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

Temperature Controlled Storage & Transportation of Pharmaceuticals
(Includes Cold Chain)

22, 23 & 24 May 2017 (Monday to Wednesday)
Radisson Blu Royal Hotel, Copenhagen

Fridges, Freezers, Incubators, Cold Stores, Environmental Chambers, Controlled Temperature Warehouses, Passive & Active Cold Boxes, REEFERs, Temperature Controlled Vehicles

System Design:
- Importance of understanding your operating environments
- Importance of getting your requirements correct (URS) and understanding regulatory guidance
- Examples of systems/equipment available and comparison of performance
- Designing systems that will reliably perform correctly (reducing risk by good design)
- Equipment selection and explaining how systems operate
- Monitoring and mapping equipment, including latest technology
- Analysing risk and mitigating/reducing it by design and correct equipment selection

Qualification:
- Checking and testing required at various stages of qualification, e.g. DQ, IQ, OQ and PQ
- Sensor/data logger selection and number and location of sensors (risk assessments and example location/placement maps) and relating instrument tolerance to acceptance criteria
- Duration of studies for various systems and examples of approaches used, including requirements for empty and loaded state mapping (OQ & PQ)
- Reviewing alarm range, monitoring probe positions, control set points and monitoring/mapping data correlation against qualification data
- Data management and report writing (use of Mean Kinetic Temperature [MKT])
- Approach for mapping of existing facilities (includes facility risk assessments)

Operation:
- On-going Risk Management, Continuous Improvement and performance review
- Managing change and requalification requirements,
- Reuse of transit containers and monitors (management and inspection requirements)
- Evaluating and reporting the temperature data and applying good data management
- Managing non-conformance, e.g. transit temperatures go out of specification or data loggers fail
This course has been restructured to follow a typical life-cycle approach to the design, qualification and operation of temperature controlled storage and distribution systems. Systems, facilities and equipment have been placed into logical groups, which will be taken through their respective life-cycle (design, qualification and operation). The course aims to cover as many types of systems involved in the storage and distribution of drug products as practicable in the allotted time (controlled temperature and cold chain), taking care not to overload the information. The course includes new sections on operational considerations for each system/facility/equipment group, with ongoing risk management, continuous improvement, data reporting/management and dealing with non-conformance, e.g. failure to include shipment loggers, lost loggers and logger failure. So to sum up the course, we take people through system/equipment/facility design + selection for compliant and consistent operation, how to qualify the systems/equipment/facilities (with example approaches) and then through ongoing operational considerations for compliant and consistent operation. The course will be presented by industry experts who collectively have worked with storage units, facilities and cold chain distribution for many years. Their considerable hands-on experience and knowledge base will provide learning on current industry best practice, using practical real-life examples. There will be numerous opportunities to put the learning into practice during carefully chosen workshops.

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

Presenters

Mike James, Training 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.

Richard Peck, Managing Director, RP Pharma Consulting Ltd: Richard has worked in the Life Sciences industry for over 15 years, and has spent the past 10 years within the temperature-controlled supply chain sector. He began his career at GlaxoSmithKline before moving to Wyeth Pharmaceuticals, managing the Cold Chain Technology group at their EMEA Cold Chain Centre of Excellence. To further expand his knowledge and expertise, Richard moved to the supplier side of the industry working for leading providers of both disposal and reusable passive temperature controlled packaging. He has also worked for a leading provider of temperature data-logging devices. As an active member of the PDA’s Pharmaceutical Cold Chain Interest Group, he sits on the European Steering Committee and has chaired and been involved in the authoring of several technical reports and training seminars. As a GDP consultant and trained Responsible Person, Richard provides both consultancy and training services to customer's challenged by global GDP regulations.

John Welbourn, Consultancy Director, Compliance & Validation Services Limited: A validation professional with over 20 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.

Philip de Freitas, Sales Manager at Withnell Sensors Ltd. Philip has over 30 years experience in supplying temperature monitoring/mapping equipment and advice to the pharmaceutical industry. For the last 9 years, he has been providing temperature and humidity validation/monitoring solutions, including wired multichannel loggers, wireless and stand alone loggers, to the Pharmaceutical and Biotech industries. Previously, Philip spent 25 years with Kaye, and was one of their key technical sales representatives in Europe.

Who Should Attend

Individuals to benefit from attending this course include anyone involved in the management, operation, engineering, quality assurance and validation of fridges, freezers, cold stores, cold boxes, incubators, warehouses/intermediate storage facilities and temperature controlled vehicles / transit container. The course will also benefit people involved in distribution management of pharmaceutical products/materials. On leaving the course delegates will: be equipped with the latest regulation and guidelines; have a broad and detailed understanding of the design, construction and qualification of storage and distribution systems; be able to apply and share their new knowledge; improve their individual effectiveness; and look back on an enjoyable experience.

Venue

Radisson Blu Royal Hotel, Copenhagen, Hammerichsgade 1, Copenhagen V, DK-1611, Denmark: Situated across from the city's main train station, this Copenhagen hotel's city centre address makes it easy for guests to explore the area. Stroll to the fashionable stores of Strøget shopping district and the fun of magical Tivoli Gardens.

Tel: +45 3342 6000
Fax: +45 3342 6100
Email: info.cphzh@radissonblu.com
Room reservations: Tel: +45 3815 6500; Fax: +45 3815 6501; Europe toll free: 00800 3333 3333
Email: reservations.royal.copenhagen@radissonblu.com

Delegates are kindly requested to arrange their own accommodation. Course fees are £1,495.00 (GBP) per delegate. Accommodation is NOT included in the course fees.
**Temperature Controlled Storage & Transportation of Pharmaceuticals - Radisson Blu Royal Hotel, Copenhagen - Course Programme:**

**Registration (08:45 to 09:00) – Delegates arrive at the meeting room and sign the attendance register. Each day will include at least 1 interactive workshop.**

|-----------------------------|-----------------------------|-----------------------------|
| **09:00 Opening/Welcome [Mike James]:** | **Temperature & Relative Humidity Mapping and Monitoring [John Welbourn]:** | **Temperature Controlled Storage & Transportation**
| • The purpose of controlling the temperature at which drugs are stored and distributed. | • Temperature and humidity sensor selection (types available and their relative performance) | **[Richard Peck]:**
| • Consequences of getting it wrong in terms of what can happen to drug products when exposed to high and low temperatures | • Mapping systems for qualification studies | **Importance of fully understanding route conditions and realistic transit times**
| • Overview of key regulations and guidance, timeline/history and how it fits together | • Permanent monitoring systems | • Challenges involved with using cold boxes and qualifying them
| • Understanding your storage/distribution equipment, systems and processes | • Different type of systems currently available, e.g. RF and hard-wired | • Controls required to ensure consistent performance of units
| • The importance of identifying, evaluating and reducing/mitigating risks and examples of typical risks involved | • Advantages and disadvantages of different types of systems | • Validation approaches for active and passive temperature transportation units, including reducing some of the burden of qualification using the climatic zone approach and data provided by the container supplier
| • Importance of ensuring storage and distribution are integrated into your quality risk management system | • Load monitoring | • Overview of what is required at various stages of the qualification/validation
| • Regulatory focus and who is responsible ensuring compliance | • Data management and data integrity of monitoring and mapping data | • Qualification of active and passive temperature controlled transportation [Richard Peck]

**Design of Fridges, Freezers, Incubators, Environmental Chambers and medium to large Cold Stores [Mike James]:**

| Operational Considerations for Warehouses and Cold Store Facilities [Mike James]: | | Qualification of active and passive temperature controlled transportation [Richard Peck]
| • Importance of getting your requirements correct and the use of risk assessments at an early stage | • On-going risk management (RM) and continuous improvement | Covers: Active and passive cold boxes, temperature controlled containers (including REEPERS) and temperature controlled vehicles:
| • How refrigeration systems work and how they are utilised in domestic fridges, pharmaceutical fridges and cold stores | • Controls required | **Importance of fully understanding route conditions and realistic transit times**
| • Fridges and freezer selection | • Facility maintenance and management | • Challenges involved with using cold boxes and qualifying them
| • Typical examples of what is available | • Managing change and requalification requirements | • Controls required to ensure consistent performance of units
| • Pros and Cons and risks associated with various types | • Handling of data and dealing with non-conformance | • Validation approaches for active and passive temperature transportation units, including reducing some of the burden of qualification using the climatic zone approach and data provided by the container supplier
| • Selection criteria | • Performance and qualification reviews/monitoring | • Overview of what is required at various stages of the qualification/validation
| • Risk reduction by design | | • Qualification of temperature controlled vehicles using a matrix of data, based on vehicle grouping, temperature mapping, and in-transit load monitoring and storage space monitoring
| • Cold store design | • Reviewing alarm range, monitoring probe/endpoint positions, control set points and monitoring/mapping data correlation against qualification data | • Deciding where transit loggers should be placed
| • Cooling systems and air distribution | • Determining the number and location of sensors | • Data management and report writing
| • Impact of location, facility layout and risk reduction by design | • Risk assessments | |...
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.

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 website 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.

Alternative Booking Form (* indicates required fields)

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| *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 800833 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 | 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 (£1,794 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. |

| £1,495 [GBP] per delegate |          |