Compliance & Validation Services

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

Restricted Access Barrier Systems (RABS) and Isolator Technology

Hotel Scandic Copenhagen, Denmark

12, 13 and 14 March 2024

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March 2024

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Click here to visit the web page for this course

- Key regulations and guidelines, including the 2022 EU Vol 4, Annex 1
- Latest industry trends for Aseptic Manufacturing
- Management of contamination
- Risk assessments
  - General RABS / Isolators vs. cleanroom operational risk assessments and quantification of risk
- Uses for RABS and Isolator Systems
- Types of systems available and key design / operational considerations
  - E.g. positive pressure, negative pressure, open or closed, rigid walled and flexible walled
- Particle monitoring and systems available (including airborne rapid micro sampling)
- Facility and HVAC system design considerations
- Development and optimisation of cleaning and sanitisation cycles
- Equipment, facility and environmental qualification / verification
- Performance qualification of automated H_2O_2 decontamination cycles
- Routine testing and maintenance requirements
  - Leak tests, inspection, typical maintenance requirements, Requalification requirements

Course Summary - Restricted Access Barrier Systems (RABS) and Isolator Technology - 12, 13 & 14 March 2024 - Hotel Scandic Copenhagen

This course covers the design, installation, qualification and operation of isolator systems and restricted access barrier systems (RABS), as used in aseptic manufacturing. It looks at the choices of systems available and the advantages and disadvantages of using Isolators and RABS over traditional Aseptic Manufacturing. The course also covers system design (types of systems, ergonomics, air classification and air-flow requirements) and the qualification of the equipment systems involved, including facility and HVAC systems for isolators/RABS and surrounding/supporting areas.

Also included in the course, is the development, optimisation and qualification of sporicidal decontamination cycles, together with requirements for operation, maintenance, testing, inspection and monitoring of the systems and environments involved. The impact of changes to EU Annex 1 on the design and operation of RABS/isolator systems will be discussed, together with the latest developments in gloveless automated isolators.

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 12 March 2024), are included in the overall package

Presenters

Mike James, 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.

Philip Templeton, Managing Director, Aseptic Technology & Design Ltd: Phil has over 20 years of aseptic processing experience and speaks regularly on the practical application of isolator and barrier technology with particular focus on projects involving new developments and validation techniques. He's previous experience includes client-side project management for major new facility builds for aseptic processes and production operations management with Medeva, Celltech and Smith and Nephew. Phil holds a BSc (Hons) in Bacteriology and Virology from the University of Manchester.

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

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 new to Isolator / RABS technology or those who are looking to expand their knowledge in this area. On leaving this course, delegates will: have a better understanding of the types of systems and options available for Aseptic Manufacturing; appreciate the pros / cons and applicability of the different types of systems; understand key considerations for the design, qualification / verification and operation / maintenance of RABS and Isolator systems; appreciate the different requirements for facility / HVAC systems in supporting areas; be able to apply and share their new knowledge; improve their individual effectiveness and look back on a valuable 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)***

RABS and Isolator Technology - 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 12 March 2024)

Start: 09:00 CET

Introduction to Cleanrooms, Isolators and RABS *[Industry Expert]:*
- A brief history of cleanroom and cleanroom technology development
- Achieving and maintaining cleanliness levels
- How unidirectional airflow is achieved and explaining why it is so effective at controlling low particle levels
- How combinations of unidirectional and turbulent airflow are used to create/maintain cleanliness to different levels

RABS, Key Design and Operational Considerations *[Industry Expert]:*
- Introduction to RABS
- Basic Operating Principles
- Types of RABS and RABS Developments
- Gaseous Vapour Phase Decontamination
- Interventions and Transfers
- Use of localised unidirectional airflow (L-UDAF) to protect open doors interventions
- Operating Systems and RABS Selection Matrix

Isolator Design Considerations *[Phil Templeton]:*
- What do we mean by the term isolator?
- Uses and types
- Construction materials and compatibility
- Generic isolator sub-systems:
  - Air handling systems, sanitisation systems, transfer systems
  - Monitoring and control
  - Ergonomics & Automation

Facility Design Considerations for RABS and Isolators *[Industry Expert]:*
- Regulatory authority considerations and expectations
- Layout, flow and personnel entry
- L-UDAF zones and transfer karts used for material/equipment transfers
- High screen technology used to create effective Grade B / L-UDAF aerodynamic separation (in place of hanging strip curtains)
- Surfaces and finishes
- General cleanroom fittings
- Plant room
- Cleanroom garments for effective control
- Aseptic behaviours and practices

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

Day 2 (Wednesday 13 March 2024)

Start: 09:00 CET

Risk Management of Contamination *[Industry Expert]:*
- Fundamental mechanism of contamination
- Sources of contamination (particularly humans)
- Routes of transfer and risk diagrams
- General RABS/Isolators vs. cleanroom operational risk assessments and quantification of risk
- Management/control of risk

Particle Monitoring & Classification [Mike James]:
- How optical particle counters work
- Particle counting technology (including airborne rapid micro sampler)
- Isokinetic sampling and avoiding under/over-sampling of larger particles
- Classification v monitoring of clean zones
- Classification worked examples
- US FDA CGMP & EU GMP Annex 1 compliance

High Efficiency Air Filtration *[Industry Expert]*:
- The origins of the HEPA filter
- HEPA filters as a key contamination control method
- HEPA filter installation leak testing
- Regulatory guidelines for cleanroom HEPA filters
- HEPA filter in-situ leak testing failure - Workshop

Operational Considerations for Isolators *[Phil Templeton]:*
- Regulatory perspectives
- Product related considerations
  - Environmental requirements
  - What components will need aseptic manipulation
  - Hazardous properties
- Manufacturing related considerations
  - What activities will take place inside/outside of the isolator?
  - Transfer mechanisms

Cleanrooms, RABS or Isolators *[Industry Expert]:*
- Aseptic Integrity Spectrum
- Assessment of microbial risk to patient from aseptically prepared products
- Microbial risk during manufacture
- Microbial risk during shelf life
- Operational considerations for RABS or Isolators

Finish: 17:00

Day 3 (Thursday 14 March 2024)

Start: 09:00 CET

Automated H_2O_2 Decontamination Cycles *[Phil Templeton]:*
- Why use automated H_2O_2 decontamination cycles?
- Cycle deliverables
- Properties of H_2O_2 vapour
- Considerations for cycle design
- Structure of cycle development studies
- Room decontamination cycles

System/Facility Qualification Overview *[Mike James]:*
- System Impact Classification and System Risk Assessment (what systems/aspects require qualification and what do not)
- Overview of Quality Risk Assessments and how these can be used to determine level, depth and scope of testing required
- Typical tests required to qualify systems/facilities

PQ of H_2O_2 Decontamination Cycles *[Phil Templeton]:*
- Interpretation of BI data
- BI variability
- How should BIs be used
- PQ strategy
- BIs as sensors

Environmental Monitoring *[Mike James}:*
- Typical routine non-viable and viable particle monitoring requirements for RABS and Isolators (including regulatory requirements)
- Periodic Monitoring (Re-Qualification) requirements
- Key differences between surrounding environment testing for RABS and Isolators
- Equipment used for sampling/counting micro-organisms and potential pitfalls of different types of equipment/methods.
- Establishing alert and action limits for Total Particles and Microorganisms
- Dealing with non-conformance.

Routine Testing and Maintenance of Isolators *[Phil Templeton]:*
- Leak tests
- Inspection
- Typical maintenance requirements
- Requalification requirements

Course Finish: 17:00

BOOKING DETAILS - RABS and Isolator Technology - 12, 13 & 14 March 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 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.

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