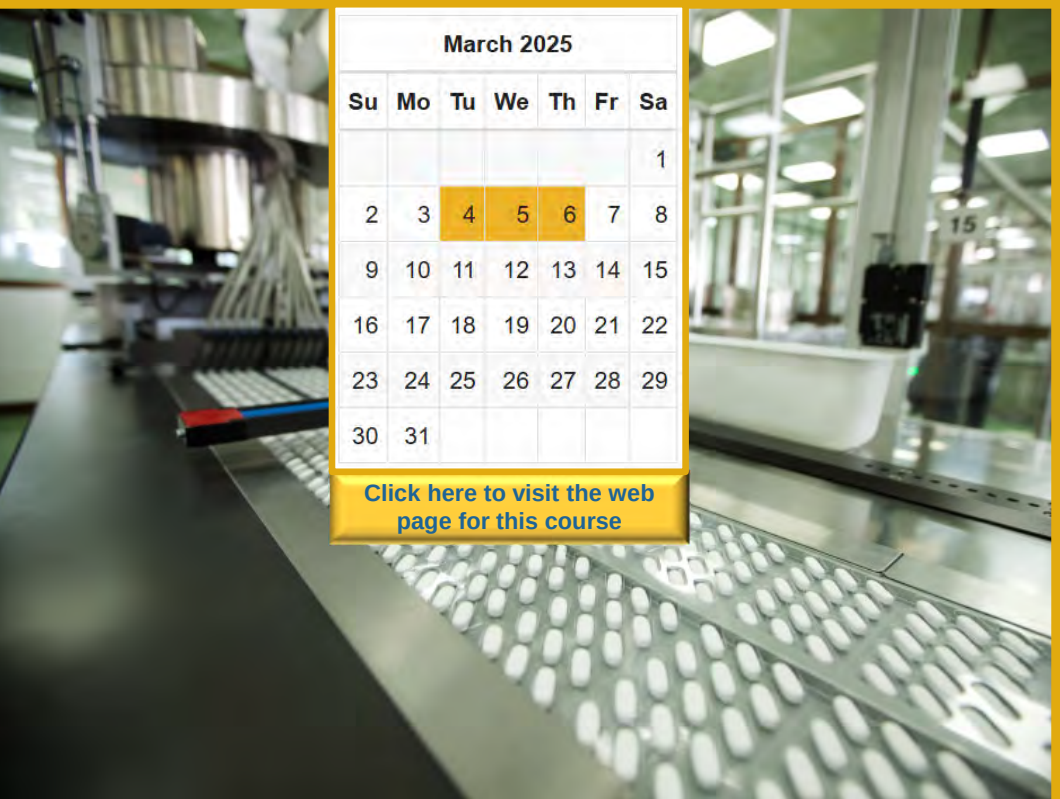
Compliance & Validation Services

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

Pharmaceutical Process Validation

Hotel Scandic Copenhagen, Denmark

4, 5 & 6 March 2025



March 2025

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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 - 4, 5 & 6 March 2025 - Hotel Scandic Copenhagen

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 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.

Attendees 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 attendee after the course.

Day-time meals and refreshments are included in the overall package. There will be an informal social gathering of attendees and presenters on the evening of Day 1 (Tuesday 4 Mar 2025, 18:30 onwards) that will include drinks and a sit-down dinner (fully complementary and everyone is welcome).

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.

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 and cleaning validation. During his time in industry, he has worked as a Quality Control Chemist, an Analytical Development Chemist and a Senior Technical Support Scientist. Peter has overseen the successful technical transfer of commercial manufacturing of several biotechnology processes, including Insulin and growth hormone products.

Bruce Davis: Bruce has over 25 years experience with the pharmaceutical industry having previously worked for AstraZeneca. He is an engineer by profession and has put in place many development and manufacturing facilities, in the EU, the Americas and Asia. He is a 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.

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.

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)***

Pharmaceutical Process Validation - 4, 5 & 6 March 2025 - Hotel Scandic Copenhagen - Course Programme

Registration (Day 1): 08:30 to 09:00 Central European Time (CET) - Attendees arrive at the meeting room and sign the attendance register.

Day 1 (Tuesday 4 March 2025)

Start: 09:00 CET

Introduction *[Mike James]*
- Fundamental reasons for undertaking process validation and for getting it right
- Examples of what can happen if you get things wrong

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
- 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

Finish: 17:00; Drinks: 18:30; Dinner: 19:30 (Informal)

Day 2 (Wednesday 5 March 2025)

Start: 09:00 CET

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 (Stage 3) *[Bruce Davis]*
- CPV plan
- Product Quality and Process Performance Monitoring System
- Statistical Process Control tools
- Link to Annual Product Quality Review (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

Finish: 17:00 CET

Day 3 (Thursday 6 March 2025)

Start: 09:00 CET

Introduction to Qualification and Validation of Pharmaceutical Packaging *[Mike James]*
- Scope and key concepts
- Scope
- Key concepts
- System Classification and System Risk Assessment
- Quality Risk Assessment
- Development of the packaging system URS

Process Validation - Biopharmaceutical API Manufacturing *[Peter Whyment]*
- 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 Equipment Qualification Overview *[Mike James]*
- Impact assessments and risk assessments to determine the scope and depth of testing
- Typical testing carried out at Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ) and Performance Qualification (PQ)
- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)
- What testing can we carryout FAT and SAT and what tests can we leverage into the IQ and OQ to avoid repetition

Packaging Process Validation *[Mike James]*
- Objective of packing process validation
- Bracketing
- Packaging process risk assessment

Sampling *[Mike James]*
- Sampling by variables and by attributes
- Sampling standards
- Tables and Plans (covering Lot Tolerance Percentage Defect (LTPD) levels and Acceptable Quality Limits (AQL)
- Example sampling plans
- Sample inspection.

Finish: 17:00 CET

BOOKING DETAILS - Pharmaceutical Process Validation - 4, 5 and 6 March 2025 - Hotel Scandic, Copenhagen

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**

Alternative Booking Form *('*' indicates required fields)*

***Booking Contact Name:**		
***Booking Contact E-mail Address:**		
***Booking Contact Telephone Number:**		
***Company Name & Address:**		
***Billing Address** *(Only complete if different to Company Address)*		
***Attendee Information:** *Please let us know if any attendee has any special dietary requirements by emailing the information to info@candvs.com, or by using the space below.*	**Attendee Name(s):**	**Attendee Email Address:**
Company VAT Number (or Sales Tax Number) – *EU Countries Only		
***Method of payment, e.g. card or invoice payment**		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.
Payment Reference (if available)		NOTE: For invoice payments we will need a valid purchase order number to fully confirm the booking.
***Total Fees Due** **£2,500 [GBP]** 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 (**£3,000** 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 Terms & Conditions

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 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 attendees 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 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 attendees may incur.
CVS does not take responsibility for ensuring the well being of attendees 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 attendees 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