



Compliance & Validation Services

Presents a 3-Day Training Course on:

Restricted Access Barrier Systems (RABS) and Isolator Technology

15, 16 & 17 October 2019

Copen Hagen 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		

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- Key regulations, guidelines
- 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 H₂O₂ 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 - 15, 16 & 17 October 2019, Copenhagen Marriott Hotel, Copenhagen

This course covers the A-Z of Isolator Technology and Restricted Access Barrier Systems (RABS) used in Aseptic Manufacturing. It looks at the choices of systems available and the advantages and disadvantages of using Isolators or RABS over traditional Aseptic Manufacturing, together with an overview of all key applicable guidelines, standards and regulations. The course also covers design (types of systems, ergonomics, air classification and air-flow requirements) and the qualification/verification of the equipment systems involved, including facility and HVAC systems for Isolators/RABS and surrounding/supporting areas. Also included is the development, optimisation and qualification of sanitisation cycles, together with requirements for operation, maintenance, testing, inspection and monitoring of the systems and environments involved. The course is heavily orientated towards basing decisions for design, qualification/verification, operation and routine monitoring/testing/inspection on risk to product quality and ultimately risk to patient.

Presenters



Mike James, 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.



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.

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 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)



RABS and Isolator Technology - Copenhagen Marriott Hotel - Course Programme:

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

DAY 1 (Tuesday 15 October 2019)	Day 2 (Wednesday 16 October 2019)	Day 3 (Thursday 17 October 2019)
09:00 Opening/Welcome [Mike James]	Day 2 Introduction (09:00)	Day 3 Introduction (09:00)
Introduction to Cleanrooms, Isolators and RABS [Industry Expert]: <ul style="list-style-type: none"> History of cleanrooms Classification of controlled environments Achieving and maintaining cleanliness levels Cleanrooms, isolators and RABS for the pharmaceutical industry 	Facility Design Considerations for RABS and Isolators [Industry Expert]: <ul style="list-style-type: none"> Regulatory authority considerations and expectations Layout, flow and personnel entry Surfaces and finishes General cleanroom fittings Plant room Cleanroom garments for effective control Aseptic behaviours and practices 	Automated H₂O₂ Decontamination Cycles [Phil Templeton]: <ul style="list-style-type: none"> Why use automated H₂O₂ decontamination cycles? Cycle deliverables Properties of H₂O₂ vapour Considerations for cycle design Structure of cycle development studies Room decontamination cycles
RABS, Key Design and Operational Considerations [Industry Expert]: <ul style="list-style-type: none"> Introduction to RABS Basic Operating Principles Types of RABS and RABS Developments Gaseous Vapour Phase Decontamination Interventions and Transfers Operating Systems RABS Selection Matrix 	Terminal HEPA Filters [Industry Expert]: <ul style="list-style-type: none"> 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 - Group Exercise 	System Qualification Overview [Mike James]: <ul style="list-style-type: none"> System and component level impact summary (what systems require qualification and what so not) What will adoption of ASTM E2500-07 mean? Overview of Quality Risk Assessments and how this can be used to determine level, depth and scope of testing required Typical tests required to qualify systems
Isolator Design Considerations [Phil Templeton]: <ul style="list-style-type: none"> What do we mean by the term isolator? Uses and types Construction materials and compatibility Generic isolator sub-systems: <ul style="list-style-type: none"> Air handling systems, sanitisation systems, transfer systems Monitoring and control Ergonomics & Automation 	Cleanrooms, RABS or Isolators [Industry Expert]: <ul style="list-style-type: none"> 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 	PQ of H₂O₂ Decontamination Cycles [Phil Templeton]: <ul style="list-style-type: none"> Interpretation of BI data BI variability How should BIs be used PQ strategy BIs as sensors
Risk Management of Contamination [Industry Expert]: <ul style="list-style-type: none"> 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 	Operational Considerations for Isolators [Phil Templeton]: <ul style="list-style-type: none"> Regulatory perspectives Product related considerations <ul style="list-style-type: none"> Environmental requirements What components will need aseptic manipulation Hazardous properties Manufacturing related considerations <ul style="list-style-type: none"> What activities will take place inside/outside of the isolator? Transfer mechanisms 	Routine Testing and Maintenance of Isolators [Phil Templeton]: <ul style="list-style-type: none"> Leak tests Inspection Typical maintenance requirements Requalification requirements
Particle Monitoring [Mike James]: <ul style="list-style-type: none"> How optical particle counters work Particle counting technology (including airborne rapid micro sampler) Classification v monitoring of clean zones Classification worked examples FDA CGMP & EU GMP Annex 1 compliance. 	HVAC System Requirements For Surrounding Areas [Mike James]: <ul style="list-style-type: none"> Differences between HVAC requirements for RABS & Isolators Typical HVAC system requirements and Considerations for areas supporting RABS/Isolators Impact of Isolators on the surrounding environment Typical HVAC system control requirements 	Environmental Monitoring [Mike James]: <ul style="list-style-type: none"> Typical routine non-viable and viable particle monitoring requirements for RABS and Isolators Periodic Monitoring requirements Key differences between surrounding environment testing for RABS and Isolators

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.

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Tel: +44 (0)1625 500833 or +44 (0)1270 760882

E-mail: info@candvs.com

Alternative Booking Form (* indicates required fields)

Booking Terms & Conditions

*Booking Contact Name:		
*Booking Contact E-mail Address:		
*Booking Contact Telephone Number:		
*Company Name & Address:		
*Billing Address <i>(Only complete if different to Company Address)</i>		
*Delegate Information:	Number of delegates:	Delegate Name(s):
Delegate E-mail Address(es): <i>(if different to booking contact)</i>		
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 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.

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Please note: By completing and submitting the booking form (opposite), you are agreeing to our Terms and Conditions.

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