Compliance & Validation Services

Presents a 4-Day Training Course on:

Pharmaceutical Process Validation & Equipment System Qualification

9, 10, 11 & 12 April 2019

Copenhagen Marriott Hotel, Denmark

Please Note: *This course is the combination of a 2-day Pharmaceutical Process Validation Course and a 2-day Equipment Verification / Qualification Course. Each course can be booked separately, but the 4-day option carries a substantial discount – see Page 6.*

Pharmaceutical Process Validation (9 & 10 April 2019)

- 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 and the use of Statistics
- Process Validation approaches for APIs (small and large molecules) and pharmaceutical product manufacture
- Validation of Packaging equipment systems and processes
- Maintaining the Validated State
  - Continued/Ongoing Process Verification & Statistical Process Control
  - Quality Systems, e.g. effective change control

Equipment System Verification / Qualification (11 & 12 April 2019)

- Regulations, guidelines and current industry trends (including Annex 15)
- Basing testing requirements on risk to GMP & Product Quality (incorporating ISPE, ASTM E2500-13 and Quality Risk Assessment concepts)
- Design Review (Design Qualification)
- Verification / qualification of automated/computerised control systems (GAMP 5)
- GMP compliance during equipment system construction
- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)
- Mechanical completion, pre-commissioning and commissioning
- Using Vendor documentation e.g. FAT/SAT/commissioning testing documents for verification/qualification (leveraging)
- Verifying the installation (Installation Verification/Qualification)
- Functional testing (Operational Verification/Qualification)
- Verifying system performance (Performance Verification/Qualification)

Course Summary: Pharmaceutical Process Validation – 9 & 10 April 2019, Copenhagen Marriott Hotel, Denmark

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: Pharmaceutical Process Validation – 9 & 10 April 2019, Copenhagen Marriott Hotel, Denmark

Mike James, Compliance & Validation Services Limited: Mike has 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 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.

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.

4-Day Course Venue – 9, 10, 11 & 12 April 2019

Marriott Hotel, Copenhagen: The Hotel is close to the city centre and located right at the water's edge of the harbour canal. It is around 8 minutes walk from Copenhagen Central Station and Tivoli Gardens (the Gardens are opposite the station). An excellent location to explore the city from.

Address: Copenhagen Marriott Hotel, Kalvebod Brygge 5, Copenhagen 1560, Denmark
Tel: +45-88-33-99-00

Click on images to visit the Hotel's website

Delegates are kindly requested to arrange their own accommodation. ***Course fees are £2,495.00 (GBP) per delegate.*** ***Accommodation is NOT included in the course fees***

Course Summary: Equipment System Verification / Qualification – 11 & 12 April 2019, Copenhagen Marriott Hotel, Denmark

This pharmaceutical validation training course provides delegates with an in-depth appreciation of project life-cycle activities associated with equipment system verification / qualification. These activities range from early project planning through to design review and verification / qualification of critical aspects / components of manufacturing systems. A pivotal theme of the course is a risk-based approach to verification / qualification of manufacturing equipment systems, as defined under the ISPE baseline guides and ASTM E2500-13. As a result, System level Impact Assessments, Component Criticality Assessments and the process of identifying critical aspects of manufacturing systems during the design phase are covered in detail.

With an ever increasing regulatory expectation and requirement that the level of system / function testing is based on risk to product quality / patient safety and system complexity / novelty, a typical process used to achieve this goal is included in the course (Quality Risk Assessment). Also included is how the integration of verification / qualification with commissioning can minimise duplication of effort and maximise the use of supplier's documentation. Up-to-date information on current applicable regulatory and international standards / guidelines will be provided and 'real-life' examples will be used throughout the course. Equipment systems covered include manufacturing and filling equipment. 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: Equipment System Verification / Qualification – 11 & 12 April 2019, Copenhagen Marriott Hotel, Denmark

Mike James, Compliance & Validation Services Limited.: Mike has 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.

Dr Justin Burndred, Independent Validation Contractor: Justin has 25 years experience in the pharmaceutical industry, including 19 years in validation related roles. He is currently working with Baxter Healthcare as a validation engineer. Justin’s experience includes the qualification of a wide range of manufacturing systems (small and large molecule APIs, and sterile / non-sterile pharmaceutical product related), critical utility systems (e.g. WFI systems) and facility / HVAC systems. He also has a significant level of process development experience and process understanding which complements his qualification / validation skills. Justin is a Chemical Engineer by qualification**.**

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John Welbourn, Compliance & Validation Services Limited: A validation professional with over 25 years experience, John has been responsible for the management and execution of validation projects for many major pharmaceutical companies. He has broad experience in the qualification of equipment, utilities and computerised systems, and thermal mapping to support storage conditions. He has presented at conferences in the UK, Europe and the US and has authored several articles on various aspects of validation. John has contributed to The University of Manchester’s, Pharmaceutical Engineering Advanced Training (PEAT) Course and Dublin Institute of Technology’s (DIT) MSc. course in Pharmaceutical Process Validation.

Who Should Attend (4-Day Course - 9, 10, 11 & 12 April 2019)

Individuals to benefit from attending this course include anyone involved directly or indirectly in equipment system verification/qualification and process validation activities. The course is ideally suited to people who are new to equipment system verification/qualification and 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 equipment system verification/qualification and 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.

Pharmaceutical Process Validation - Copenhagen Marriott Hotel, Denmark - Course Programme:

Registration (08:45 to 09:00) – Delegates arrive at the meeting room and sign the attendance register. Each day will include at least one interactive workshop

DAY 1 (Tuesday 9 April 2019)

09:00 Opening/Welcome

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

Finish: 17:30 **Drinks Reception: 19:00** **Course Dinner: 20:00**

Day 2 (Wednesday 10 April 2019)

09:00 Introduction to Day 2

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: 16:50

Please Note: These 2-days can be booked independently as a 2-day course – see Page 6 for details.

Equipment System Verification / Qualification - Copenhagen Marriott Hotel, Denmark - Course Programme:

Registration (08:45 to 09:00) – Delegates arrive at the meeting room and sign the attendance register.

DAY 3 (Thursday 11 April 2019)

09:00 Opening/Welcome

Introduction *[Mike James]*
- What are we trying achieve and why do we qualify critical equipment systems.
- Overview of latest regulatory and international rules and guidance applicable to equipment system verification / qualification, including:
  - ISPE Baseline Guides
  - ASTM E2500-13
  - PIC/S
  - EMA (including EU Volume 4 [GMP] Annex 15)
  - US FDA
- Overview of typical qualification activities and documentation structure (plans, protocols, reports, assessments and assessment reports).

Risk-Based Approach to Equipment System Verification/ Qualification *[Mike James]*
- Purpose and impact assessment timing
- Defining systems and their boundaries
- Importance of understanding the manufacturing process
- System Impact Assessments and Component Criticality (includes worked examples)
- Documentation (procedures and reports)
- Equipment system verification in accordance with ASTM E2500-13 and its impact on what we do now
  - Determining critical aspects during the design phase and how this relates to critical components

Quality Risk Assessments (QRA) *[Mike James]*
- Purpose, scope and timing
- Risk assessment process and associated documentation
- How risk scores for risk scenarios can be linked to the level and depth of testing
- Reports (includes worked examples)
- How QRA's can be used to support validation/verification plans and for a key rationale for the verification / qualification approach

Design Review/Qualification *[Mike James]*
- Importance of Design Review (why carry it out?)
- Vendor assessments and audits
- GMP review of design
- Links to impact assessment and Quality Risk Assessments
- Compilation of key documentation into a design dossier
- Examples of documentation involved

Factory Acceptance Testing (FAT) *[John Welbourn]*
- Why is acceptance testing performed at the vendor's site?
- What are the differences between FAT and Site Acceptance testing (SAT)?
- Key components of FAT and working effectively with vendors
- Documentation requirements and integrating FAT with Qualification activities (use of vendor's documentation)
- Execution and close-out

Mechanical Completion, Pre-commissioning and Commissioning *[John Welbourn]*
- Construction/mechanical completion process
- Stages/activities associated with pre-commissioning
- Commissioning activities and examples of the type and level of testing carried out
- Vendor Package Site Acceptance Testing (SAT)
- Integration with qualification (Leveraging)
  - Real documentation examples for leveraging
- Documentation involved

Finish: 17:20; Drinks Reception: 19:00; Course Dinner: 20:00

Day 4 (Friday 12 April 2019)

Day 2 Introduction (09:00)

GMP Compliance During Construction & Construction Verification *[John Welbourn]*
- Control of materials, fabrication processes and work practices
- Consequences of poor practice
- Construction testing/checking (welding Quality Control, line slope, dead-leg)
- Materials of construction verification (traceable)
- Typical documentation

Installation Verification/Qualification of Equipment System *[Justin Burndred]*
- Overview of testing/checking carried out
- General documentation requirements (includes example testing documents)
- Leveraging of information from FATs & SATs
- Supporting documentation and procedures

Functional Testing of Equipment Systems (Operational Verification/Qualification) *[Justin Burndred]*
- Overview of testing carried out
- Testing based on risks to patient safety, GMP and equipment system complexity
- Leveraging of commissioning documentation
- Documentation requirements (includes examples of testing documentation)

Performance Verification/Qualification *[John Welbourn]*
- System hand-over
- What is its purpose/scope and how does it differ from process validation
- Typical Approach
- Sampling and sampling plans (Utilities/Process system AQL's)
- Overview of testing carried out (using example systems)
- Documentation involved and protocol requirements

Packaged Automated Systems Verification/Qualification *[John Welbourn]*
- Overview of Packaged Systems and their characteristics
- Examples of Packaged Systems
- Elements of the Packaged control system
- Typical software description and GAMP categories
- 12 steps to qualifying/verifying Packaged Control Systems (in line with GAMP 5)

Finish: 16:45

Please Note: These 2-days can be booked independently as a 2-day course – see Page 6 for details.

BOOKING DETAILS: Pharmaceutical Process Validation & Equipment System Qualification – 9, 10, 11 & 12 April 2019, Copenhagen Marriott Hotel, Denmark

How to book on this course:

- 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 a 2-day course only (£1,120 Fee), you can book online, download a booking form, or download the relevant course brochure by clicking the links below:

<< CLICK HERE TO BOOK ONLINE>>

<< CLICK HERE FOR A 2-DAY PROCESS VALIDATION BROCHURE>>

<< CLICK HERE FOR BOOKING FORM >>

<< CLICK HERE FOR A 2-DAY EQUIPMENT SYSTEM VERIFICATION BROCHURE>>

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)*		
***Delegate Information:**	**Number of delegates:**	**Delegate Name(s):**
Delegate E-mail Address(es): *(if different to booking contact)*		
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** **£2,495 [GBP] 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 (**£2,994** 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 Terms & Conditions

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.

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