Compliance & Validation Services

Presents a 3-Day Online Training Course on:

Temperature Controlled Storage & Transportation of Pharmaceuticals

(Includes Cold Chain)

3, 4 & 5 October 2023

Online Training Course

Photograph courtesy of Pulleyn: www.pulleyn.co.uk
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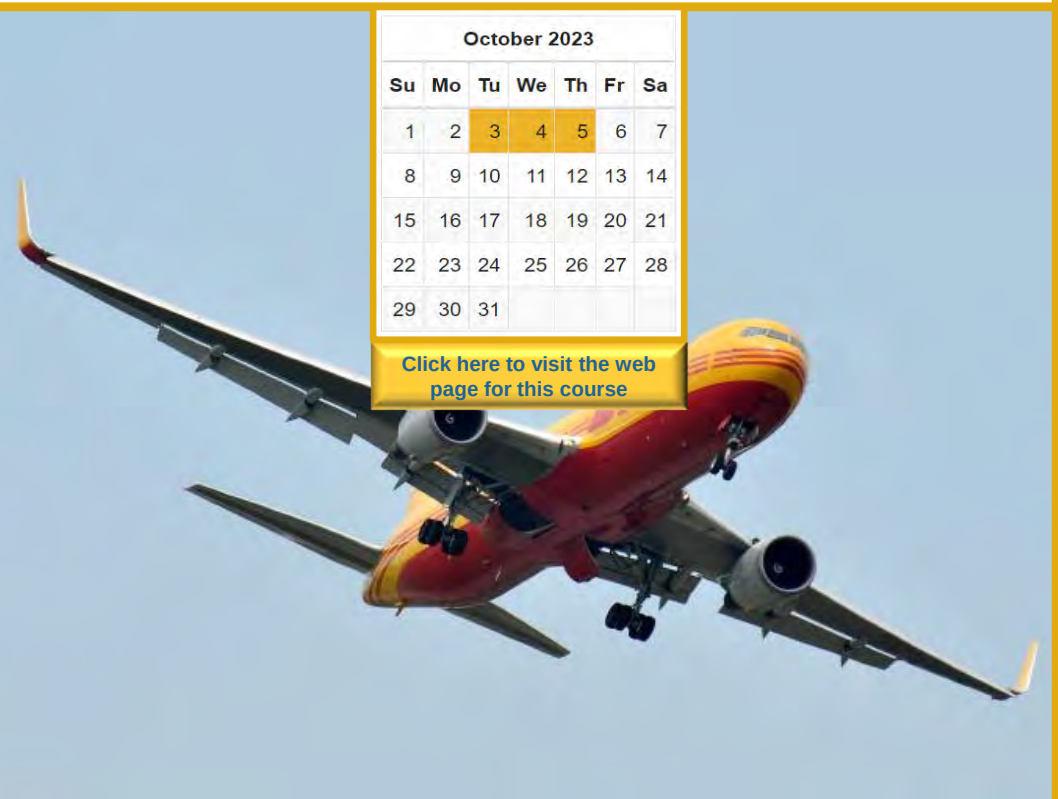

Fridges, Freezers, Incubators, Cold Stores, Environmental Chambers, Controlled Temperature Warehouses, Passive & Active Cold Boxes, REEFERs, Temperature Controlled Vehicles

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

Course Summary - Temperature Controlled Storage & Transportation of Pharmaceuticals - 3, 4 & 5 October 2023 - Online Training Course

This Live Online pharmaceutical training course has been tailored to cover 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 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. Carefully chosen workshops will help put learning into practice.

Presenters

Mike James, Training 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.

John Welbourn, Consultancy Director, Compliance & Validation Services Limited: A validation professional with over 30 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.

Richard Peck, Managing Director, RP Pharma Consulting Ltd: Richard has worked in the Life Sciences industry for over 20 years, and has spent the past 15 within the temperature-controlled supply-chain sector. In this time he has worked for several major pharmaceutical companies including GSK, Wyeth and AstraZeneca, and a start-up Biotech, Clover Biopharmaceuticals. He also spent a number of years working for several leading suppliers of both single-use and reusable passive temperature controlled shipping systems, and datalogging technologies. Richard provides consulting services and training on all aspects of Good Distribution Practice (GDP), storage & transportation qualification including thermal mapping, and is an active Responsible Person (RP).

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 10 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 attendees 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 hopefully look back on an interesting and enjoyable 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)

Temperature Controlled Storage & Transportation of Pharmaceuticals - Online Course Programme:

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

Day 1 (Tuesday 3 October 2023)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

Introduction to Temperature Controlled Storage & Distribution *[Richard Peck]:*

- Why do we need to control Storage & Distribution temperature?
- Consequences of exceeding temperature limits
- Overview of key regulations and guidance, timeline/history and how it fits together
- Understanding your storage/distribution equipment, systems and processes
- The importance of identifying, evaluating and reducing/ mitigating risks and examples of typical risks involved (including the impact of Covid-19 restrictions
- Importance of ensuring storage and distribution are integrated into your quality risk management system
- Regulatory focus and who is responsible ensuring compliance

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

- Importance of getting your requirements correct and the use of risk assessments at an early stage
- How refrigeration systems work and how they are utilised in domestic fridges, pharmaceutical fridges and cold stores
- Fridges and freezer selection
  - Typical examples of what is available and election criteria
  - Pros and Cons and risks associated with various types
  - Risk reduction by design
- Cold store design
  - Cooling systems and air distribution
  - Impact of location, facility layout and risk reduction by design
  - Use of dual systems to reduce the risk from equipment failure
- Control and monitoring considerations and their pros and cons
- Incubator types available, selection criteria and typical performance
- Types of environmental chambers (temperature and relative humidity controlled), selection criteria and performance

Design of large Controlled Room Stores and active and passive transportation equipment/systems *[Richard Peck]:*

- Warehouses
  - Specifying requirements and initial risk assessments
  - Design of modern stores, e.g. the importance of air distribution
  - Risk reduction by good design
  - Modifications to existing non-compliant stores (risk reduction)
  - Monitoring considerations and how they relate to facility design
- Transportation systems
  - Types of systems available, e.g. cold boxes, refrigerated containers (Reefers), refrigerated vehicles, and how they operate
  - Selection criteria (pros and cons)
  - Format (pack configurations)
  - Types of risks associated with each and these may be overcome
  - Route considerations and mode of transport (road, ships, planes)
  - Monitoring system considerations
  - Key design / test data provided by the container supplier
- Passive Temperature Controlled Transport Container Study
  - Prepare real examples of phase change (PCM) and water based pack outs for cold boxes
  - Discuss importance of pre-conditioning the cool packs / PCM's
  - Install temperature monitors and ship the units (CPH to UK)
  - Final data analysis will be supplied after the course

Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

Day 2 (Wednesday 4 October 2023)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

Temperature & Relative Humidity Mapping and Monitoring *[John Welbourn]:*

- Temperature and humidity sensor selection (types available and their relative performance)
- Mapping (qualification studies) and permanent monitoring systems
- Different type of systems currently available, e.g. RF and hard-wired
- Advantages and disadvantages of different types of systems
- Load monitoring devices
- Data management and data integrity of monitoring and mapping data

Monitoring/Mapping Device Demonstration *[Philp de Freitas]:*

- Latest monitoring technology
- Mapping study of the meeting room using the latest wireless data loggers
  - Assessing and agreeing data logger placement positions
- Demonstration of temperature profile of the room using data logger management software

Qualification/ Validation of fridges, freezers and incubators (small units) *[John Welbourn]*

- Types of checking and testing required at various stages of qualification, e.g. DQ, IQ, OQ and PQ (+ URS considerations)
- Deciding on the type of sensor/data logger to use
- Determining the number and location of sensors
- Risk assessments and requirements for empty and loaded mapping
- Typically sensor location/placement maps
- Mapping study duration (OQ and PQ)
- Relating instrument tolerance to acceptance criteria
- Reviewing alarm range, monitoring probe positions, control set points and monitoring/mapping data correlation against qualification data
- Managing data, report writing and monitoring considerations

Qualification/ Validation of Warehouses and Large Cold Stores *[Mike James]:*

- Types of checking and testing required at various stages of qualification, e.g. DQ, IQ, OQ and PQ (+ URS considerations)
- Deciding on the type of sensor/data logger to use
- Determining the number and location of sensors
- Risk assessments
- Typically sensor location/placement maps
- OQ and PQ durations
  - Examples of approaches used
- Requirements for empty and loaded state mapping
- Relating instrument tolerance to acceptance criteria
- 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

Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

Day 3 (Thursday 5 October 2023)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

Qualification of active and passive temperature controlled transportation *[Richard Peck]*

Covers: Active and passive cold boxes, temperature controlled containers (including REEFERS) and temperature controlled vehicles:

- Importance of fully understanding route conditions and realistic transit times
- Challenges involved with using cold boxes and qualifying them
- Controls required to ensure consistent performance of units
- 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
- Overview of what is required at various stages of the qualification/validation
- 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
- Reviewing alarm range, monitoring probe/equipment positions, control set points and monitoring/mapping data correlation against qualification data
- Deciding where transit loggers should be placed
- Data management and report writing

Operational Considerations for Smaller Units *[John Welbourn]:*

- On-going RM and continuous improvement
- Controls required
- Facility (housing the units) and unit maintenance and management
- Managing change and requalification requirements
- Handling of data and dealing with non-conformance
- Performance and qualification reviews/monitoring

Operational Considerations for Warehouses and Cold store Facilities *[Mike James]:*

- On-going risk management (RM) and continuous improvement
- Controls required
- Facility maintenance and management
- Managing change and requalification requirements
- Handling of data and dealing with non-conformance
- Performance and qualification reviews/monitoring

Operational Considerations for Passive and Active Shipping Containers/Vehicles *[Richard Peck]*

- On-going RM and continuous improvement
- Managing change and requalification requirements, e.g. vehicle changes and transit container changes, and route changes + pack configuration changes
- Revalidation/qualification requirements
- Reuse of transit units and management and inspection requirements
- Managing and reporting of transit temperature data and managing reuse of transit monitors
- Managing non-conformance

END: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

BOOKING DETAILS - Temperature Controlled Storage & Transportation of Pharmaceuticals - 3, 4 & 5 October 2023 - Online Training Course

How to book on this online training 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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