Compliance & Validation Services

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

Understanding Pharmaceutical Sterilisation

Hotel Scandic Copenhagen, Denmark
26, 27 & 28 November 2024

- **Understanding Sterilisation:**
  - Regulations, guidelines and current industry trends (includes EU Vol. 4, Annex 1, Aug 2022)
  - What are we trying to kill and what is their resistance
  - Types of sterilisation processes
  - Comparison of wet heat and dry heat processes
  - Types of steam/heat sterilisation processes
    - Porous loads versus fluids load (includes super-heated water)
    - Sterilise in Place (SIP) Systems (includes SIP case study)
    - Dry heat processes (oven and tunnels)
  - Process Understanding
    - Overkill versus bioburden cycles
    - Steam temperature versus pressure relationship
  - Other methods, including gamma irradiation, filtration, e-beam, VHP and ethylene oxide
- **Process Control, Qualification, Operation and Maintenance:**
  - Managing loading patterns
  - Correctly reviewing/interpreting chart records (electronic and paper)
  - Maintaining sterilisation equipment and maintaining performance
  - Validation and revalidation requirements, including risk/impact assessments, equipment system qualification, process performance qualification (filtration, fluid/porous load autoclaves, dry heat processes) – includes load and chamber mapping
  - Minimising/resolving typical regulatory/company inspection/audit issues

Course Summary - Understanding Pharmaceutical Sterilisation - 26, 27 & 28 November 2024 - Hotel Scandic Copenhagen

This course provides delegates with a rounded appreciation of all aspects of sterilisation, ranging from equipment design and process understanding, through to qualification and maintenance requirements. One key learning objective is to separate the facts from the myths and legends that are sometimes associated with sterilisation processes. This will help ensure that s focus on the important science based facts when making risk based decisions when they return to their daily jobs. Other learning objectives include equipping delegates with the correct knowledge to improve compliance, reducing potential regulatory issues, improving operation effectiveness and maximising the benefits/effectiveness of validation/qualification activities. The course will be presented by industry experts who collectively have worked in all areas relating to the operation and qualification of sterilisation equipment/processes. Their hands-on experience will provide current industry best practice and up-to-date regulatory authority information.

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 drinks reception and course dinner, held on the evening of Day 1 (Tuesday 26 November 2024), are included in the overall package.

Presenters

Mike James, Training 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.

John Welbourn, Director, Compliance & Validation Services Limited: A validation professional with over 30 years experience, John has been responsible for the management and execution of validation projects for many major pharmaceutical companies. He has broad experience in the qualification of equipment, critical utilities, computerised systems, and thermal mapping to support storage conditions. John has an in-depth knowledge of many types of autoclaves, covering their design, qualification/validation, operation and maintenance. He has very recent hands-on experience in taking autoclaves through their full qualification life cycle. John has presented at conferences in the UK, Europe and the US and has authored several articles on various aspects of validation.

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.

Industry Expert: Our industry expert has many years of operating sterilisation processes within the aseptic manufacturing environment and is an accomplishes presenter.

Who Should Attend

Individuals to benefit from attending this course include anyone involved directly or indirectly in managing, operating, qualifying and maintaining sterilisation equipment and processes. The course is ideally suited to people who wish to deepen there knowledge and understanding of sterilisation processes and sterilisation equipment. It can also provide useful refresher training. Target disciplines include microbiology, production (operators, supervisors and management), quality assurance, validation, technical support and engineering. The course is also suited to people who are new to sterilisation.

On completing the course delegates will: have a sound understanding of science of sterilisation, coupled with knowledge of all key the aspects related to design, operation, qualification and maintenance/calibration of sterilisers/autoclaves and sterilisation processes; 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)***

Understanding Pharmaceutical Sterilisation – 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 26 November 2024)

09:00 CET

Introduction to Sterilisation *[Industry Expert]:*
- Why sterilise ?
- Definition of sterility
- Consequences of sterilisation failure
- Probability of detecting a failed unit
- Challenges of sterile product manufacture
- Brief history of sterilisation
- Examples of uses of sterilisation processes (where they fit in)

The Sterilisation Process *[Kevin Owen]:*
- Basic microbiology and the destruction of micro-organisms
- Sterility assurance level, kill rate and D values
- Biological indicators
- Moist and dry heat sterilisations
- Effect of moisture and heat on proteins
- Typical moist and dry heat sterilisation cycles

Regulatory Authority Inspection Issues *[Industry Expert]:*
- EU, China and US Regulatory Authority Guidelines
- Regulatory Authority sterilisation focus and expectations
- Typical inspection sterilisation requests
- Regulatory authority sterilisation related observations

Moist Heat (Steam) Sterilisation *[Mike James]:*
- Principles and advantages of steam sterilisation
- Saturated steam temperature and pressure relationship
- Autoclaves and porous loads and fluids sterilisation cycles
- Overkill and bioburden cycles
- Sterilise in place (SIP)

Dry Heat Sterilisation *[Kevin Owen]:*
- Principles and uses of dry heat sterilisation
- Advantages and disadvantages of dry heat
- Endotoxins and depyrogenation
- Tunnel and oven dry heat sterilisation and depyrogenation

Porous load Autoclaves *[John Welbourn]:*
- Typical autoclave design and operation
- Effective air removal and steam penetration
- Sterilisation and cool down
- Steam penetration and Bowie Dick testing
- Autoclave chamber and filter housing leak testing
- Air detector function test and process control test

Fluid Load Autoclaves *[Kevin Owen]:*
- Process and operation (how it differs from porous loads)
- Typical equipment components and configuration explained
- Different types of autoclaves, e.g. steam / steam + air ballasted and superheated water.
- Typical cycles and control

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

Day 2 (Wednesday 27 November 2024)

09:00 CET

Sterilisation By Other Methods *[Industry Expert]:*
- Filtration
- Ionising and non-ionising irradiation methods
- Chemical processes
- Surface sterilisation
- Selection of sterilisation method

Thermocouples and Data Loggers *[Roman Loretts, Ellab A/S (Instrument Manufacturer)]:*
- Thermocouple selection and use
- Calibration approach
- Pressure and time calibrations
- Data collection devices requirements

Sterilising Grade Vent Filters *[Industry Expert]:*
- Vent filters as a contamination control method
- Typical applications
- Vent filter requirements
- Particle removal mechanisms
- Regulatory authority guidelines
- Autoclave vent filter failure – Workshop

Cycle Lethality (Sterilisation kinetics) *[Kevin Owen]:*
- The F_0 approach to sterilisation
- Understanding D and Z values
- F_0 and Sterility Assurance Levels
- Biological indicators for the determination of F_0 values
- F_H concept for dry heat sterilisation

Routine Testing of Autoclaves *[John Welbourn]:*
- Test required and their frequency
  - e.g. Bowie Dick Test, Calibration and Maintenance, Revalidation, Air Detector Function Test, Leak Rate Test, Automated Process Control Verification

Steam Quality *[John Welbourn]:*
- Importance of steam quality for effective sterilisation
- What is superheated, saturated & wet steam?
- Dryness fraction
- Non-condensable gases
- Superheat

17:00 CET

Day 3 (Thursday 28 November 2024)

09:00 CET

Qualification of Depyrogenation Tunnels *[John Welbourn]:*
- Vial filling line and tunnel configurations
- Machine settings and configured parameters
- Typical IQ/OQ testing
- HEPA filter integrity testing and demonstration of Grade A conditions
- Thermometric testing and endotoxin spiking
- Integrated line PQ

Equipment System Qualification *[Mike James]:*
- User Requirement Specification
- Risk and impact assessments
- Identifying critical components/aspects of the system
- Aligning testing (depth and scope) with criticality/complexity
- Static and functional testing overview
- Example tests

Validation (Performance Qualification) *[John Welbourn]:*
- Validation requirements
- Approach to steriliser validation
- Thermocouple positioning and placement
- Validation frequencies and schedule of validation tests
- Basis for routine steriliser operation

Steriliser Loading Patterns, Chart Records and Process Control *[Mike James]:*
- Requirements for loading patterns
- The link between validation and loading patterns
- Routine load preparation
- Paper chart and electronic cycle records and their interpretation

Steam in Place Systems *[John Welbourn]:*
- Gravity discharge vis vacuum air removal
- Thermometric Testing – deciding where to position thermocouples and BI's
- Dealing with SIP challenges – heat exchangers / vent filters / multiple flow paths / large mass heat sinks / narrow bore tubes

SIP Case Studies *[John Welbourn]:*
- Freeze Dryer and a Large Scale Fermenter SIP case studies
- Commissioning issues concerning SIP
- Rectification of issues

17:00 CET

BOOKING DETAILS - Understanding Pharmaceutical Sterilisation - 26, 27 & 28 November 2024 - Hotel Scandic Copenhagen

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 attendee 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