Compliance & Validation Services

Presents a 2-Day Training Course on:

Equipment System Verification / Qualification

Copenhagen Marriott Hotel, Denmark

11 & 12 April 2019

Please Note: There is an option to attend both this course and the preceding 2-Day course on Pharmaceutical Process Validation (9 & 10 April 2019) – see Page 4 for details.

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

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. Manufacturing equipment systems and utility systems examples will be used. 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, 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.

John Welbourn, Compliance & Validation Services Limited: A validation professional with over 30 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

Individuals to benefit from attending this course include anyone involved directly or indirectly in equipment system verification/qualification activities. The course is ideally suited to people who are new to equipment system verification/qualification roles or people whose job roles require them to have a general understanding of validation activities throughout a project life-cycle. 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 the commissioning/verification/qualification of equipment systems; be able to apply and share their new knowledge; improve their individual effectiveness; and look back on an enjoyable experience.

Venue

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 £1,495.00 (GBP) per delegate.*** ***Accommodation is NOT included in the course fees***

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 1 (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 2 (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: There is an option to attend both this course and the preceding 2-Day course on Pharmaceutical Process Validation (9 & 10 April 2019) – see Page 4 for details.

BOOKING DETAILS: Equipment System Verification / Qualification, 11 & 12 April 2019, Copenhagen Marriott Hotel, Denmark

How to book on this course: (Note: You can also book the 4-day course option which includes the preceding Pharmaceutical Process Validation course [9, 10, 11 & 12 April 2019])

- 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 Pharmaceutical Process Validation, you can book online, download a booking form, or complete the booking form below, but remember to enter the total fees due in the 4-day course option at the bottom of the form below. A 4-day course brochure can be downloaded using the link below.

<< CLICK HERE TO BOOK ONLINE>> **<< CLICK HERE FOR 4-DAY COURSE BROCHURE >>** *Includes 2-day Process Validation Course* **<< CLICK HERE FOR BOOKING FORM >>**

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-day course)** **£1,495 [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 (**£1,794** [2-day)] or £2,994 [4-day] 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.
Total Fees Due (4-day option) **£2,495 [GBP] per delegate**		

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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