Cleaning Validation

Annual Summit

ONLINE | OCTOBER 1ST- 2ND, 2024 CET

WORKSHOP:

Fred Ohsiek, USA
Principal Cleaning Process Consultant
Validation Resolution

MEDIA PARTNER

rapid microbiology
FOCUSED ON MICROBIOLOGY

Key Speakers:

Brook Meadows, USA
Senior Technical Service Associate
STERIS Corporation

Brian Bosso, USA
Technical Service Manager
STERIS Corporation

William A. Hawkins, UK
Senior Managing Toxicologist
SafeBridge Europe, Ltd.

Mariann Neverovitch, USA
Sr. Manager Logistics Operations
Bristol Myers Squibb

Liz Dallison, UK
Principal Scientist
Cleaning Validation lead
Pfizer, (Retired)

Ram Kouda, USA
Scientific Associate Director
Amgen

Jenna Carlson, USA
President & Quality Consultant
Mindful Quality

Dr. Ute Reichert, DE
CEO
Biotechnology & Pharma Consulting GmbH

Rui Almeida, PT
Director Consultancy Services
ValGenesis

Witold Woroniecki, USA
Senior Managing Consultant, Analytical Services
SafeBridge Consultants

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October 1 - 2, 2024

CONFERENCE OVERVIEW

Drug products and active pharmaceutical ingredients (APIs) may be contaminated by other drug products or APIs, raw materials, intermediates, cleaning aids, microorganisms, particles and other materials. Contamination causes costly raw materials to be scrapped, triggers regulatory actions and, most importantly, endangers the safety of patients.

In order to avoid contamination of the product, robust cleaning procedures must be performed. Our online meeting facilitates peers' reflection and discussion on approaches to establishing and revising CV programs to meet regulatory requirements, verifying CV protocols and preventing ineffective or incorrect approaches to cleaning validation programs, risk based cleaning validation, selecting the right equipment/cleaning procedure combinations, testing for API residues and calculating residue limits, considerations on combining cleaning and sanitization, finding and developing practical analytical methods and sampling procedures.

Be a part of our webinar sessions to build practical and compliant cleaning validation program and ensure that the quality of your next product is not affected by contamination.

WHO IS IT FOR?

CxO, VPs, Directors, Heads, Managers of

- Cleaning Validation/ Containment
- Bioprocessing/ Bioproduction
- Aseptic Processing/ Sterility Assurance
- Manufacturing Science & Technology/ Good
- Manufacturing Practice (GMP)
- Cleaning Products/ Detergents
- Risk Management/ Quality Assurance/ Quality Control
- Analytical Development/ Analytical Methods
- Regulatory Affairs/ CMC

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Uventia Global s.r.o. is a modern conference and business information company. To help businesses advance, we carry out in-depth research and establish connections with risk-takers and deal-makers throughout Europe & US and emerging markets. With cutting-edge strategies, products, procedures, and technology, our conferences, events, and training programs are created for senior decision-makers operating at the top of their respective sectors.

We believe that delivering timely topics and facilitating person-to-person interaction make a sustainable change.

WE WILL TALK ABOUT

- towards adequate cleaning procedure: assessing cleaning processes and validation efforts
- properly detailing and documenting cleaning process steps, conditions and parameters
- common pitfalls and mistakes in implementing cleaning validation planning strategies
- cleaning process design, parameters and quality attributes, equipment considerations
- GMP and regulatory expectations, cleaning process LCM from development to validation
- developing analytical methods and sampling procedures, establishing acceptable limits
- toxicological concerns and the safety assessment of contaminants and residuals
- risk-based approach to CV to reduce validation workload while maintaining compliance

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12:30 - 12:40 Registration

12:40 - 12:50 Opening Address from the Chairman

CRITICAL STEPS IN CLEANING VALIDATION

12:50 - 13:20

Rui Almeida, PT
Director Consultancy Services
ValGenesis

VALGENESIS

Implement a risk and data-driven approach to achieve right first time Cleaning Validation

- Apply a lifecycle approach to cleaning validation, from process design (Phase I) to process qualification (Phase II) and continued process verification – CPV (Phase III).
- A methodology applied for each phase is presented with examples of what elements should be considered when building a CV strategy.
- Present a workflow for the creation of a risk-based cleaning CPV plan with key performance metrics to ensure process consistency and where process insights are used for continuous improvement throughout process life cycle.
- Benefits of going digital in end-to-end cleaning validation life-cycle management.

13:20 - 13:30 Short Break

13:30 - 14:00

William A. Hawkins, UK
Senior Managing Toxicologist
SafeBridge Europe, Ltd.

Trinity Consultants

Permitted daily exposure (PDE) for Cleaning Validation

- What is a Permitted Daily Exposure (PDE).
- Calculation and Implementation.
- Regulatory Implications.

14:00 - 14:30 Break

WORKSHOP

14:30 - 15:15

Fred Ohsiek, USA
Principal Cleaning Process Consultant
Validation Resolution

VTI LIFE SCIENCES

Product bracketing and equipment grouping during Cleaning Validation

- Bracketing and grouping regulatory expectations.
- Common mistakes and misconceptions when bracketing and grouping.
- Science and risk-based approaches when grouping.
- Equipment grouping case study.

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WORKSHOP

15:15 - 15:20 Short Break

15:20 - 16:05

CIP cleaning process optimization and sustainability

- CIP cleaning recipe.
- Elements of an optimized cleaning process.
- How to efficiently optimize a CIP cleaning process.
- Hidden benefits of optimizing legacy cleaning process.
- Explore cleaning development sampling strategy.

16:05 - 16:10 Short Break

16:10 - 16:55

Maintaining the Cleaning Validation program

- Efficient restart after a shut-down and cleaning after maintenance.
- When re-validation makes sense .
- Explore process for creating an efficient and robust science risk-based CPV program.
- Routine monitoring case study.
- Protocol reporting and validation compliance.

16:55 - 17:10 Break

17:10 - 17:40

Jenna Carlson, USA
President & Quality Consultant
Mindful Quality

MINDFULQUALITY

Regulatory and GMP aspects for Cleaning Validation

- Regulatory emerging trends for industry.
- EMA and FDA guidelines.
- PIC/S, ICH guidelines.
- Current Health Agency observations & warning letters related to cleaning.

17:40 - 17:50 Short Break

17:50 - 18:20

Ram Kouda, USA
Scientific Associate Director
Amgen

AMGEN

Biopharmaceutical molecule degradation during the Cleaning Process

- Bench Scale studies to demonstrate the Biological protein degradation during the cleaning process.
- Application of cleaning induced fragments in MAC(maximum allowable carryover) and acceptance limit calculation.
- Application of sensitive Analytical method to demonstrate greater than 99% degradation during cleaning process.

18:20 - 18:30 Chairman's closing remarks and end of day one

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12:50 - 13:00 Registration

13:00 - 13:10 Opening Address from the Chairman

SAMPLING AND ANALYTICAL REQUIREMENTS

13:10 - 13:40

Liz Dallison, UK
Principal Scientist Cleaning Validation lead
Pfizer, (Retired)

Sampling methods and sampling recoveries

- Product Contact vs non product contact surfaces.
- Selection of sampling points.
- Swabs VS Rinse.
- Translating MACO to sample limits.
- Recovery studies.

13:40 - 13:50 Short Break

13:50 - 14:20

William A. Hawkins, UK
Senior Managing Toxicologist
SafeBridge Europe, Ltd.

Establishing Acceptance Limits

- Acceptance criteria based on toxicity data (NOAEL, ADE/PDE, TTC).
- MACO levels for worst-case product.
- Challenges of establishing residual limits.
- Identifying the hazards with contamination data.

14:20 - 14:30 Short Break

14:30 - 15:00

Brian Bosso, USA
Technical Service Manager
STERIS Corporation

Selection of Cleaning Agents

- Cleaning agents based on cleanability studies, cleaning method, supplier qualification.
- Rinsability of cleaning agents.
- The safety of cleaning agent.
- Limit calculations for cleaning agent residues.

15:00 - 15:10 Short Break

15:10 - 15:40

Brook Meadows, USA
Senior Technical Service Associate
STERIS Corporation

Visual inspection for Cleaning Validation

- Benefits and limitations of visual inspection (VI).
- Establishing visual residue limits (VRL).
- Qualification of personnel and visual inspection training.
- Visual inspection, surface sampling and rinse sampling.
- Risk assessment and management as justification of VI.

15:40 - 15:50 Short Break

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15:50 - 16:20

Mariann Neverovitch, USA
Sr. Manager Logistics Operations
Bristol Myers Squibb

Bristol Myers Squibb

Lifecycle management of analytical methods for Cleaning Verification support

- Equipment Cleaning is a critical GMP element of the Manufacturing Process. It ensures quality and safety of future batch. Cleaning Validation/verification is a measurement of the effectiveness of the cleaning process.
- In this presentation we will go over advantages and challenges of specific and non-specific analytical methods based on risk assessment of the residual product.
- Case studies, training and qualification programs will also be discussed.

16:20 - 16:30 Short Break

16:30 - 17:00

Dr. Ute Reichert, DE
CEO
Biotechnology & Pharma Consulting GmbH

Bio - Technology & Pharma Consulting

Microbiological aspects of Cleaning Validation

- Cleaning, disinfection, sterility.
- Risk management.
- Microbiological testing and acceptance criteria.
- Microbiology flora.
- Microbial Aspects on cleaning Validation and CCS.

17:00 - 17:10 Short Break

17:10 - 17:40

Witold Woroniecki, USA
Senior Managing Consultant, Analytical Services
SafeBridge Consultants

Trinity Consultants SafeBridge

Developing suitable occupational health analytical methods

- Air.
- Surface.
- Cleaning Procedures.

17:40 - 17:50 Chairman's closing remarks and end of day two

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Speakers Biographies

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Fred Ohsiek
Principal Cleaning Process Consultant
Validation Resolution

Fred Ohsiek, who earned his BS in Chemistry from University of South Florida, resides in the NC RDU area. He has 24 plus years of validation experience as a FTE and consultant, with emphasis in cleaning validation. Prior to transitioning to pharma his experience includes 7 years in R&D while at the USDA.
He has been fortunate to work for 7 major pharmaceuticals (Catalent, AstraZeneca, Boehringer Ingelheim, Teva, Astellas, Bayer, and Novo Nordisk) where he was considered the cleaning validation SME in most of his roles.
Working with various routes of administration (OSD, parenteral, softgels) in green and brown field small and large molecule manufacturing projects has provided Fred a very broad cache of experience.
Fred also obtained "cleaning chemistry" experience while working as a Sr Global Technical Manager at Ecolab (Life Science division).
In his current role as Principal Cleaning Process Consultant, he supports industry by creating tailored justifications, reducing the validation footprint via risk assessments, creating startup CV programs, remediating legacy processes, and increasing manufacturing capability.
He was one of the authors of the ISPE Cleaning Validation Lifecycle – Application, Methods, and Controls guidance, and he regularly presents at conferences, nationally and globally.

Liz Dallison
Principal Scientist Cleaning Validation lead
Pfizer, (Retired)

Liz Dallison has 20 plus years of experience in Cleaning Validation in the Pharmaceutical industry. She holds a BSc in Analytical Sciences from the University of Greenwich. Her expertise in cleaning validation was gained at Pfizers investigational medicinal products facility at Sandwich. Liz has a breadth of knowledge on the subject, including equipment grouping strategy, limit setting, sampling, method validation, risk assessments and documentation of cleaning studies.
Liz has led a team providing validated methods for residue testing following both solid and liquid dosage product manufacturing. She is also experienced in training colleagues in all aspects of the cleaning validation program.
Liz was one of the contributors to the ISPE Cleaning Validation Lifecycle – Application, Methods and Controls guidance.

Rui Almeida
Director Consultancy Services
ValGenesis

Rui Almeida leads ValGenesis Product Lifecycle Management consultancy group, offering a range of services where science and engineering are coupled in areas such as process lifecycle management, quality risk management, and CMC strategy. Rui has a licentiate degree in biological engineering and a master's degree in engineering management and nearly two decades of pharmaceutical industry experience, holding senior positions in technical services, quality assurance of IMP / commercial products, and project management in small and large pharmaceutical companies. Before joining ValGenesis, he served as PMO group leader in the services business segment of a CDMO.

Mariann Neverovitch
Sr. Manager Logistics Operations
Bristol Myers Squibb

Mariann Neverovitch, MS Pharmacy; Research Scientist at Bristol-Myers Squibb. Cleaning Validation Subject Matter Expert with 15+ years of experience in cleaning verification method development and support. Leading cleaning verification program in Support of Clinical Supply Operations for the ten years. Presented a number of papers on Cleaning Validation Lifecycle management and co-authored number of papers along with the international team of industry experts on Cleaning Validation in the 21st Century.
Co-Author of ASTM Standard Guide for Science-Based and Risk-Based Cleaning Process Development and Validation (E3106-17), Standard Guide for Derivation of Health-Based Exposure Limits (HBELs) (E3219-20),and Standard Practice of Visual Inspection of Pharmaceutical Manufacturing Equipment and Medical Devices for residues (E3263-20).
Member of the task force team for PDA TR 29.
Member of Eastern Analytical Symposium Governing Board
Member of USP Expert Committee

Brook Meadows
Senior Technical Service Associate
STERIS Corporation

Brook Meadows is a Senior Technical Services Associate for the Life Sciences Division of STERIS Corporation. She has over 20 years' experience developing, validating, and authoring analytical methods (HPLC, UHPLC, TOC, UV-VIS, SDS-PAGE) to support cleaning validations. She has generated methods for swab recovery and rinse water analysis in addition to studies on visual residue limits (VRL), rinsability studies, and substrate compatibility.
Brook acts as a consultant and resource to pharmaceutical and biopharma industries around the globe. She assists with analytical method validation, troubleshooting, and data generation. Before STERIS, Brook performed quality control testing for the release of pharmaceuticals. She earned a B.S. in Chemistry with Magna Cum Laude from the University of Missouri, Springfield.

William A. Hawkins
Senior Managing Toxicologist
SafeBridge Europe, Ltd.

William A. Hawkins is a Managing Toxicologist for SafeBridge Regulatory and Life Sciences Group. He has spent over 21-years working in toxicology, with experience in the pharmaceutical industry, as a consumer safety toxicologist in the fast moving consumer goods industry and as a study director at a Contract Research Organization (CRO). Additional experience in REACH, GHS and SDSs. He has practiced as an Occupational Toxicologist within the pharmaceutical industry for the last 11-years, specializing in worker safety hazard assessments and patient safety, Quality cleaning validation hazard assessments.

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Brian Bosso
Technical Service Manager
STERIS Corporation

Brian Bosso is a Technical Services Manager for STERIS Life Sciences. He has responsibility for providing global technical support for pharmaceutical detergents and critical environment products and their application and validation. Brian has over 13 years of experience in the pharmaceutical and biopharmaceutical industries having previously worked at Sandoz, Aldevron, and as an onsite consultant on projects in North America, Europe and Asia. He has held supervisory and management positions with responsibilities in areas including developing and implementing cleaning validation process lifecycle, process design, analytical method development, GMP quality and regulatory remediation. He earned a Bachelor of Science degree in chemistry from the Colorado School of Mines.

Dr. Ute Reichert
CEO
Biotechnology & Pharma Consulting GmbH

Dr. rer. nat. Dipl. Ing Ute Reichert has more than 20-year experience in the biopharmaceutical and pharmaceutical industry, the last years as Head of an aseptic fill and finish production in Sandoz. During her work for other major companies as Lonza, Novartis or Biogen, she collected the broad experience in varying positions in project management, process development, quality and production.
As Head of quality the technical knowledge was completed by the legal framework, she was intimately involved in set up of business processes, definition of interfaces and streamlining of the processes to increase the efficiency and optimized working conditions. In Quality and in Production.

Witold Woroniecki
Senior Managing Consultant,
Analytical Services
SafeBridge Consultants

Witold Woroniecki is a Senior Managing Chemist at SafeBridge Regulatory and Life Sciences Group. He holds a Master's degree in Chemistry from Gdańsk University of Technology, Poland. He has over 20 years of experience in analytical chemistry.
At SafeBridge, he leads a team of chemists developing cutting-edge, sensitive methods to detect potent drugs at very low concentrations in the workplace. These include potent drugs such as steroids, peptide hormones, antibody-drug conjugates (ADCs), and cytotoxic compounds.
His diverse background includes roles as an Application Scientist at Sciex, where he supported instrument sales and trained others in mass spectrometry, and as a researcher at Roche, where he focused on bioanalysis, pharmacokinetics, and laboratory automation.

Jenna Carlson
President & Quality Consultant
Mindful Quality

Jenna Carlson is a Cleaning Validation Subject Matter Expert (SME) with over 24 years of experience working in corporate, site, and external manufacturing roles throughout the US, Europe, & Asia.
While working in various Validation and Quality Assurance roles, Jenna has gained extensive knowledge of global cGMP requirements and best practices. Jenna has a proven track record, including supporting Regulatory Inspections, Observations, Untitled Letters, Complete Response Letters, and Warning Letters. She has also been instrumental in developing and remediating cleaning programs throughout her career.
Jenna has co-authored PDA Technical Reports #29 and #49, Cleaning & Cleaning Validation Volume 1, and various other articles.

Ram Kouda
Scientific Associate Director
Amgen

Ram Kouda has more than 10 years of experience of leading Validation and engineering teams in Pharmaceutical/Biopharmaceutical and Medical Device industries. Ram holds PhD in Chemical Engineering.
As an Associate Scientific Director in Amgen, Ram is leading Amgen Cleaning program as an SME, his team is supporting the assessment of Amgen clinical and Commercial Biological Molecules prior to manufacturing in Multiproduct facility. He has experience of successfully defending Validation programs as SME of different regulatory agencies in Biopharmaceutical and Medical Device industry.
Ram led several scientific initiatives supporting multiproduct manufacturing in same facility, it resulted in several industry-first scientific data and multiple Manuscripts.

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	Recording of 2 days event sessions, PDF.	Recording of 1 day event sessions, PDF.	PDF presentations.

1st Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

2nd Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

3rd Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

4th Attendee

Full Name:
Job Title:
Company:
Country: Phone:
Email:

SEND

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Full Name:
Job Title:
Company:
Country: City:
Address:
Postcode: Phone:
EU VAT #:
Email:

PAYMENT METHOD

Bank Transfer: ☐ Credit Card: ☐ PayPal: ☐

Signature: «I agree to be bound by Terms and Conditions of registration»

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