Compliance & Validation Services
Presents a 3-Day Training Course on:
Pharmaceutical Critical Utility Systems

6, 7 & 8 October 2015
Radisson Blu Hotel, Amsterdam

General System Requirements and Design
• Hygienic engineering considerations
• Applicable regulations and standards
• Quality requirements for utilities
• Methods for production and distribution of critical utilities
• Typical equipment used, testing requirements and specifications
• Managing rouging problems

Commissioning and Qualification
• System and Component Level Impact Assessments and Quality Risk Assessment
  • Determining the depth and scope of testing, based on:
    • Complexity and novelty of the component/aspect/functionality
    • The impact of the component/function on the quality of system outputs
• 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
• Installation and operational qualification (verification of build and function)
• Successful plant handover and subsequent performance qualification
• On-going monitoring, performance reviews and risk management.

Purified Water, Highly Purified Water, Water For Injection (WFI), Pure Steam, Clean Steam, Compressed Air and Specialist Gases
The correct design, construction, commissioning and qualification/verification, on-going operation and maintenance of 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 (including planning) 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 and there will be numerous opportunities to put the learning into practice during carefully chosen case studies.

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 23 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 25 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.

**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 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 center and excellent conference and banqueting facilities.

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 hotel image to visit the hotel’s website]

Delegates are kindly requested to arrange their own accommodation. Course fees are £1,395.00 (GBP) per delegate. Accommodation is NOT included in the course fees.

See Page 4 for further details on fees/bookings.
### Day 1 (Tuesday 6 October 2015)

**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

**Design Review/Design Qualification** [John Welbourn]:
- 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
- Materials used for construction
- Regulations, guidelines and standards

**Generation of Purified Water and Highly Purified Water** [Mike James]:
- Types of processes and equipment involved
- 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

**Water For Injection (WFI)** [John Welbourn]:
- Where/when is it used
- 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

**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

### Day 2 (Wednesday 7 October 2015)

**Drug Pure Steam and Clean Steam** [John Welbourn]:
- Steam types, steam quality requirements and applications
- 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

**Factory Acceptance Testing (FAT)** [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

**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

### Day 3 (Thursday 8 October 2015)

**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
- Ongoing risk management

### Course Programme:

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<tr>
<th>Day 1 (Tuesday 6 October 2015)</th>
<th>Day 2 (Wednesday 7 October 2015)</th>
<th>Day 3 (Thursday 8 October 2015)</th>
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<tr>
<td>09:00 Opening/Welcome</td>
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<td>• Types of water, quality requirements (chemical and microbiological) and uses</td>
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<td>• How do you determine which grade of water is required?</td>
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<td>• Equipment used and key design considerations</td>
<td><strong>Design Review/Design Qualification</strong> [John Welbourn]:</td>
<td><strong>Pre-treatment Methods for Water Generation</strong> [Mike James]:</td>
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<td>• Testing requirements (when, where and how to test)</td>
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<td><strong>Introduction to Pharmaceutical Water</strong> [John Welbourn]:</td>
<td>• Systems within the scope of the course and those not included</td>
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<td>• Final questions and answers</td>
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<td>• Course evaluation form completion</td>
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Finish: 17:20; Drinks Reception: 19:00; Course Dinner: 20:00
**BOOKING DETAILS:** Pharmaceutical Critical Utility Systems  
6, 7 & 8 October 2015 – Radisson Blu Hotel, Amsterdam

**How to book on this course:**
- The simplest and quickest way is to book online. Please visit/return to the CVS website, 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]

**Alternative Booking Form (’*’ indicates required fields)**

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<th><strong>Booking Contact Name:</strong> *</th>
<th><strong>Booking Contact E-mail Address:</strong></th>
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<td><em>Method of payment, e.g. card, bank transfer or cheque</em></td>
<td>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 &amp; Validation Services Limited, 8 Sedgefield Close, Macclesfield, Cheshire, SK10 2WF, United Kingdom.</td>
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<tr>
<td>Payment Reference (if available)</td>
<td>NOTE: For bank transfer payments we will need a valid reference number or purchase order number to fully confirm the booking.</td>
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**Total Fees Due**  
£1,395 [GBP] per delegate

**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.