



## Compliance & Validation Services

Presents a 3-Day Online Training Course on:

# Pharmaceutical Equipment System Qualification

22, 23 & 24 November 2022

Live Online Training Course



November 2022						
Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

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 - Live Online Training Course – 22, 23 & 24 Nov 2022 – 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 the industry leading GotoWebinar®, by GoTo, 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 **£1,495.00 (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 22 November 2022)

Day 2 (Wednesday 23 November 2022)

Day 3 (Thursday 24 November 2022)

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

## Introduction [Mike James]

- What are we trying to 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 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

## 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 (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
  - 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
- 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

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

## 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

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

## 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: 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.

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**E-mail: info@candvs.com**

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**Booking Terms & Conditions**

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<b>*Booking Contact Telephone Number:</b>		
<b>*Company Name &amp; Address:</b>		
<b>*Billing Address</b> <i>(Only complete if different to Company Address)</i>		
<b>*Attendee Information:</b>	<b>Attendee Name(s):</b>	<b>Attendee Email Address:</b>
<b>Company VAT Number (or Sales Tax Number) – *EU Countries Only</b>		
<b>*Method of payment, e.g. card or invoice payment</b>	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.	
<b>Payment Reference (if available)</b>	NOTE: For invoice payments we will need a valid purchase order number to fully confirm the booking.	
<b>* Total Fees Due</b> <b>£1,495 [GBP]</b> 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 ( <b>£1,794</b> 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 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.  
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