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

Pharmaceutical HVAC Systems

5, 6 & 7 November 2019
Copenhagen Marriott Hotel, Denmark

- 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, 5, 6 & 7 November 2019, Copenhagen Marriott Hotel, Denmark

This course provides delegates 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, ATmosphere EXplosibles (ATEX) compliance are 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. Delegates 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 numerous opportunities throughout the three days to put the learning into practice during carefully chosen group exercises. 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, Director, Compliance & Validation Services Limited.: Mike has 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 responsibilities for the derivation, optimisation and implementation of best practices for aseptically prepared products. They have over 20 year's experience of sterile product manufacture and have had roles in technical support, production management and specialist activities for aseptically prepared products. Our expert has also had pivotal involvement in design, construction, start up and validation of multimillion pound aseptic manufacturing facilities. They have also managed the introduction, technical transfer and scale-up activities for a number of sterile products and published a number of papers relating to cleanroom activities.

Who Should Attend

This interactive 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 leaving this course delegates 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; improve their individual effectiveness; and look back on an enjoyable experience.

Venue

Marriott Hotel, Copenhagen: The Hotel is close to the city centre and located right at the water's edge of the harbour canal. It is around 8 minutes walk from Copenhagen Central Station and Tivoli Gardens (the Gardens are opposite the station). An excellent location to explore the city from.

Address: Copenhagen Marriott Hotel, Kalvebod Brygge 5, Copenhagen 1560, Denmark
Tel: +45-88-33-99-00

Click on images to visit the Hotel's website

Delegates are kindly requested to arrange their own accommodation. ***Course fees are £1,995.00 (GBP) per delegate.*** ***Accommodation is NOT included in the course fees***

Pharmaceutical HVAC Systems -, Copenhagen Marriott Hotel, Denmark - 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.

DAY 1 (Tuesday 5 November 2019)	Day 2 (Wednesday 6 November 2019)	Day 3 (Thursday 7 November 2019)
09:00 Opening/Welcome *[Mike James]*	**Day 2 Introduction (09:00)**	**Day 3 Introduction (09:00)**
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 ▪ Classification versus monitoring of clean zones ▪ Classification of the meeting room following ISO14644-1, FDA Aseptic Processing Guide and EU Annex 1	**Course Closure** • Final questions and answers • Couse evaluation • Course certificates.
Finish: 17:00; Drinks Reception: 19:15; Course Dinner: 20:00	**Finish: 16:45**	**Finish: 16:40**

BOOKING DETAILS: Pharmaceutical HVAC Systems - 5, 6 & 7 November 2019, Copenhagen Marriott Hotel, Denmark

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to the CVS web-site, find the course you are interested in and follow the simple instructions (link included below).
- Alternatively, download a booking form, complete it electronically or print and annotate, and return it to us by fax or email (link and contact details included below).
- Or finally, print out this page, complete the form below by hand and return by fax, email or post.

<< CLICK HERE TO GO TO CVS WEBSITE >> **<< CLICK HERE FOR BOOKING FORM >>**

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:**	**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 500833 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** **£1,995 [GBP]** **per delegate**		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 (**£2394** 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: 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.

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.

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 web site 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.

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