Compliance & Validation Services

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

Aseptic Manufacturing of Pharmaceutical Products

Hotel Scandic Copenhagen, Denmark
3, 4 & 5 September 2024

September 2024						
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Click here to visit the web page for this course

Aseptic Manufacturing:

- Unique challenges of aseptic manufacture and the potential consequences of inadequate contamination control and poor practice
- Product sterility testing and the probability of detecting failure units
- Understanding and controlling contamination from cleanroom personnel
- Effective aseptic practices and cleanroom behaviours
- Risk management of microbial contamination
- Cleaning and disinfection for contamination control
- Preparation of product, components and equipment for aseptic manufacture
- Overview of sterilisation processes and requirements for effective microbial control
- Key regulatory authority documents and international standards
- Environmental monitoring

Facility Design and Support Systems:

- HVAC systems and facility (cleanroom) design principles
- Facility qualification and ongoing monitoring and management
- Fundamental principles of unidirectional and turbulent airflow for effective airborne contamination control
- RABS and Isolators
  - Risk spectrum for advanced aseptic manufacture
  - Comparison of RABS and Isolators and system options for aseptic manufacture
- Cleanroom clothing systems and assessment of garment life
- Aseptic Process Simulation (ASP) [Media fills]

Course Summary - Aseptic Manufacturing of Pharmaceutical Products - 3, 4 & 5 September 2024 - Hotel Scandic Copenhagen, Denmark

The course covers one of the most challenging and high risk activities undertaken by the pharmaceutical and biopharmaceutical industry. To operate effectively in the field of aseptic manufacturing, it is essential to understand the sources/basic mechanisms of contamination in conjunction with the associated systems and procedures required to effectively control such contamination. This course provides delegates with an in-depth appreciation of contamination sources and mechanisms, together with effective controlling and monitoring mechanisms such as: good cleanroom operation; effective facility/HVAC design, operation and maintenance; good aseptic behaviours/disciplines; effective personnel clothing systems, sterilisation processes, process simulation trials, risk management initiatives and environmental monitoring.

Our very experienced presenters will provide current industry best practice, up-to-date regulatory authority information and will enhance the learning using real life examples.

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 3 September 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.

Industry Expert: Our industry expert has many years of experience in the field of aseptic manufacturing and is an accomplished presenter.

Kevin Owen, Director of Aseptic Technologies, IPS:
A microbiologist by profession (Hospital and Pharmaceutical) who has over 30 years of aseptic operational experience and responsibility for aseptic processing capability within multinational Pharma. He ensured that all Industry and regulatory expectations (current and anticipated) were met across multiple sites by embedding a systemic approach to aseptic manufacturing. He has led draft Annex 1 compliance strategy and set up and developed Aseptic centres of excellence to transform aseptic assurance cultures. Expert fields include Regulatory compliance, positive and negative pressure cleanrooms, toxin handling, ADC, lyophilisation, specials manufacturing, clinical trial to commercial manufacturing, ATMP's and Laboratory design. He has led major aseptic facility improvement projects without interruption to the commercial supply of product to patients. His position as Director of Aseptic Technologies provides great technical leadership and operational depth on Aseptic fill finish projects across the global footprint of IPS. Kevin is always patient centric.

Who Should Attend

This interactive course has been designed for personnel from a range of disciplines. These include production, technical, engineering and quality assurance roles. It is aimed at those who are either new to aseptic manufacturing or at those who would like to expand their existing knowledge. 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; be able to apply and share their new knowledge; improve their individual effectiveness; and look back on an 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)***

Aseptic Manufacturing of Pharmaceutical Products - 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 3 September 2024)

Start: 09:00 CET

Introduction to Aseptic Manufacture *[Industry Expert]:*
- Sterile medicinal products and the concept of sterility (sterility definition)
- Unique challenges of aseptic manufacturing
- Probability of detecting contaminated units with the product sterility test
- Potential consequences of poor aseptic practices
- Regulatory authority considerations

Cleanrooms, RABS and Isolators *[Industry Expert]:*
- History of cleanrooms
- Classification of controlled environments
- Achieving and maintaining cleanliness levels
- Cleanrooms for the pharmaceutical industry
- Isolators and RABS

The Focus on RABS & Isolators *[Industry Expert]:*
- The aseptic integrity spectrum
- Isolators and RABS
- Comparison isolators and RABS
- RABS operating principles
- RABS types
- Interventions and transfers
- Gaseous vapour phase decontamination

HVAC System Overview *[Mike James]:*
- Fundamentals principles of HVAC system, e.g. particle level control by continuous removal of particle laden air
- Control of differential pressure, pressure regimes, airflows, temperature and humidity
- Design concepts
- Overview of system qualification
- Maintaining systems for effective control of airborne contamination

Cleanroom Design Principles *[Industry Expert]:*
- Layout, flow, personnel entry, room shape
- General surfaces, floors, walls and ceilings
- Windows, doors, hatches, communication systems
- Conveyor systems, drains, sinks, pipes, conduits, lighting and plant rooms
- Fittings and equipment

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

Day 2 (Wednesday 4 September 2024)

Start: 09:00 CET

People as a Source of Contamination *[Industry Expert]:*
- Contamination from personnel
- Personnel movements and contamination dispersal rates
- Inert particles and microbe carrying particles
- Mechanisms and routes for product contamination
- Risk assessment approach for microbial contamination during cleanroom manufacture

Cleanroom Clothing Systems *[Industry Expert]:*
- Garment requirements for effective contamination control and assessment of garment life
- Garment management activities
- Gowning requirements, practical gowning procedures and initial and ongoing qualification
- Undergarments – long or short sleeves?
- Goggles – disinfection or sterilisation?

Particle Counting *[Mike James]:*
- Particle counters and how they work
- Approximations and assumptions used in particle counting
- Avoiding over and under-sampling large particle (use of Isokinetic sampling probes)
- Installation considerations

Cleanroom Behaviours and Aseptic Practices *[Industry Expert]:*
- Cleanroom change protocols and garments
- Gloves and hand disinfection procedures
- Personnel movements in cleanrooms
- Workstation planning
- How to behave and how not to behave
- Video demonstration

Component Preparation and Handling *[Industry Expert]:*
- Clarification of terms
- Types of components and mechanisms used to wash / sterilise / depyrogenise, e.g. WFI rinsing and wet/dry heat sterilisation / depyrogenation
- Qualification of the processes involved, e.g. temperature mapping and endotoxin spiking
- Equipment decontamination/preparation and sterilisation

Finish: 17:00

Day 3 (Thursday 5 September 2024)

Start: 09:00 CET

Introduction to Sterilisation *[Kevin Owen]:*
- Why do we sterilise (including milestone incidents)?
- Wet heat and dry heat sterilisation (processes involved)
- Porous load sterilisation
- Fluid load sterilisation (types of sterilisers available)
- Irradiation sterilisation
- Filtration – is it a sterilisation process?
- Control of the sterilisation process
- Regulatory Inspection issues

Aseptic Validation *[Kevin Owen]:*
- Process simulation trials (PST)
- Frequency and batch/lot sizes required for PST
- Design of PST
- Inclusion of 'worst case' scenarios
- PST microbiological media
- Interpretation of PST results
- Consequences of failure and dealing with non-conforming results

Room Classification and Environmental Monitoring *[Mike James]:*
- Room Classification - worked example
- Environmental Monitoring
  - 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?
    - Example risk assessments
  - What standards should be applied?
  - Location and frequency examples
  - Setting alert and action limits and dealing with non-conformances
  - Effective data management and reacting to data

Contamination Control & Cleaning *[Kevin Owen]:*
- Where does it fit?
- Sources of contamination
- Barriers to contamination, including decontamination
- Types of cleaning and disinfection processes
- Material transfers
- Maintenance intervention and how to manage it

Final Questions & Course Closure

Course End: 17:00

BOOKING DETAILS - Aseptic Manufacturing of Pharmaceutical Products - 3, 4 & 5 Sep 2024 - Hotel Scandic Copenhagen, Denmark

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 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:**
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 reference number or 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