Compliance & Validation Services

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

Pharmaceutical Water, Steam and Compressed Gas Systems

Hotel Scandic Copenhagen, Denmark

17, 18 & 19 September 2024

September 2024						
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 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
- Reduced energy and chemical usage options
- 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 - 17, 18 & 19 September 2024 - Hotel Scandic Copenhagen

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.

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 17 Sep 2024), are included in the overall package.

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. This will include, production managers/supervisors, operators, technical support personnel, engineers, quality assurance and validation personnel. On leaving the course delegates will: have with a broad and detailed understanding of the design, construction and commissioning/qualification of critical utility 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 Water, Steam and Compressed Gas Systems - 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 17 September 2024)

Start: 09:00 CET

Introduction to Pharmaceutical Utilities *[John Welbourn]:*
- Types of utility systems and what they are used for
- Systems within the scope of the course and those not included
- Basic structure and purpose of the course

Introduction to Hygienic Engineering of Utilities *[John Welbourn]:*
- Basic design principles and definition
- Surfaces finishes
- Piping and fittings
- Welding – Best Practices
- Materials of construction (MOC)
- Current industry guidelines

Introduction to Pharmaceutical Water *[John Welbourn]:*
- Why is it so important?
- Types of water, quality requirements (chemical and microbiological) and uses
- How do you determine which grade of water is required?

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

Generation of Purified Water and Water For Injection *[Mike James]:*
- Types of processes and equipment involved
- Different approaches/strategies for generation
- Purifications 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

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

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

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

Day 2 (Wednesday 18 September 2024)

Start: 09:00 CET

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

Key Preparation and Planning Activities *[Mike James]:*
- Commissioning and qualification strategy
- User requirement specification (URS)
- System definition, system impact and component level impact assessments, including ASTM approach to identifying critical aspects
- Quality Risk Assessments (QRA) – aligning scope and depth of testing to system complexity, risk and novelty
- Supporting documentation and procedures

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

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)

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

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: 17:00

Day 3 (Thursday 19 September 2024)

Start: 09:00 CET

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

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

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)

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

Course Closure *[All]*
- Final questions and answers
- Course evaluation form completion
- Certificates

Finish: 17:00

BOOKING DETAILS - Pharmaceutical Water, Steam and Compressed Gas Systems - 17, 18 & 19 September 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.

CLICK HERE TO VIEW OUR PRIVACY POLICY