



Compliance & Validation Services

Presents a 3-Day (In-Person) Training Course on:

Pharmaceutical HVAC Systems

8, 9 & 10 April 2025

Radisson Blu Royal Hotel, Dublin, Ireland



April 2025						
Su	Mo	Tu	We	Th	Fr	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

[Click here to visit the web page for this course](#)

- Applicable to Sterile and Non-Sterile and Operations
- HVAC system applications and the impact on product quality
- Key regulations, guidelines and standards, including the ISO 14644 series and the latest EU Volume 4, Annex 1
- People as a source of contamination (understanding particle generation and how to control it)
- Fundamental purposes of HVAC systems
- Fundamental components and configuration of HVAC systems
- Facility design principles for prevention of contamination and cross contamination
- Control / preservation of key room parameters by HVAC systems
- Energy savings / carbon emission reduction opportunities
- Particle monitoring and systems available (including airborne rapid micro sampling)
- Risk based approach to the qualification of HVAC systems and the validation / qualification of room environments
- Routine and periodic environmental monitoring requirements, including setting alert and action limits for particle monitoring
- HVAC system maintenance considerations and typical issues that can arise if systems are not maintained properly

Course Summary - Pharmaceutical HVAC Systems - 8, 9 & 10 April 2025 - Radisson Blu Royal Hotel, Dublin, Ireland

This course provides attendees with an in-depth understanding of the key aspects of Heating Ventilation & Air Conditioning (HVAC) System design (designed in tandem with the facility), construction, operation and maintenance. It covers facility HVAC systems for a range of drug product types and APIs, including non-sterile drug products, for example oral solid dose/oral liquids, inhalation non-sterile products, terminally sterilised products and aseptically manufactured products. Key considerations such as dust removal and compliance with explosive atmosphere regulations (e.g., ATMosphere EXplosibles [ATEX]) also covered by this course. To ensure this course is properly rounded, areas such as a risk-based approach to the qualification of HVAC system equipment and the validation / qualification of environmental conditions, for sterile and non-sterile facilities, are carefully integrated into the course. The course also recognises the current drive towards energy savings / carbon emission reduction and includes useful information on how the energy usage of Pharmaceutical HVAC Systems can be correctly assessed and subsequently reduced by changing the operating philosophy and making suitable modifications. Effective distribution of supply air to turbulently ventilated rooms will be discussed in detail, as this is a foundation stone for effective particulate control and energy reduction initiatives. Attendees will also be provided with up-to-date information on key regulatory rules / guidance and international standards / guidelines.

The course will be presented by industry experts who have worked in the field of HVAC system design, operation /maintenance and qualification for many years. Their combination of knowledge, together with recent hands-on experience, will provide current industry best practice and up-to-date regulatory authority information.

Attendees 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 attendee after the course.

Day-time meals and refreshments are included in the overall package. There will be an informal social gathering of attendees and presenters on the evening of Day 1 (Tuesday 8 April 2025, 18:30 onwards) that will include drinks and a sit-down dinner (fully complementary and everyone is welcome).

Presenters



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



Industry Expert: Our industry expert has many years of experience of operating and risk assessing HVAC systems within the pharmaceutical manufacturing environment and is an accomplished presenter.



Nigel Lenegan, Managing Director, Energy & Carbon Reduction Solutions Ltd: Nigel has over 20 years of experience in the design and operation HVAC Systems and associated Controlled Environments and Cleanrooms in the Pharmaceutical, High Technology and Micro-electronic Industries. Nigel has played a key role within a number of large manufacturing facility projects, including Sterile Injectibles, tableting and coating, granulation and packaging. He is also experienced in projects relating to research and development laboratories, including high value compound management and high throughput screening facilities. Nigel is Chartered Engineer and co-chair of the ISPE Global Sustainable Facilities CoP. He is also an accredited Low Carbon Consultant (design) with the Chartered Institution of Building Services Engineers (CIBSE).

Who Should Attend

This course has been designed for personnel from a range of disciplines whose day-to-day responsibilities involve the need to understand the fundamentals of HVAC / Facility design operation, qualification and maintenance. It will also benefit anyone who is interested in energy saving initiatives. Target disciplines include, but are limited to, production, technical, engineering, validation and quality assurance. On completing this course, attendees will: have a better understanding of the applicable regulatory rules and guidance and other pertinent international standards/guides; have a clear understanding of the fundamental principles and best industry practice of/in aseptic facility/HVAC design, operation, and maintenance; in depth knowledge of key supporting systems; understand methods by which energy may be saved; be able to apply and share their new knowledge; and improve their individual effectiveness.

Venue & Course Fees

Radisson Blu Royal Hotel (Dublin): The hotel is located in the heart of the Irish capital and has a gym and Spa.

Address: Golden Lane, Dublin 8, D08 VRR7, Ireland

Tel: +353 (1) 898 2931 (Reservations)

Email: reservations.royal.dublin@radissonblu.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 attendee. Accommodation is NOT included. (See Page 4 for further details on fees/bookings)



Day 1 (Tuesday 8 April 2025)	Day 2 (Wednesday 9 April 2025)	Day 3 (Thursday 10 April 2025)
Start: 09:00 Local Time (London/Dublin Time)	Start: 09:00 Local Time	Start: 09:00 Local Time
Introduction & Background <i>[Mike James]:</i> <ul style="list-style-type: none"> Course Overview Brief history of HVAC systems Uses of HVAC Systems Key Regulations, Guidelines and Standards, including the latest ISO Standards and the latest EU Annex 1 (Aug 2022) 	Terminal HEPA Filters <i>[Industry Expert]:</i> <ul style="list-style-type: none"> The origins of the HEPA filter Filtration mechanisms involved and how filters are constructed HEPA filters as a key contamination control method HEPA filter installation leak testing Regulatory guidelines for cleanroom HEPA filters HEPA filter in-situ leak testing failure - Group Exercise 	Facility Design for Particle Control <i>[Mike James]:</i> <ul style="list-style-type: none"> Facility layout and typical controlled area specifications Design features for the control of contamination / cross-contamination, Pressure / Airflow regimes Control of dust and prevention of cross-contamination Differential Pressure Regimes and room grading Use of barrier systems + unidirectional airflow devices
Introduction to Cleanrooms <i>[Industry Expert]:</i> <ul style="list-style-type: none"> Cleanroom definition and interpretation History of cleanrooms The origins of today's cleanroom air velocities, room change rates and particle limits Cleanroom classification and pharmaceutical cleanrooms Achieving and maintaining cleanroom cleanliness levels 	Key Room Parameter Control <i>[Nigel Lenegan]:</i> <ul style="list-style-type: none"> Differential Pressures (different control philosophies/mechanisms) Pressure Stabilisers and controlled room leakage Preserving room volumetric flows Temperatures Relative Humidity Monitoring Systems 	Qualification of HVAC Systems and Room Environments <i>[Mike James]:</i> <ul style="list-style-type: none"> Risk-based approach Impact assessments Quality Risk Assessments IQ/OQ/PQ activities Typical test equipment
Fundamental Purposes of HVAC Systems <i>[Nigel Lenegan]:</i> <ul style="list-style-type: none"> Preservation of product quality Particle removal (effective air distribution & air change rates) Particle and dust containment Comfort conditions Product related conditions 	Cleanroom HVAC And Contamination Control - A Green Challenge To The Orange Guide <i>[Industry Expert]:</i> <ul style="list-style-type: none"> Principles and origins of unidirectional airflow and traditionally ventilated cleanrooms Regulatory authority cleanroom control parameters Comparison of in operation performance vs. regulatory authority guidelines Further investigations for energy savings whilst maintaining adequate contamination control Realistic and achievable cleanroom energy reductions 	HVAC Maintenance Considerations <i>[Nigel Lenegan]:</i> <ul style="list-style-type: none"> Proactive filter changes Cleaning Equipment servicing Calibration Real examples of what can happen if systems are not properly maintained
HVAC System Fundamental Components <i>[Nigel Lenegan]:</i> <ul style="list-style-type: none"> Components/configuration of air handling system Methods of air distribution and extraction Typical filter regime Types of filters Filtration processes Sizing/application of air handling units (AHU), e.g. one per facility, or multiple AHUs for different grades of areas ATmosphere EXplosibles (ATEX) Considerations 	Energy Saving / Carbon Emission Reduction Initiatives <i>[Nigel Lenegan]:</i> <ul style="list-style-type: none"> System review / energy survey Formulating solutions Implementation Measuring effectiveness Continuous improvement Overview of Oral Solid Dose environmental requirements and energy saving initiatives 	Environmental Monitoring <i>[Mike James]:</i> <ul style="list-style-type: none"> EU Volume 4, Annex 1 requirements What has to be monitored and when? Routine and periodic monitoring requirements Differences between Aseptic and Non-Sterile Areas What equipment is needed? Where should we monitor? What standards should be applied? Locations and frequency examples Setting alert and action limits Effective data management and reacting to data
Contamination in the Cleanroom <i>[Industry Expert]:</i> <ul style="list-style-type: none"> Fundamental mechanism of contamination Derived models for cleanroom contamination General sources and routes of contamination and the associated central role of air in contamination Personnel as a source of microbial contamination Inert particles and microbe carrying particles Risk assessment approach for microbial contamination during cleanroom operation 	Particle Monitoring and Classification <i>[Mike James]</i> <ul style="list-style-type: none"> How optical particle counters work Particle counting technology (including airborne rapid micro sampler and how they work) Monitoring systems Cleanroom Classification following ISO14644-1, FDA Aseptic Processing Guide and EU Annex 1 (Aug 2022) 	Course Closure <ul style="list-style-type: none"> Final questions and answers Couse evaluation Course certificates.

How to book on this 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 Terms & Conditions

*Booking Contact Name:		
*Booking Contact E-mail Address:		
*Booking Contact Telephone Number:		
*Company Name & Address:		
*Billing Address <i>(Only complete if different to Company Address)</i>		
*attendee Information: <i>Please let us know if any attendee has any special dietary requirements by emailing the information to info@candvs.com, or by using the space below.</i>	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 £2,500 [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 (£3,000 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 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 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 attendees 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 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 attendees may incur.

CVS does not take responsibility for ensuring the well being of attendees 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 attendees 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 attendee 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 attendee has registered for and there shall be no future liability on the part of either party.

[CLICK HERE TO VIEW OUR PRIVACY POLICY](#)