kingdom (location where invoices are managed) the indicated course fee will be subject to an additional 20% UK VAT charge. Also, anyone booking as a private individual (not through a company) will be charged UK VAT. CVS has to charge this by law.

All participating EU based companies (based on the site location), must provide CVS with a valid VAT/Sales Tax reference number, in order for the booking to be completed. CVS is required by law to collect this information.

#### Liability

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

Please be advised that CVS is not responsible for any airfare and/or hotel penalties or other travel charges that delegates may incur.

CVS does not take responsibility for ensuring the well being of delegates during their travel to and from the venue or at any time during their stay at the residential location. We will however do everything within our power to help ensure delegates remain safe and well during the course and related activities.

Where government intervention, military activities, natural phenomenon, strikes or any other circumstances make it impossible or inadvisable to run the course at the designated time and place, the delegate shall waive any claim for damages or compensation except the amount paid for registration after the deduction of actual expenses incurred by CVS in connection with the course that the delegate has registered for and there shall be no future liability on the part of either party.

[CLICK HERE TO VIEW OUR PRIVACY POLICY](#)