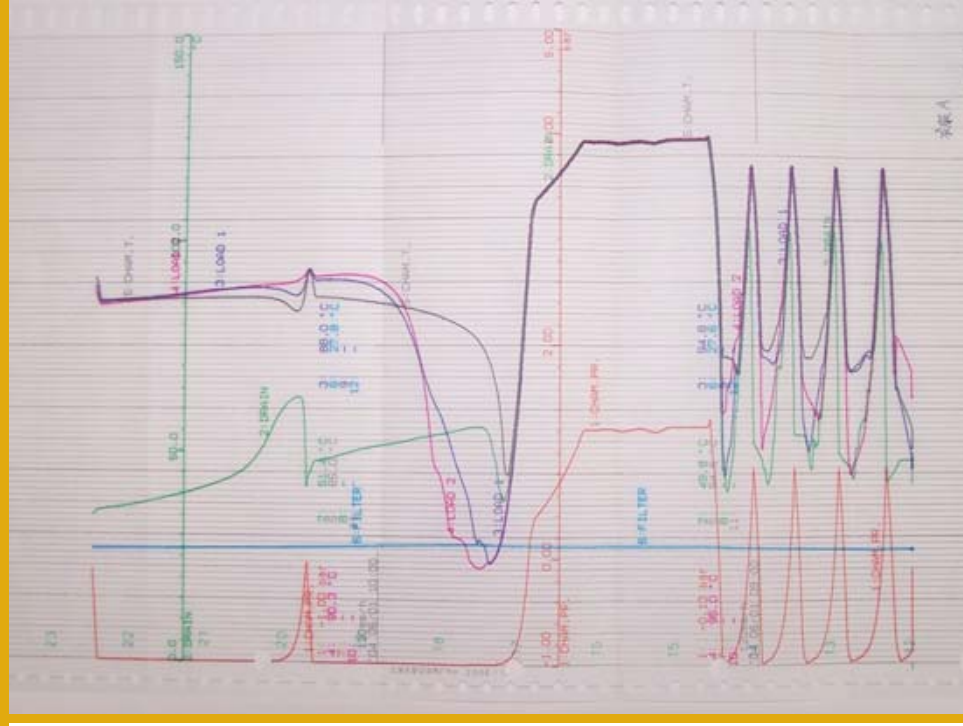
Compliance & Validation Services
Presents a 3-Day Training Course on:

Understanding Pharmaceutical Sterilisation

11, 12, 13 June 2019
Copenhagen Marriott Hotel, Denmark



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- **Understanding Sterilisation:**
  - Regulations, guidelines and current industry trends
  - 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 sterilisation processes
    - Porous loads versus fluids load
    - Sterilise in Place (SIP) Systems
  - Process Understanding
    - Overkill versus bioburden cycles
    - Steam temperature versus pressure relationship
  - Example SIP Case Studies
- **Process Control, Qualification, Operation and Maintenance:**
  - Managing loading patterns
  - Maintaining sterilisation equipment and maintaining performance
  - Correctly reviewing/interpreting chart records
  - Validation and revalidation requirements, including equipment verification and risk assessments
  - Minimising/resolving typical regulatory/company inspection/audit issues
  - Importance of having effective supporting quality systems, e.g. change management

Course Summary: Understanding Pharmaceutical Sterilisation – 11, 12 & 13 June 2019 – Copenhagen Marriott Hotel, Denmark

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 attendees 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 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 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 25 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.

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

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 leaving 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

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***

Understanding Pharmaceutical Sterilisation - Copenhagen Marriott Hotel, Denmark

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

DAY 1 (Tuesday 11 June 2019)

09:00 Opening/Welcome

Introduction to Sterilisation *[Industry Expert]:*
- Brief history of sterilisation
- Definition of sterility
- Aseptic preparations and terminal sterilisation
- Consequences of failure
- Probability of detecting a failed unit
- The Devonport Incident (consequences, investigation, root cause and conclusions – could it happen again?)

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

DAY 2 (Wednesday 12 June 2019)

Day 2 Introduction (09:00)

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

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

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

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

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

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

Finish: 17:15

DAY 3 (Thursday 13 June 2019)

Day 3 Introduction (09:00)

Steriliser Equipment Qualification/Verification *[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

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

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

Course Closure
- Final questions and answers
- Course evaluation
- Course certificates

Finish: 16:45

BOOKING DETAILS: Understanding Pharmaceutical Sterilisation - 11, 12 & 13 June 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 (**£2,394** 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 agree to our Terms and Conditions.

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