Compliance & Validation Services

Presents a 3-Day Online Training Course on:

Understanding Pharmaceutical Sterilisation

25, 26 & 27 May 2021

Live Online Training Course

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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/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 - 25, 26 & 27 May 2021 - Live Online Training Course

This course provides attendees 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 attendees 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.

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.

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

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, 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 completing the course attendees 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.

Online System & Course Fees

We use the industry leading GotoWebinar©, LogMeIn, Inc. platform for our online training courses. It's intuitive and simple to use, however we do recommend that you check your system's compatibility using the 'CHECK SYTEM COMPATIBILITY' link provided below (we use 'standard webinar'). To find out more about how our online training process works, from booking through to the end of the course, please click on the 'HOW IT WORKS' link provided below.

CHECK SYSTEM COMPATIBILITY

Course fees are £1,495.00 (GBP) per attendee.

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

HOW IT WORKS

Understanding Pharmaceutical Sterilisation - Live Online Training Course - Programme

Start Time: 08:00 London/Dublin; 09:00 Berlin/Amsterdam - Please join the course at least 5 minutes before the start.

DAY 1 (Tuesday 25 May 2021)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

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: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

DAY 2 (Wednesday 26 May 2021)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

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

Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

DAY 3 (Thursday 27 May 2021)

Start: 08:00 London/Dublin; 09:00 Berlin/Amsterdam

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

Finish: 16:00 London/Dublin; 17:00 Berlin/Amsterdam

BOOKING DETAILS: Understanding Pharmaceutical Sterilisation - 25, 26 & 27 May 2021 - Live Online Training Course

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to our web-site, find the online course you are interested in and follow the simple instructions (link included below), 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)*		
***Attendee Information:**	**Attendee Name(s):**	**Attendee 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** **£1,495 [GBP]** per attendee		NOTE: If your finance centre or attendees are based in the United Kingdom (UK), or attendees are booking as private individuals (non-company), the course fee will be subject to an additional 20% UK VAT charge (**£1,794** per attendee including UK VAT). For EU Countries where finance centres and attendees are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule. For non-EU countries and non-EU attendees, 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 Attendees
Cancellation refunds will depend on how long before the course start date the cancellation is received. The following refund structure will apply:

- More than 7 days will quality for a refund of the course fee paid after the deduction of actual expenses incurred by CVS in connection with the course that the attendee has registered for and there shall be no future liability on the part of either party.
- No refund will be given for cancellations received with less than 7 days' notice.
- Substitutions for registered attendees from the same company 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 attendees 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 attendees. 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 Attendees
If you click 'yes' to 'include my name/company' on the attendees list', when completing the online booking form, your name and company will be included on the list and distributed to all the participants.
Before you commit to booking onto a webinar, we expect you to check your system compatibility with the GoToWebinar® platform using the links provided.

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 / EEA 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.
CVS will not provide a refund for an online course, if an attendee cannot use the GoToWebinar® (by LogMeIn) system, because of local IT restrictions.

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