Compliance & Validation Services

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

Pharmaceutical Equipment System Qualification

Hotel Scandic Copenhagen, Denmark
1, 2 & 3 October 2024

October 2024

Su	Mo	Tu	We	Th	Fr	Sa
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20	21	22	23	24	25	26
27	28	29	30	31		

Click here to visit the web page for this course

- **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 and Quality Risk Assessment concepts
  - Design Review / Design Qualification
  - 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 qualification (leveraging)
- **Equipment System Qualification Activities (supported with real examples):**
  - Installation Qualification
  - Operational Qualification (functional testing)
  - Performance Qualification

Course Summary - Pharmaceutical Equipment System Qualification - 1, 2 & 3 October 2024 - Hotel Scandic Copenhagen

This pharmaceutical validation training course provides delegates with an in-depth appreciation of project life-cycle activities associated with equipment system qualification. These activities range from early project planning through to design review and the qualification of critical aspects / critical design elements of manufacturing systems. A pivotal theme of the course is a risk-based approach to qualification of manufacturing equipment systems, as defined under the ISPE baseline guides and ASTM E2500. As a result, System Classification, System Risk Assessments and the process of identifying critical aspects/critical design elements of manufacturing systems are covered in detail. Underpinning all of this is the understanding of the processes involved and having clear definitions of Critical Quality Attributes, Critical Material Attributes, Critical Process Parameters and control ranges/philosophy, which will be covered in the introductory presentations.

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 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. There will be many Mentimeter based interactive workshops used throughout this course to help the learning process.

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 1 October 2024), 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 qualification (verification) activities. The course is ideally suited to people who are new to equipment system 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 completing 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 a valuable experience.

Venue Hotel

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 Equipment System Qualification - Hotel Scandic Copenhagen - Programme

Registration (Day 1): 08:45 to 09:00 Central European Time (CET) - Delegates arrive at the meeting room and sign the attendance register

Day 1 (Tuesday 1 October 2024)

Start: 09:00 CET

Introduction *[Mike James]*
- EU and US Terminology
- Overview of Process Validation Stages and supporting guidance
- Key concepts, e.g. Commissioning, Qualification and Validation (what is meant by theses terms); Quality Attributes (CQAs), Critical Material Attributes (CQAs) and Critical Process Parameters (CPPs); Process Parameter Operating Ranges; Proven Ranges; and Design Space and Control Space.
- Regulatory/key guidance, e.g. Annex 15 , Annex 11, ISPE, ICH and ASTM
- Comparison of ASTM and Annex 15 stages and use of supplier's documentation (Leveraging) to reduce/replace testing at qualification/verification stages

Risk-Based Approach to Equipment System Qualification *[Mike James]*
- Defining systems and their boundaries
- Importance of understanding the manufacturing process
- Example of key process steps and CQAs, CMAs, CPPs and critical aspects for a bottle filling process
- System Classification and System Risk Assessments (includes worked examples) – As per ISPE Baseline Guide 5

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
- How QRA's can be used to support validation plans and for a key rationale for the qualification approach

Design Qualification / Review *[Mike James]*
- Importance of Design Review (why carry it out?)
- Vendor assessments and audits
- User Requirement Specification and verifying the design meets the URS
- Links to impact assessment and Quality Risk Assessments
- 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 (including virtual FAT) and close-out

GMP Compliance During Construction & Construction Qualification *[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

Finish: 17:00; 18:30: Drinks Reception; 19:30: Course Dinner

Day 2 (Wednesday 2 October 2024)

Start: 09:00 CET

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

Measurement & Instrumentation *[John Welbourn]*
- Measurement systems
- Measurement uncertainty and its impact on acceptable range limits
- Instrument selection criteria
- Hints and tips
  - Calibration
  - Performing measurements
  - Initial qualification/validation

Preparation of Effective Testing Documentation *[Mike James]*
- General structure and main sections of protocols and reports
- Responsibilities of approvers, executors and authors, e.g. what are you signing for
- Good and bad documentation practices
- Writing effective test scripts in order to fully document the test method step completion, to capture the required data and to verify the data meets acceptance criteria (including the handling of calculations)
- Handling of units, significant figures and decimal places.
- Documenting and handling comments and deviations
- Determining whether a deviation can be accepted or not
- When to use initials, when to use signatures and when is a second signature required, e.g. for calculations
- The careful use of conditional pass to avoid full repeats of testing
- How to document test completion when leveraged from an earlier testing exercise, e.g. FAT

Installation 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

Finish: 17:00

Day 3 (Thursday 3 October 2024)

Start: 09:00 CET

Functional Testing of Equipment Systems (Operational 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 Qualification *[John Welbourn]*
- System hand-over
- What is its purpose/scope and how does it differ from process validation
- Typical approaches
- Sampling and sampling plans (Utilities/Process system AQL's)
- Overview of testing carried out for various systems, examples include:
  - Sterilisers (porous and fluid loads)
  - Vial/ampoule washers
  - De-pyrogenation ovens
  - Filling machines
  - Freeze dryer and vial capper
  - Cleanroom/HVAC
  - Utility systems, e.g. water systems
  - Temperature controlled storage systems, e.g. fridges, freezers and stores

Qualification of Automated Packaged Systems *[John Welbourn]*
- Characteristics of automated packaged systems
- Using risk assessment to develop the qualification testing strategy
- Steps involved in qualifying automated packaged systems
- Techniques / considerations for integrating commissioning to support qualification

Finish: 17:00

BOOKING DETAILS - Pharmaceutical Equipment System Qualification - 1, 2 & 3 October 2024 - Hotel Scandic Copenhagen

How to book on this course:

- The simplest and quickest way is to book online. Please click on the link below to visit the web page for this course, or
- 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)*		
***Delegate Information:** *Please let us know if any delegate has any special dietary requirements by emailing the information to info@candvs.com, or by using the space below.*	**Delegate Name(s):**	**Delegate 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 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 (**£3,000** 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

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.

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