Compliance & Validation Services

Presents a 3-Day Online Training Course on:

Pharmaceutical Water, Steam and Compressed Gas Systems

25, 26 & 27 February 2025

February 2025						
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Click here to visit the web page for this course

Purified Water, Water For Injection (WFI), Pure Steam, Clean Steam, Compressed Air and Specialist Gases

General System Requirements and Design

- Hygienic engineering considerations
- Applicable regulations and standards
- Quality requirements for utilities
- Methods for production and distribution of critical utilities (includes updates to the European Pharmacopeia, EU GMPs, including Annex 1 [2022])
- Typical equipment used, testing requirements and specifications
- Managing rouging problems associated with ‘hot’ systems

Commissioning and Qualification

- System and Component Level Impact Assessments and Quality Risk Assessments
- Testing matrices – what to test at each stage of the project lifecycle
- Risk based approach to Qualification (Annex 15, ISPE & ASTM approaches)
- Design review/qualification
- GMP compliance during construction (key, often overlooked, considerations)
- Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT)
- Mechanical completion, pre-commissioning and commissioning
- Use of vendors testing documentation/data for qualification purposes (leveraging)
- Installation and operational qualification (verification of build and function)
- Successful plant handover and subsequent performance qualification
- On-going monitoring, performance reviews and risk management

Course Summary - Pharmaceutical Water, Steam and Compressed Gas Systems - 25, 26 & 27 February 2025 - Online Training Course

This pharmaceutical training course covers current and best practice in the areas of design, construction and commissioning / qualification of critical utility systems. It includes generation and distribution systems for purified water, water for preparation of extracts and water for injection (WFI), clean steam, pure steam, compressed air and process gases.

The course provides an insight into the underlying hygienic design principles/requirements/guidance involved in the specification, construction and completion of these systems. Testing requirements (qualification and routine) are also covered. It also provides information on suitable system design solutions and configuration, together with a detailed systematic approach to the key stages (including planning) involved in the project life-cycle. Typical examples of operational issues and recommended actions/precautions that can be taken, are also covered by this course. The course will be fully updated to reflect requirements from the latest pharmacopoeias and EMA regulatory guidelines, including Annex 1 and the Q & A's for the production of water for injection using non-distillation methods.

The course will be presented by industry experts who collectively have worked in all areas of critical utility system design, commissioning and qualification. Their hands-on experience will provide current industry best practice and up-to-date regulatory authority information.

Presenters

Mike James, Director, Compliance & Validation Services Limited.: Mike has nearly 30 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.

Richard Ryrie: Richard has over 25 years' experience of working in the Biopharmaceutical Manufacturing Industry and has a wealth of knowledge/expertise in process engineering related to process and utility systems, including automation. His experience extends to the commissioning and qualification of facilities, utilities and process equipment. A process engineer by profession, he attained an MSc. in Pharmaceutical Engineering in 2001.

John Welbourn, Director, Compliance & Validation Services Limited: A validation professional with over 30 years experience in the pharmaceutical industry. 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 production equipment, utilities, 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

This course will benefit anyone who is involved in the management, use, design, commissioning/qualification and operation/use of critical utility systems. The target audience will include, production managers/supervisors, operators, technical support personnel, engineers, quality assurance and validation personnel. On leaving the course, attendees should have with a broader and detailed understanding of the design, construction and commissioning/qualification of critical utility systems. They should 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)

Pharmaceutical Water, Steam and Compressed Gas Systems - Live Online Training Course - Programme

Start Time: 08:00 London/Dublin; 09:00 Central European Time (CET) - Please join the course at least 5 minutes before the start.

Day 1 (Tuesday 25 February 2025)	Day 2 (Wednesday 26 February 2025)	Day 3 (Thursday 27 February 2025)
Start: 08:00 London/Dublin; 09:00 CET (Berlin/Amsterdam Time)	**Start: 08:00 London/Dublin; 09:00 CET**	**Start: 08:00 London/Dublin; 09:00 CET**
Introduction to Pharmaceutical Utilities *[John Welbourn]:* • Critical utilities - definition • Water systems • Steam systems • Compressed air / gases • Chemical and microbiological limits for critical utilities (covering worldwide applicable standards and guidelines) • Instrumentation approaches • Overview of key regulatory requirements	**Water Storage and Distribution Systems** *[John Welbourn]:* • Types of systems (hot and cold) • Approaches to sanitisation (continuous and periodic) • Loop velocities and their importance • Typical equipment configurations • Points of use (key design requirements) and testing • Usage considerations • Key equipment design features • Regulations, guidelines and standards	**IQ/OQ (Verification Activities)** *[Mike James]:* • Pre-requisites (what must be in place/complete before starting) • Key activities involved • Instrument calibration and alarm/interlock testing • Functional testing and quality checks (basing testing on level of risk) • Sampling considerations
Introduction to Hygienic Engineering of Utilities *[John Welbourn]:* • Basic design principles and definition • Surface finishes • Piping and fittings • Welding – Best Practices • Materials of construction (MOC) • Current industry guidelines	**Key Preparation and Planning Activities** *[Mike James]:* • Commissioning and qualification strategy • User requirement specification (URS) • System definition, system impact (Classification) assessment and System Risk Assessment • Linking Critical Quality Attributes (CQA's) to Critical Process Parameters (CPPs) and defining Critical Aspects and design/procedural controls for direct impact systems • Quality Risk Assessments (QRA) - aligning scope and depth of testing to system complexity, risk and novelty	**Plant Handover & Performance Qualification (PQ)** *[Richard Ryrie]:* • Sequence of events involved • Key PQ activities • Verifications, e.g. operator training • Sampling and evaluation programme and ongoing performance monitoring/review • Real-life examples of sampling/monitoring plans • Managing deviations and ongoing risk management

Pre-treatment Methods for Water Generation *[Mike James]:*
• Why do we need pre-treatment?
• Typical feed water contaminants
• Processes used for removal of contaminants, e.g. pre-filtration, organic matter removal (activated carbon), water softening
• Types of equipment used, materials of construction and how the equipment may be configured
	Design Review/Design Qualification *[Richard Ryrie]:*
	• When to carry it out
	• Key elements
	  • Vendor assessments and vendor audits
	  • CGMP review of the design
	  • Specification qualification (ensuring design/functional specifications meet the user requirements)
	  • Compilation of key design documentation into a design dossier
		Pure Steam and Clean Steam *[John Welbourn]:*
		• Steam types, steam quality requirements and applications
		• Regulations, standards and guidance
		• Strategies for production and distribution
		• Equipment used and key design considerations
		• Testing requirements (when, where and how to test)

Generation of Purified Water and Water For Injection *[Mike James]:* • Types of processes and equipment involved • Different approaches/strategies for generation • Purification processes involved, e.g. Ion Exchange, Reverse Osmosis and Continuous Electro-deionisation. • Equipment configuration and requirements for generating WFI by non-distillation methods in Europe • Materials used for construction • Regulations, guidelines and standards	**Factory Acceptance Testing (FAT)** *[Richard Ryrie]:* • What do we gain by performing testing at the vendor's site? • Differences between FAT and Site Acceptance Testing (SAT) • Activities, working with vendors and documentation requirements • FAT execution and close-out (+ handling discrepancies) • FAT, SAT and qualification integration (avoiding testing duplication)	**Compressed Air and Specialist Gases** *[John Welbourn]:* • Air and gas quality requirements • Components of the generation systems • Configuration of distribution systems • Types of system employed • Testing/qualification requirements
Water For Injection (WFI) *[John Welbourn]:* • Where/when is it used and regulations, standards and guidance • Production processes/methods employed, e.g. multi-effect stills and vapour compression • Equipment systems used and design considerations such as materials of construction	**GMP Compliance During Construction** *[John Welbourn]:* • Consequences of poor practice • Control and storage of materials - Key 'watch-outs' • Good fabrication practices • Construction testing and documentation involved • Auditing construction practices • System handover for commissioning	
Rouging *[John Welbourn]:* • What is it, what types are there and what is it made of? • Parameters affecting rouge formation • Control measures and treatments/removal	**Mechanical Completion, Pre-Commissioning and Commissioning** *[John Welbourn]:* • Construction completion process • Mechanical completion process, construction testing and system handover for commissioning • Stages and activities involved, including typical commissioning tests and documentation	
Finish: 16:00 London/Dublin; 17:00 CET	**Finish: 16:00 London/Dublin; 17:00 CET**	**Finish: 16:00 London/Dublin; 17:00 CET**

BOOKING DETAILS: Pharmaceutical Water, Steam and Compressed Gas Systems - 25, 26 & 27 February 2025 - 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** **£1,750 [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 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 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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