Compliance & Validation Services

Presents a 3-Day Online Training Course on:

Pharmaceutical HVAC Systems

15, 16 & 17 June 2021

Live Online Training Course

June 2021						
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			

- Applicable to Sterile and Non-sterile Operations
- HVAC system applications and the impact on product quality
- Key regulations, guidelines and standards, including the ISO 14644 series and discussions around Annex 1 updates.
- 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, 15, 16 & 17 June 2021 - Live Online Training Course

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 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. There will be opportunities to put the learning into practice during carefully chosen workshops.

Presenters

Mike James, Compliance & Validation Services Limited.: Mike has over 25 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.

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, tabletting 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).

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.

Who Should Attend

This online 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.

Online System & Course Fees

We use the industry leading GotoWebinar©, LogMeIn, Inc. platform for our online training courses. It's intuitive and simple to use, however we do recommend that you check your system's compatibility using the 'CHECK SYTEM COMPATIBILITY' link provided below (we use 'standard webinar'). To find out more about how our online training process works, from booking through to the end of the course, please click on the 'HOW IT WORKS' link provided below.

CHECK SYSTEM COMPATIBILITY

Course fees are £1,495.00 (GBP) per attendee.

(See Page 4 for further details on fees/bookings)

HOW IT WORKS

Pharmaceutical HVAC Systems - Live Online Course Programme:

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

DAY 1 (Tuesday 15 June 2021)	Day 2 (Wednesday 16 June 2021)	Day 3 (Thursday 17 June 2021)
Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam	**Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam**	**Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam**
Introduction & Background *[Mike James]:* ▪ Course Overview ▪ Brief history of HVAC systems ▪ Uses of HVAC Systems ▪ Key Regulations, Guidelines and Standards, Including changes to ISO Standards and potential changes to EU Annex 1	**Terminal HEPA Filters** *[Industry Expert]:* ▪ 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** *[Mike James]:* ▪ 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 *[Industry Expert]:* ▪ 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** *[Nigel Lenegan]:* ▪ 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** *[Mike James]:* ▪ Risk-based approach ▪ Impact assessments ▪ Quality Risk Assessments ▪ IQ/OQ/PQ activities ▪ Typical test equipment
Fundamental Purposes of HVAC Systems *[Nigel Lenegan]:* ▪ 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** *[Industry Expert]:* ▪ 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** *[Nigel Lenegan]:* ▪ Proactive filter changes ▪ Cleaning ▪ Equipment servicing ▪ Calibration ▪ Real examples of what can happen if systems are not properly maintained
HVAC System Fundamental Components *[Nigel Lenegan]:* ▪ 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** *[Nigel Lenegan]:* ▪ System review / energy survey ▪ Formulating solutions ▪ Implementation ▪ Measuring effectiveness ▪ Continuous improvement ▪ Overview of Oral Solid Dose environmental requirements and energy saving initiatives	**Environmental Monitoring** *[Mike James]:* ▪ 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 *[Industry Expert]:* ▪ 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** *[Mike James]* ▪ 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 (including impact of Annex 1 updates).	**Course Closure** • Final questions and answers • Couse evaluation • Course certificates.
Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam	**Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam**	**END: 16:00 London/Dublin; 17:00 Berlin/Amsterdam**

BOOKING DETAILS: Pharmaceutical HVAC Systems - 15, 16 & 17 June 2021 - Live Online Training Course

How to book on this 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** **£1,495 [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 (**£1,794** 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 Attendees
If you click 'yes' to 'include my name/company' on the attendees list', when completing the online booking form, your name and company will be included on the list and distributed to all the participants.
Before you commit to booking onto a webinar, we expect you to check your system compatibility with the GoToWebinar® platform using the links provided.

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 GoToWebinar® (by LogMeIn) system, because of local IT restrictions.

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