## Compliance & Validation Services

**Presents a 3-Day In-Person Training Course on:**

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

## Hotel Scandic Copenhagen, Denmark
## 11, 12 & 13 June 2024


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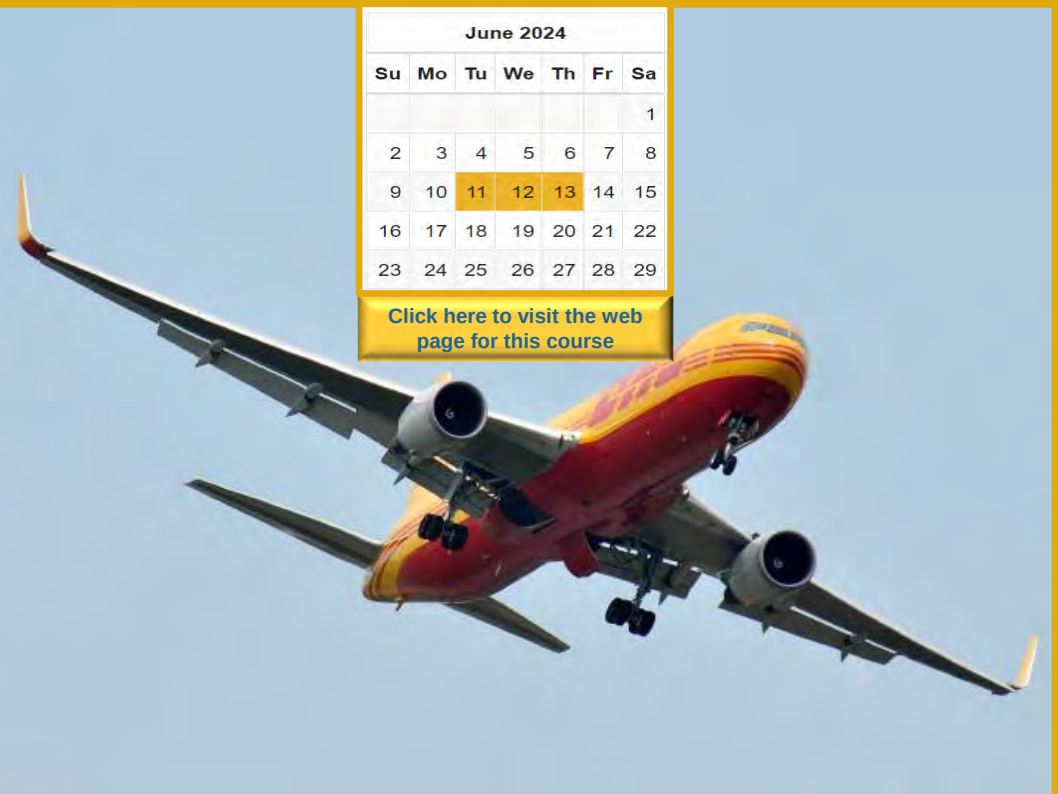


**Fridges, Freezers, Incubators, Cold Stores, Environmental Chambers, Controlled Temperature Warehouses, Passive Shipping Systems, Active Containers and Vehicles**

**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 uncertainty 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
- 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 and the use of Mean Kinetic Temperature (MKT)

## Course Summary - Temperature Controlled Storage & Transportation of Pharmaceuticals - 11, 12 & 13 June 2024 - Hotel Scandic Copenhagen, Denmark

This pharmaceutical training course covers typical life-cycle approaches to the design, qualification and operation of temperature controlled storage and transportation systems, facilities and equipment. Systems, facilities and equipment have been placed into logical groups and delegates will be taken through their respective life-cycle (design, qualification/validation and operation). The course aims to cover the common and latest systems involved in the storage and transportation of drug products. It includes detailed information concerning how to map internal conditions across the spectrum of storage and transportation conditions used in the pharmaceutical industry. Also covered, are the wide range of instrumentation available for monitoring and mapping and how the placement of monitoring probes can be linked to/integrated into the mapping exercises undertaken as part of the validation life-cycle. The potential adjustment of upper and lower limits for storage conditions, to allow for instrument uncertainty, will be covered as part of the instrumentation presentation. The course will also focus on operational considerations for each system/facility/equipment group, covering areas such as ongoing risk management, continuous improvement, data reporting/management and dealing with non-conformance, e.g. temperature excursions. There will be multiple interactive exercises to break up the presentation material and reinforce learning throughout the course.

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 course dinner, held on the evening of Day 1 (Tuesday 11 June 2024), are included in the overall package.

## 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 / temperature-controlled shipping systems. 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 hopefully look back on an interesting and enjoyable experience.

## Venue & Course Fees

**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)***

# Temperature Controlled Storage & Transportation of Pharmaceuticals - Hotel Scandic Copenhagen - Course 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 11 June 2024)

**Start: 09:00 CET**

**Introduction to Temperature Controlled Storage & Distribution** *[Richard Peck]:*
- Why do we need to control Storage & Distribution temperature?
- Consequences of exceeding temperature limits (upper and lower)
- Overview of key regulations and guidance
- Understanding your storage/distribution equipment, systems and processes
  - The importance of identifying, evaluating, ranking and reducing/mitigating all risks within your manufacturing, storage and distribution chain
- Understanding external climatic challenges for both storage and distribution
- Importance of ensuring storage and distribution are integrated into your quality risk management system

**Fridge/Freezer/Incubator/Environmental Chamber Design** *[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 different types of refrigerators/freezers (gravity versus fan ventilated units, ultra low temperature and cryogenic storage systems)
- 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
- Incubator types available, selection criteria and typical performance
- Types of environmental chambers (temperature and relative humidity controlled), selection criteria and performance

**Design of Medium to Large Cold Stores and Controlled Temperature Warehouses/Stores***[Mike James]:*
- Specifying requirements and initial risk assessments
- Design of modern stores, e.g. the importance of effective air distribution to prevent temperature stratification and risk reduction by good design
- Material flow types
- Door systems - avoiding infiltration of warm or cold air
- Modifications to existing, possibly non-compliant stores (risk reduction)
- Challenges/advantages of automated warehouse systems

**Design of Passive Shippers** *[Richard Peck]:*
- The influence of thermodynamics on packaging performance
- Modes of heat transfer and how they apply to packaging design
- Insulation materials, their properties and performance comparison
- Examples of cooling elements and their properties and performance, e.g. phase change materials
- Examples of passive shippers (further information, including a practical demonstration will be given on Day 2.

**Design of Active Transportation** *[Richard Peck]:*
- Principle types of vehicles, e.g. temperature controlled vehicles, aircraft (active containers), ships (REEFERs) and rail (active containers)
- Insulation, airflow and thermal integrity
- Key components and areas of risk, e.g. conductive pathways and poor seals
- Monitoring systems: Location of sensors, recording intervals, calibration, and retention of data
- Upper/lower temperature limits and alarms (visual, audible, SMS/email alert)

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

## Day 2 (Tuesday 12 June 2024)

**Start: 09:00 CET**

**Temperature and Relative Humidity Mapping and Monitoring** *[John Welbourn]:*
- Temperature and humidity sensor selection (types available and their relative performance)
- Sensor calibration and understanding instrument uncertainty and how/when acceptance criteria should be adjusted based on uncertainty values (also linking data from monitoring/mapping probes to the control probe)
- Typical systems used for mapping and permanent monitoring
- Different type of systems currently available, e.g. wired or wireless
- Advantages and disadvantages of different types of systems
- Load monitoring devices

**Monitoring/Mapping Device Demonstration** *[Philp de Freitas]:*
- Latest monitoring technology and application
- Cloud or local server data storage
- Example temperature profiling of a room using a modern wireless system and the graphical data produced by the management software application

**Passive Shipping 'Box' Demonstration** *[Richard Peck]:*
- Components of different types passive containers
- How the packs are assembled and key aspects of the system explained
- Addition of monitoring probes

**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/loaded mapping
- Typically sensor location/placement maps and load sensors
- Typical tests carried out and example door open challenge test data (interpretation and acceptance criteria)
- Mapping study duration (OQ/PQ) - empty and loaded conditions

**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)
- Risk assessments
- Example sensor location/placement maps
- OQ and PQ durations
  - Examples of approaches used, including example sensor location maps
- Requirements for empty and loaded state mapping
- Alarms, control set points and approaches for installing a permanent monitoring system based on qualification data.
- Data management and report writing
- Approach for mapping of existing facilities, using a real-life recent example

**Finish: 17:00 CET**

## Day 3 (Thursday 13 June 2024

**Start: 09:00 CET**

**Qualification of Passive Temperature Controlled Transportation** *[Richard Peck]:*
- Typical user requirements
- Overview of qualification phases and requirements
- Understanding and simulation of environmental challenges using test chambers
  - Ambient Temperature Profiles
  - Shipping lanes
- Stress testing
- Temperature studies and sensor locations for thermal OQ testing
- Bracketing
- Collecting shipping lane data
- Simulation modelling

**Qualification of Active Temperature Controlled Transportation** *[Richard Peck]:*
- Understanding variable parameters, e.g. climate and transport system complexity
- Use of large environmental chambers
- Typical qualification testing, including example probe locations
- Qualification of temperature controlled vehicles using a family approach, based on vehicle equivalency, a percentage of mapping studies, in-transit load monitoring and in-transit storage space monitoring
- Use of accurate simulation software to support qualification

**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/system maintenance and management
- Managing change and requalification requirements
- Mean Kinetic temperature (MKT) and when it can and when can't be used to support storage conditions

**Operational Considerations for Passive and Active Shipping Containers/Vehicles** *[Richard Peck]:*
- Vendor quality management
- Managing single use passive systems, e.g. using effective delivery inspection
- Storage and conditioning of media
- Control of packing time limits and preconditioning of media
- Control over winter and summer configurations
- Management of shipping lanes and retrieval of transit data
- Requalification requirements, e.g. after design change (enhancements)
- Trailer/REEFER management (may be part of a family approach)

**Course Finish: 17:00 CET**

# BOOKING DETAILS - Temperature Controlled Storage & Transportation of Pharmaceuticals - 11, 12 & 13 June 2024 - Scandic Copenhagen Hotel

**How to book on this training 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:** |
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| **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**