



Compliance & Validation Services
Presents a 3-Day Online Training Course on:

Pharmaceutical Equipment System Qualification

23, 24 & 25 May 2023



May 2023						
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Click on the calendar to go to 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 E2500-20 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 - 23, 24 & 25 May 2023 - Online Training Course

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 of critical aspects / components 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 E2500-20. As a result, System Impact Assessments (System Classification), Component Criticality Assessments and the process of identifying critical aspects of manufacturing systems (System Risk Assessment) 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 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.

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.



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.



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.

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 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 industry standard online meetings software platforms to run our live online training courses. Once we have received your booking, you will be contacted by email with details on how to join each day of the course. Please note that we do not record our courses.

Course fees are £1,750.00 (GBP) per attendee.

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



DAY 1 (Tuesday 23 May 2023)	Day 2 (Wednesday 24 May 2023)	Day 3 (Thursday 25 May 2023)
Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam	Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam	Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam
Introduction <i>[Mike James]</i> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> ISPE Baseline Guides and ASTM E2500-20 PIC/S and EMA (including EU Volume 4 [GMP] Annex 11 and Annex 15) US FDA Brief overview of typical sequences of qualification activities 	Mechanical Completion, Pre-commissioning and Commissioning <i>[John Welbourn]</i> <ul style="list-style-type: none"> 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) <ul style="list-style-type: none"> Real documentation examples for leveraging Documentation involved 	Functional Testing of Equipment Systems (Operational Qualification) <i>[Justin Burndred]</i> <ul style="list-style-type: none"> 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)
Risk-Based Approach to Equipment System Qualification (Verification) <i>[Mike James]</i> <ul style="list-style-type: none"> Purpose and impact assessment timing Defining systems and their boundaries Importance of understanding the manufacturing process System Impact Assessments (System Classification) and Component Criticality / Critical Aspects determination (includes worked examples) Equipment system verification in accordance with ASTM E2500-20 and its impact on what we do now <ul style="list-style-type: none"> Determining critical aspects during the design phase and how this relates to critical components 	Measurement & Instrumentation <i>[John Welbourn]</i> <ul style="list-style-type: none"> Measurement systems Measurement uncertainty and its impact on acceptable range limits Instrument selection criteria Hints and tips <ul style="list-style-type: none"> Calibration Performing measurements Initial qualification/validation 	Performance Qualification <i>[John Welbourn]</i> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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
Quality Risk Assessments (QRA) <i>[Mike James]</i> <ul style="list-style-type: none"> 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 	Preparation of Effective Testing Documentation <i>[Mike James]</i> <ul style="list-style-type: none"> 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 	Qualification of Automated Packaged Systems <i>[John Welbourn]</i> <ul style="list-style-type: none"> 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
Design Qualification / Review <i>[Mike James]</i> <ul style="list-style-type: none"> 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) <i>[John Welbourn]</i> <ul style="list-style-type: none"> 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 	Installation Qualification of Equipment System <i>[Justin Burndred]</i> <ul style="list-style-type: none"> Overview of testing/checking carried out General documentation requirements (includes example testing documents) Leveraging of information from FATs & SATs Supporting documentation and procedures 	
GMP Compliance During Construction & Construction Qualification <i>[John Welbourn]</i> <ul style="list-style-type: none"> 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: 16:00 London/Dublin; 17:00 Berlin/Amsterdam	Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam	Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam 3

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 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>		
*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 £1,750 [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 (£2,100 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 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 qualify 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 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 online system, because of local IT restrictions/issues.

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