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

# Pharmaceutical Water, Steam and Compressed Gas Systems

**22, 23 & 24 October 2019**

**Radisson Blu Hotel, Amsterdam**


### 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 and EU GMPs, including ‘Draft’ Annex 1)
- 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 - 22, 23 & 24 October 2019, Radisson Blu Hotel. Amsterdam

The correct design, construction, commissioning and qualification/verification, on-going operation and maintenance of pharmaceutical water, steam and compressed gas systems (critical utility systems) play a crucial role in ensuring the quality of pharmaceutical products and intermediates. Minimal requirements for the design, validation, operation and maintenance of these systems are defined by Good Manufacturing Practice for all drug, biologic and medical device manufacturing and they continue to be a major focus of attention for industry regulators and inspectors.

The 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, highly purified water, Water for Injection (WFI), clean steam, pure steam, compressed air and specialist gases. The course provides an insight into the underlying hygienic design principles/requirements/guidance involved in the specification, construction and completion of these systems. It also provides information on suitable system design solutions and configuration, together with a detailed systematic approach to the key stages involved in the project life-cycle.

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.

Day-time meals and refreshments together with a course dinner, held on the evening of Day 1, are included in the overall package.

## Presenters

**Mike James, Director, Compliance & Validation Services Limited.:** Mike has over 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.

**Biopharmaceutical Utility System Industry Speaker:** Our Industry Expert Speaker has over 20 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. Their experience extends to the commissioning and qualification of facilities, utilities and process equipment.

**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 an enjoyable experience.

## Venue

**Radisson Blu Hotel, Amsterdam:** Ideally situated in the historical heart of Amsterdam, close to the main tourist attractions, museums, theatres, shopping areas, red-light and business districts. The hotel has a fitness centre and excellent conference and banqueting facilities.

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|---|---|
| Address: | Rusland 17, NL-1012 CK Amsterdam, Netherlands |
| Tel: | +31 20 623 1231 |
| Fax: | +31 20 520 8200 |
| Reservations (email): | reservations.amsterdam@radissonblu.com |

**Click on the images to visit the hotel's website**

***Delegates are kindly requested to arrange their own accommodation. Course fees are £1,995.00 (GBP) per delegate. Accommodation is NOT included in the course fees.***

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

# Pharmaceutical Water, Steam and Compressed Gas Systems - Radisson Blu Hotel, Amsterdam - Course Programme:

**Registration (08:45 to 09:00) – Delegates arrive at the meeting room and sign the attendance register.**

## Day 1 (Tuesday 22 October 2019)

**09:00 Opening/Welcome**

**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: 17:20; Drinks Reception: 19:00; Course Dinner: 20:00**

## Day 2 (Wednesday 23 October 2019)

**Day 2 Introduction (09:00)**

**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** *[Industry Expert Speaker]:*
- 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)** *[Industry Expert Speaker]:*
- 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: 17:15**

## Day 3 (Thursday 24 October 2019)

**Day 3 Introduction (09:00)**

**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)** *[Industry Expert Speaker]:*
- 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: 16:45**

## BOOKING DETAILS: Pharmaceutical Water, Steam and Compressed Gas Systems - Radisson Blu Hotel, Amsterdam 22, 23 & 24 October 2019

**How to book on this course:**

- The simplest and quickest way is to book online. Please visit/return to the CVS web-site, find the course you are interested in and follow the simple instructions (link included below).
- Alternatively, download a booking form, complete it electronically or print and annotate, and return it to us by fax or email (link and contact details included below).
- Or finally, print out this page, complete the form below by hand and return by fax, email or post.

**<< CLICK HERE TO GO TO CVS WEBSITE >>** **<< CLICK HERE FOR BOOKING FORM >>**

**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:** | **Number of delegates:** | **Delegate Name(s):** |
| **Delegate E-mail Address(es):** *(if different to booking contact)* | | |
| **Special dietary requirements?** | | |
| **Disability Requirements?** | | |
| **Company VAT Number (or Sales Tax Number) – *EU Countries Only** | | |
| ***Method of payment, e.g. card, bank transfer or cheque** | | 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. Cheques should be sent with a completed booking form to Compliance & Validation Services Limited, 8 Sedgefield Close, Macclesfield, Cheshire, SK10 2WF, United Kingdom. |
| **Payment Reference (if available)** | | NOTE: For bank transfer payments we will need a valid reference number or purchase order number to fully confirm the booking. |
| ***Total Fees Due** **£1,995 [GBP]** **per delegate** | | NOTE: If your finance centre or delegates are based in the United Kingdom (UK), the course fee will be subject to an additional 20% UK VAT charge (£2,394 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:** A booking confirmation will be sent to the delegate or booking contact on receipt of payment, or in the case of bank transfer, following receipt of a valid purchase order reference.

**Course Fee & VAT Liability:** For the majority of participating countries, VAT will be ZERO rated or not applicable. However, for companies whose finance centre is based in the United Kingdom (location where invoices are managed) or delegates are UK based, the indicated course fee will be subject to an additional 20% UK VAT charge. CVS has to charge this by law. 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.

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.

**Cancellation**: Cancellation refunds will depend on how long before the course start date the cancellation is received. The following refund structure will apply, based on the date the cancellation is received by CVS:

- 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

CVS reserves 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. 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.

Please visit our web site for full terms and conditions (see the link at the top of this page).

**Please note that by completing the booking form (opposite) you are agreeing to our Terms and Conditions**.

**<< Click here to view our Privacy Policy >>**