



## Compliance & Validation Services

Presents a 2-Day Training Course on:

# Pharmaceutical Process Validation

12 & 13 May 2016

Radisson Blu Royal Hotel, Copenhagen

*Please Note: There is an option to attend both this course and the preceding 2-Day course on Equipment System Verification/Qualification (10 & 11 May 2016) – see Page 4 for details.*



- **Effective process development (ensuring we fully understand our processes)**
  - **Design Space (establishing/verifying)**
    - **Identifying Critical Quality Attributes and establishing Critical Process Parameters and their inter-relationships**
  - **Quality by Design (QbD) (ICH Q8 and Q11)**
  - **Use of risk assessment tools**
- **Latest regulatory guidance (USFDA, EMA & 2015 EU Volume 4 [GMP] Annex 15)**
- **Process Validation approaches for:**
  - **Small and large molecule Active Pharmaceutical Ingredient (API) manufacture**
  - **Pharmaceutical product manufacture (fill/finish type activities)**
  - **Pharmaceutical Packaging**
- **Maintaining the Validated State**
  - **Continued Process Verification**
  - **Statistical process control**
  - **Quality Systems, e.g. effective change control**

## Course Summary: Pharmaceutical Process Validation – 12 & 13 May 2016, Radisson Blu Royal Hotel, 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 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.

Day-time meals and refreshments together with a course dinner, held on the evening of Day 1, are included in the overall package

### Presenters



**Mike James, Training Director, Compliance & Validation Services Limited:** Mike has over 23 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



**Dr Line Lundsberg-Nielsen, Lundsberg Consulting Limited:** Line has over 15 years' experience in the pharmaceutical industry. Her current role involves advising industry on Quality by Design (QbD) used in process development, on the use and implementation of Process Analytical Technology (PAT) and implementation and execution of a lifecycle approach to Process Validation. Line is also a well-recognised trainer in QbD, PAT, Process Validation and Equipment Qualification. She has played a leading role in the International Society for Pharmaceutical Engineering (ISPE) and is co-author of Good Practise Guides on how to implement QbD. She has recently been an executive member of the ASTM E55 Committee on Pharmaceutical Manufacturing. In previous roles at Novo Nordisk and Lundbeck, Line had the responsibility for implementation of PAT and QbD both in chemical and drug product production. Her experience also includes Quality Assurance, Quality Control and technical support relating to the development and manufacture of APIs, oral solid dosage forms and sterile products.



**Biopharmaceutical Cleaning Validation Industry Speaker:** Our Industry Expert Speaker has over 30 years' experience of working in the Biopharmaceutical Manufacturing Industry and has a wealth of knowledge/expertise in the areas of process validation and cleaning validation.

### 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 an enjoyable experience.

### Venue

#### Radisson Blu Royal Hotel, Copenhagen, Hammerichsgade 1, Copenhagen V, DK-1611, Denmark:

Situated across from the city's main train station, this Copenhagen hotel's city centre address makes it easy for guests to traverse the area. Stroll to the fashionable stores of Strøget shopping district and the fun of magical Tivoli Gardens.

Tel: +45 3342 6000

Fax: +45 3342 6100

Email: info.cphzh@radissonblu.com

**Room reservations:** Tel: +45 3815 6500; Fax: +45 3815 6501; Europe toll free: 00800 3333 3333  
Email: reservations.royal.copenhagen@radissonblu.com

Click on images  
to visit the  
Hotel's website



Delegates are kindly requested to arrange their own accommodation.

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

Accommodation is NOT included in the course fees.



**DAY 1 (Thursday 12 May 2016)**

**Day 2 (Friday 13 May 2016)**

**09:00 Opening/Welcome**

**Introduction [Mike James]**

- Fundamental reasons for undertaking process validation and for getting it right
- Overview of regulations
- Summary of documentation requirements (detail provided in notes)

**A lifecycle approach to Product Development and Manufacture (QbD) [Line Lundsberg]**

- 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

**Systems Supporting QbD [Line Lundsberg]**

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

**Tools Supporting QbD [Line Lundsberg]**

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

**09:00 Introduction to Day 2 [Mike James]**

**Process Performance Qualifications, US & The different EU approaches to Process Validation [Line Lundsberg]:**

- 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 [Line Lundsberg]**

- CPV plan
- Product Quality and Process Performance Monitoring System
- Statistical Process Control tools
- Link to PQR & APR

**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]**

- Draft 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: 17:30

Drinks Reception: 19:00

Course Dinner: 20:00

Finish: 16:45

# BOOKING DETAILS: Pharmaceutical Process Validation - 12 & 13 May 2016 - Radisson Blu Hotel, Copenhagen

**How to book on this course:** (Note: You can also book the 4-day course option which includes the preceding Equipment System Verification / Qualification course [10, 11, 12 & 13 May 2016])

- The simplest and quickest way is to book online. Please visit/return to our web-site, find the course you are interested in and follow the simple instructions (link included below).
- Alternatively, download a booking form (complete it electronically or print and annotate) and return it to us by fax or email (link and contact details included below).
- Or finally, print out this page, complete the form below by hand and return by fax, email or post.
- If you wish to attend both this course and the preceding 2-day course on Equipment System Verification/Qualification, you can book online, download a booking form, or complete the booking form below, but enter the total fees due in the 4-day course option at the bottom of the form. A 4-day course brochure can be downloaded from the link below.

[<< CLICK HERE TO BOOK ONLINE >>](#)

[<< CLICK HERE FOR 4-DAY COURSE BROCHURE >>](#)

[<< CLICK HERE FOR BOOKING FORM >>](#)

Fax: +44 (0)1625 800833

Includes the preceding 2-day Equipment Verification Course

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

*Booking Contact Name:		
*Booking Contact E-mail Address:		
*Booking Contact Telephone Number:		
*Company Name & Address:		
*Billing Address <i>(Only complete if different to Company Address)</i>		
*Delegate Information:	Number of delegates:	Delegate Name(s):
Delegate E-mail Address(es): <i>(if different to booking contact)</i>		
Special dietary requirements?		
Disability Requirements?		
Company VAT Number (or Sales Tax Number) – *EU Countries Only		
*Method of payment, e.g. card, bank transfer or cheque	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. Cheques should be sent with a completed booking form to Compliance & Validation Services Limited, 8 Sedgefield Close, Macclesfield, Cheshire, SK10 2WF, United Kingdom.	
Payment Reference (if available)	NOTE: For bank transfer payments we will need a valid reference number or purchase order number to fully confirm the booking.	
* Total Fees Due (2-day course) <b>£1,120 [GBP]</b> per delegate	NOTE: If your finance centre or delegates are based in the United Kingdom (UK), the course fee will be subject to an additional 20% UK VAT charge (£1,344 [2-day]) or £2,244 [4-day] per delegate including UK VAT).	
Total Fees Due (4-day option) <b>£1,870 [GBP]</b> per delegate	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:** A booking confirmation will be sent to the delegate or booking contact on receipt of payment, or in the case of bank transfer, following receipt of a valid purchase order reference.

**Course Fee & VAT Liability:** For the majority of participating countries, VAT will be ZERO rated or not applicable. However, for companies whose finance centre is based in the United Kingdom (location where invoices are managed) or delegates are UK based, the indicated course fee will be subject to an additional 20% UK VAT charge. CVS has to charge this by law. 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.

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.

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

- 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

CVS reserves 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. 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.

Please visit our web site for full terms and conditions (see the link at the top of this page).

**Please note that by completing the booking form (opposite) you agree to our Terms and Conditions.**



The CGMP regulations for validating pharmaceutical (drug) manufacturing require that drug products be produced with a high degree of assurance of meeting all the attributes they are intended to possess (21 CFR 211.100(a) and 211.110(a)). A. Process Validation and Drug Quality. Effective process validation contributes significantly to assuring drug quality. The basic principle of quality assurance is that a drug should be produced that is fit for its intended use. Pharmaceutical software systems for process validation Validation software systems help manage and keep track of all types of activities that take place over the lifecycle of the product and process. Whether a piece of equipment designed to manufacture something, a process/recipe to make something, or a computer program to control somethingâ€”the pharmaceutical industry has a need for validation, which is best done not manually but rather using a sophisticated system. Learn the idiosyncrasies of Pharmaceutical Validation by using Validation Onlineâ€™s uniquely intuitive cGMP compliant templates. An integrated SOP in each document will guide you through the process of converting the template into your own company bespoke document.Â Bio-Med and Pharmaceutical Validation & Qualification is more than just raising an IQ and OQ. It requires an understanding of the the overall quality requirements as detailed in 21 CFR Part's 820, 211, 210 and 11.