Compliance & Validation Services

Presents a 2-Day Online Training Course on:

Pharmaceutical Equipment System Qualification

11 & 12 May 2021

Live Online Training Course

- **Qualification (Verification) 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 qualification (verification) documentation
  - Design Review (Design Qualification)
  - Qualification (verification) 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 Qualification (Verification) Activities:**
  - Verifying the installation (Installation Qualification [Verification])
  - Functional testing (Operational Qualification [Verification])
  - Verifying system performance (Performance Qualification / [Verification])

Course Summary: Pharmaceutical Equipment System Qualification - Live Online Training Course – 11 & 12 May 2021

This pharmaceutical validation training course provides attendees 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 qualification (verification) of critical aspects / components of manufacturing systems. A pivotal theme of the course is a risk-based approach to qualification (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 qualification (verification) 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.

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 (verification) 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 attendees 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.

Online System & Course Fees

We use the industry leading GotoWebinar©, LogMeIn, Inc. platform for our online training courses. It's intuitive and simple to use, however we do recommend that you check your system's compatibility using the 'CHECK SYTEM COMPATIBILITY' link provided below (we use 'standard webinar'). To find out more about how our online training process works, from booking through to the end of the course, please click on the 'HOW IT WORKS' link provided below.

CHECK SYSTEM COMPATIBILITY

Course fees are £1,120.00 (GBP) per attendee.

(See Page 4 for further details on fees/bookings)

HOW IT WORKS

Pharmaceutical Equipment System Qualification - Live Online Training Course - Programme

Start Time: 08:00 London/Dublin; 09:00 Berlin/Amsterdam - Please join the course at least 5 minutes before the start.

DAY 1 (Tuesday 11 May 2021)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

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 qualification (verification), including:
  - ISPE Baseline Guides
  - ASTM E2500-13
  - PIC/S
  - EMA (including EU Volume 4 [GMP] Annex 15)
  - US FDA
- Overview of typical qualification activities

Risk-Based Approach to Equipment System Qualification (Verification) *[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 qualification/verification approach

Design Qualification / Review *[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: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

Day 2 (Wednesday 12 May 2021)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

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

Installation Qualification (Verification) 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 Qualification [Verification]) *[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 (Verification) *[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 Qualification (Verification) *[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: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

BOOKING DETAILS: Pharmaceutical Equipment System Qualification - 11 & 12 May 2021 - Live Online Training Course

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to our web-site, find the online course you are interested in and follow the simple instructions (link included below), 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)*		
***Attendee Information:**	**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** **£1,120 [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 (**£1,344** 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 7 days will quality for a refund of the course fee paid after the deduction of actual expenses incurred by CVS in connection with the course that the attendee has registered for and there shall be no future liability on the part of either party.
- No refund will be given for cancellations received with less than 7 days' notice.
- Substitutions for registered attendees from the same company 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 Attendees
If you click 'yes' to 'include my name/company' on the attendees list', when completing the online booking form, your name and company will be included on the list and distributed to all the participants.
Before you commit to booking onto a webinar, we expect you to check your system compatibility with the GoToWebinar® platform using the links provided.

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 / EEA 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.
CVS will not provide a refund for an online course, if an attendee cannot use the GoToWebinar® (by LogMeIn) system, because of local IT restrictions.

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