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

Aseptic Manufacturing of Pharmaceutical Products

8, 9 & 10 October 2019
Copenhagen Marriott Hotel, Denmark

October 2019

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	31		

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

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
- Process simulation trials (PST) [Media fills]

Course Summary: Aseptic Manufacturing of Pharmaceutical Products - 8, 9 and 10 October 2019 - Copenhagen Marriott Hotel

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.

Their hands-on experience will provide current industry best practice and up-to-date regulatory authority information and there will be opportunities to put the learning into practice during carefully chosen workshops. A complimentary drinks reception and course dinner will be held on the evening of Day 1.

Presenters

Mike James, Training Director, 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.

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.

Kevin Owen, Global Aseptic Processing subject matter expert at PM Group: A microbiologist by profession (Hospital and Pharmaceutical), who has 30 years of aseptic operational experience and responsible for all aseptic processing capability within multinational Pharma. He ensured all industry and regulatory expectations were met (and anticipated) across sites by embedding a systemic approach to aseptic manufacturing. He has led draft Annex I 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, lyophilisation, specials manufacturing, clinical trials, and Laboratory design. He has led major aseptic facility improvement projects without interruption to the commercial supply of products to patients. His position as Aseptic Processing subject matter expert provides great technical leadership and operational depth on aseptic fill finish projects across the global footprint of the PM group. Kevin is always Patient centric**.**

Who Should Attend

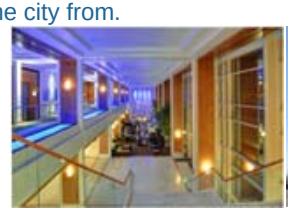
This interactive course has been designed for personnel from a range of disciplines. These include production, technical, engineering and quality assurance roles. It is aimed at those who are either new to aseptic manufacturing or at those who would like to expand their existing knowledge. On leaving 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

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 approximately 10 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.
(See Page 4 for further details on fees/bookings)

Aseptic Manufacturing of Pharmaceutical Products - Copenhagen Marriott Hotel, Denmark

Registration (08:45 to 09:00) – Delegates arrive at the meeting room and sign the attendance register.

DAY 1 (Tuesday 8 October 2019)

09:00 Opening/Welcome

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: 17:20; Drinks Reception: 19:00; Course Dinner: 20:00

Day 2 (Wednesday 9 October 2019)

Day 2 Introduction (09:00)

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 10 October 2019)

Day 3 Introduction (09:00)

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 & Answers & Course Closure

Finish: 16:40

BOOKING DETAILS: Aseptic Manufacturing of Pharmaceutical Products - 8, 9 & 10 October 2019 – Copenhagen Marriott Hotel, Denmark

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to our 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 BOOK ONLINE>> **<< 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.

<< Click here to view our Privacy Policy >>