



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

Cleaning & Cleaning Validation

6, 7 & 8 March 2019
Copenhagen Marriott Hotel, Denmark



Photograph courtesy of Alfa Laval
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The Cleaning Process:

- Types of cleaning action involved in cleaning processes
- Chemistry of the cleaning process, optimising cleaning processes and the use/evaluation of cleaning agents
- Design of equipment for ease of cleaning (includes hygienic engineering principles):
 - Clean-in-place (CIP) systems
 - Clean-out-of-place (COP) systems
 - Spray device technology – types available and a comparison of performance
- Cleaning of biopharmaceutical plant – real life case studies
- Resolving cleaning issues that may arise in practice

Cleaning Validation:

- Key international regulations and guidance and their impact on what we do
- Establishing limits for maximum allowable levels of carryover (large molecule [biopharmaceutical residues], small molecule compounds and cleaning agents)
 - Incorporating Annex 15, EMA Guidance (including the latest EMA Questions and Answers) on Health Based Exposure Limits (HBELs)
- Using a matrix approach to multi-product non-dedicated plant cleaning validation
 - Saving time and effort by focusing on the worst case materials/residues
- Review and comparison of methods used for sampling and detecting/quantifying residues
- Application, method development and qualification/validation of Total Organic Carbon (TOC) methods (sampling and analysis)
- Spray device coverage verification – demonstrating all internal surfaces can be ‘wetted’
- Risk assessments and determining the level of testing required from the level of risk to product quality/patient safety
- Key validation considerations and validation documentation requirements
- Alternative technology – avoiding the need for cleaning validation, e.g. disposables

Course Summary: Cleaning & Cleaning Validation: 6, 7 and 8 March 2019 – Copenhagen Marriott Hotel, Denmark

This course provides delegates with an in-depth appreciation of key design features of pharmaceutical and biopharmaceutical manufacturing equipment/systems to enable 'easy', effective cleaning (usually a far greater challenge than the validation). It also provides a detailed understanding of the approach to validating cleaning processes. This includes the fundamental understanding of material carryover (contamination) mechanisms and how this is pivotal to setting appropriate limits for acceptable levels of carryover (maximum allowable carryover [MACO] limits) from one product to another. The course also covers areas such as applicable regulatory rules & guidelines; demonstration of spray device coverage; methods for calculating MACO for large/small molecule compounds & cleaning agents; methods for sampling/detecting/quantifying residues (key considerations); inclusion of clean/dirty hold times in the validation study; the use of a matrix approach to multi-product non-dedicated equipment; cleaning process monitoring/review and maintaining the validated state. To help consolidate your learning, presentations will be supplemented by case studies and workshops. Day-time meals and refreshments together with a course dinner, held on the evening of Day 1, 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, Consultancy 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, utilities and computerised systems, and thermal mapping to support storage conditions. He has presented at conferences in the UK, Europe and the US and has authored several articles on various aspects of validation. John has contributed to The University of Manchester's, Pharmaceutical Engineering Advanced Training (PEAT) Course and Dublin Institute of Technology's (DIT) MSc. course in Pharmaceutical Process Validation.



Jamie Thompson, Independent Consultant & Validation Specialist:

Jamie is currently in a laboratory equipment validation role, where he is validating an extensive range of laboratory analytical/test equipment. Up to recently he was a Specialist at Sievers TOC analysers (part of GE) and the use of TOC analysis for Ultra-Pure Water Systems and Cleaning Validation. Previous to this, Jamie spent over 10 years working in an analytical chemistry role for major pharmaceutical manufacturers (GSK and Pfizer). These roles involved raw material/finished product testing relating to pharmaceutical and bio-pharmaceutical manufacturing and specifically, chemistry testing of high purity water systems and cleaning validation samples. Other areas of Jamie's experience include working with site-wide systems such as SAP, Trackwise, laboratory information systems (LIMS), failure investigations and change control. Jamie has a Masters in Chemistry.



Peter Whyment, Independent Consultant:

Peter has worked in the Biopharmaceutical Manufacturing Industry for over 30 years and has a wealth of knowledge/expertise in the area of process validation. During his time in industry he has worked in Quality Control Laboratories, Analytical Development and as a senior scientist in a Manufacturing, Science & Technology function, Peter has overseen the successful technical transfer or commercial manufacturing of several biotechnology processes, including Insulin and growth hormone products.

Who Should Attend

This course provides essential knowledge/learning for anyone involved in any aspect of biopharmaceutical and pharmaceutical equipment cleaning and validation. Target disciplines include engineering (including equipment designers), production (management, supervisors and process operators), technical support, validation, quality assurance and quality control.

On leaving this course delegates will: have a better understanding of the applicable regulatory rules and guidance and other pertinent international standards/guides; have a clear understanding of the fundamental principles and current industry practice related to cleaning and cleaning validation; have a sound understanding of the equipment design principles for ease of cleaning; be able to calculate limits and develop a supporting rationale for maximum allowable carryover of a wide range of residues; have many practical 'real-life' examples of how cleaning and cleaning validation is actually carried out in industry; 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



DAY 1 (Wednesday 6 March 2019)	Day 2 (Thursday 7 March 2019)	Day 3 (Friday 8 March 2019)
<p>09:00 Opening/Welcome <i>[Mike James]</i></p>	<p>Day 2 Introduction (09:00)</p>	<p>Day 3 Introduction (09:00)</p>
<p>Introduction to Cleaning and Cleaning Validation <i>[Mike James]:</i></p> <ul style="list-style-type: none"> • Reasons for cleaning • Types of cleaning action and the chemistry involved • Optimising cleaning processes, including the use/optimisation of cleaning agents • Importance of assessing all cross-contamination risks • Key terminology and definitions involved • Importance of effective cleaning processes and procedures • Overview of key Regulations & Guidance 	<p>Overview of Methods Used For Sampling and Detecting Residues <i>[Mike James]:</i></p> <ul style="list-style-type: none"> • Visual inspection (including its use with other methods) • Swabbing and rinse water sampling (includes combination use) • Direct surface analysis, e.g. Fourier Transform Near Infrared Laboratory based determination methods • On location testing options (at line) • In-line methods (within process systems) <p>Demonstrating Spray Device Coverage <i>[John Welbourn]:</i></p> <ul style="list-style-type: none"> • Why, when and where is it carried out • Safety issues associated with the testing • Testing materials and equipment required • Example testing procedures used • Real life examples of problems that can be uncovered • How can time and costs be reduced? <ul style="list-style-type: none"> • e.g. Bracketing – When can this be used? • e.g. Perform test prior to installation 	<p>Detecting/Quantifying Protein Residues and Establishing Limits for Biopharmaceutical Residues, Bioburden and Endotoxin Levels <i>[Peter Whyment]:</i></p> <ul style="list-style-type: none"> • Objective of a cleaning regime • Types of residues remaining after cleaning and the types of test methods used • Specific and non-specific methods and their advantages and disadvantages • Methods of choice – Past and present • Recommendations for the swab type to use • Analytical methodology and validation • Most commonly used methods for protein residues (BCA versus TOC) • Visibly clean inspection and factors affecting it • Setting the limits (Including Bioburden and endotoxin levels)
<p>Equipment Design/Construction For Ease of Cleaning <i>[John Welbourn]:</i></p> <ul style="list-style-type: none"> • Clean in place (CIP) systems – Advantages/disadvantages of different types of systems • Issues and controls required around manual cleaning • General design features/considerations to enable easy, efficient and effective cleaning • Reducing cleaning effort by combining equipment functionality • Containment technology • Clean out of place (COP) 	<p>Establishing Maximum Allowable Carryover (MACO) for Pharmaceutical Products, Active Pharmaceutical Ingredients, Chemical Intermediates, Clinical Material and Cleaning Agents <i>[Mike James]:</i></p> <ul style="list-style-type: none"> • Material carryover mechanisms and the importance of making the correct assumptions (fundamental to limit calculations) • Current industry standards and guidelines used to calculate limits <ul style="list-style-type: none"> • Using the Annex 15, EMA Guidance on Health Based Exposure Limits (HBELs) and EMA Q & As on HBELs as a guide for establishing MACO • Use of LD50s (or not) and NOEL/NOAEL values • Conversion of MACO to swab area limits • PDA and ISPE guidance also covered • Worked examples for calculating MACO 	<p>Biopharmaceutical Plant Cleaning (Real Life Example) <i>[Peter Whyment]:</i></p> <ul style="list-style-type: none"> • Cleaning challenges • Equipment design for ease of cleaning • Issues and problem resolution • Overview of qualification work involved • Alternative technology (Disposables) – Avoiding cleaning validation <p>Key Cleaning Validation Considerations <i>[Mike James]:</i></p> <ul style="list-style-type: none"> • Summary of areas covered over previous presentations • Risk assessments – using risk assessments to target the level and depth of testing required • Documentation requirements (plans, protocols and reports) • Effectively managing deviations that may arise • Importance of ensuring that CV is a confirmation exercise and not part of development
<p>The Use of Total Organic Carbon (TOC) Analysis in Cleaning Validation Studies <i>[Jamie Thompson]:</i></p> <ul style="list-style-type: none"> • Introduction to TOC • Specificity/worst case approach • Quantifying residues • Sampling (swab and rinse samples) • Method development and validation (includes examples) • Use of TOC on CIP final rinse waters 	<p>Managing Rouging Issues <i>[John Welbourn]:</i></p> <ul style="list-style-type: none"> • What is rouge? • Consequences of detecting its presence in our equipment. • How does it form and where does it come from? • How do we detect it? • How can we minimize its formation? • How can we remove it? <p>Matrix Approach to Cleaning Validation for Multi-Product Non-Dedicated Plant <i>[Mike James]:</i></p> <ul style="list-style-type: none"> • Selection of marker compounds using attributes such as toxicity, solubility and potency • Gathering of data and formulating matrices • Advantages and Disadvantages of using a matrix approach • Incorporation of clean and dirty hold times and what this entails • Worked example 	<p>Maintaining the Validated State <i>[Mike James]:</i></p> <ul style="list-style-type: none"> • Change Management • Typical changes that impact on cleaning and cleaning validation • Routine cleaning effectiveness monitoring • Periodic cleaning validation monitoring (typical frequencies for different types of cleaning processes) • Effective cleaning validation review and when to revalidate • Ongoing operational considerations – handling incidents <p>Wrap-up <i>[All]</i></p> <ul style="list-style-type: none"> • Final questions and answers • Course evaluation (feed back for CVS) • Course Certificates (handed out midday)

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to the CVS web-site, find the course you are interested in and follow the simple instructions (link included below – takes you directly to the specific course page).
- 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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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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