PharmaED RESOURCES, Inc.

Cleaning Validation Summit 2025

January 29-30, 2025 La Jolla CA

Featuring Lessons Learned and Case Studies from Industry Experts:

Michael Moussourakis
Alconox

Fred Ohsiek
Validation Resolution

Mayank Bansal
AbbVie

Liz Brockson
Takeda

Ileana Barreto-Pettit
Parexel International

Andrew Walsh
CPCI

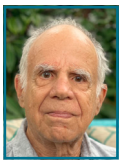
David Vincent
VTI Life Sciences

Brian Bosso
STERIS

Barbara Kanegsberg
BFK Solutions

Sharif Uddin
Rockline Industries

Jenna Carlson
Mindful Quality



Ed Kanegsberg
BFK Solutions

Can you implement the best science-, risk-, and statistics-based approaches to cleaning validation? Today's regulators are now expecting HBEL monographs and comprehensive risk assessments of your organization's cleaning validation program. Pharma Ed's Cleaning Validation Summit brings together leading industry experts to illuminate best practices and help you meet regulatory requirements.

With Comprehensive Coverage On:

- Meeting Regulatory Standards in the Global Cleaning Validation Program
- Insights into Cleaning Deficiencies from FDA GMP Inspections
- Automation of Cleaning Process Development
- Leading Innovations in Cleaning Validation
- Case Study on the Global Implementation of a Risk-Based Contamination Control Strategy
- Case Study: A Risk-Based Approach to Material Transfer Validation
- Touching Base on Annex 1, Disinfection, Contamination Control, and Environmental Monitoring
- Introduction and Overview of ASTM Cleaning Standards
- Quantitative Measurement of Risk in the Cleaning of Pharmaceuticals & Medical Devices
- A Lean Approach to Analytical Methods to Support Cleaning Validation
- Creeping Residue on Medical Devices and Pharmaceutical Contact Surfaces—Managing the Unknown
- How is that Legacy CV Program Doing?
- Hygienic Design Excellence for Enhanced Cleaning Validation
- Maintaining Your CV Program Across Your Processes
- And More!

With Representation From:

STERIS Life Sciences · CPCI · abbvie · Takeda · PAREXEL · ALCONOX CRITICAL CLEANING EXPERTS

BFK Solutions LLC Critical Cleaning Consulting · Tunnell STRONGER PERFORMANCE AHEAD · MINDFULQUALITY · VTI LIFE SCIENCES · rockline people who make it right

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STERIS Life Sciences

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Drug Development & Delivery

Wednesday, January 29, 2025

7:45 *Registration Sign-in & Complimentary Breakfast*

8:40 *Chairperson Michael Moussourakis' Welcome & Opening Remarks*

Technology Spotlight—Automation & AI

8:45 **Leading Innovations in Cleaning Validation**

Mayank Bansal, Director, Product Development-Skincare, AbbVie

This presentation will be leadership- and strategy-focused. It will be useful for leaders and managers, bring a perspective on leading and inspiring the team to find innovative solutions to validation. It will also be helpful for scientists, engineers and future leaders in building a validation approach keeping the project and organizational needs at the center of focus. The discussion will concentrate around:

- The strategic aspect of innovation.
- A real-world example of an unconventional but innovative cleaning validation.
- Challenging the conventional thinking about cleaning validation.
- The validation approach keeping the broader objective in mind.
- Using AI.
- Review of some DOs and DON'Ts.

9:30 **Automation of Cleaning Process Development**

Andrew Walsh, President, Center for Pharmaceutical Cleaning Innovation

This presentation will discuss "cleanability" testing, cleaning agent selection, "Time-to-Clean" and Design of Experiment studies and the development of automated high throughput bench scale instrumentation at CPCI™.

10:15 *Midmorning Coffee and Networking Break*

Critical Issues—FDA GMP Inspections

10:45 **Scrubbing the Surface: Insights into Cleaning Deficiencies from FDA GMP Inspections**

Ileana Barreto-Pettit, Vice President-Technical, Parexel International

Cleaning processes are a critical aspect of Good Manufacturing Practices (GMP) in the pharmaceutical industry to prevent cross-contamination, yet they continue to be a common source of deficiencies identified during regulatory inspections. This presentation delves into the realm of cleaning deficiencies, offering valuable insights gleaned from FDA-483 observations and Warning Letters.

Drawing upon the presenter's experience as a former FDA Drug National Expert, this session will examine real-world case studies that highlight frequent pitfalls in cleaning processes. Attendees will gain a deeper understanding of regulatory expectations and common mistakes that occur even after cleaning processes have been validated. This presentation aims to equip quality assurance, quality control, and manufacturing professionals with practical knowledge to enhance their cleaning processes, ensure ongoing compliance, and successfully navigate regulatory inspections. Key topics to be covered include:

- Overview of GMP requirements for cleaning processes
- Analysis of recent FDA-483 observations and Warning Letters illustrating common cleaning issues and their consequences
- Strategies for avoiding typical pitfalls in cleaning processes post-validation
- Best practices for maintaining robust cleaning procedures and documentation
- Tips for effectively responding to and addressing cleaning-related regulatory observations

11:30 **Introduction to Meeting Regulatory Standards in a Global Cleaning Validation Program**

Dr. David Vincent, Chief Scientific Officer, VTI Life Sciences

In today's interconnected market, ensuring compliance with regulatory standards in cleaning validation is more crucial than ever, particularly for organizations operating across multiple regions. Cleaning validation is critical for maintaining product quality, patient safety, and overall compliance with regulatory requirements worldwide. A well-structured cleaning validation program helps mitigate contamination risks and cross-contamination, demonstrating a commitment to quality and compliance in every market.

Key Objectives of this presentation:

- Understand the foundational elements of a global cleaning validation program.
- Explore key regulatory guidelines from agencies such as the FDA, EMA, and other international bodies.
- Identify best practices for designing, executing, and maintaining a compliant cleaning validation program across various regions.
- Learn how to navigate and align differing regional requirements to ensure a seamless, unified approach.
- Discuss common challenges in global cleaning validation and strategies to overcome them.

12:15 *Complimentary Lunch*

Critical Issues—Your Legacy CV Program: A Revalidation Case Study

1:25 **How is That Legacy CV Program Doing?**

Fred Ohsiek, Principal Cleaning Process Consultant, Validation Resolution

- How does it measure up to recent regulatory guidelines?
- Some things to look at
- Ok, if it is going to be done (re-validation), how to do it smoothly
- A Re-validation case study

Spotlight on Annex 1

2:10 **Case Study on the Global Implementation of a Risk-Based Contamination Control Strategy**

Liz Brockson, Aseptic Processing and Sterility Assurance Lead, Takeda

Recent revisions to EU Annex 1 heavily emphasize the importance of a contamination control strategy (CCS) for manufacturers, and the requirements and guidance are numerous and cover many topics. This presentation will describe the basic principles and applicability of contamination control, as well as regulatory requirements and industry best practices for CCS (including the use of risk assessments). Additionally, this presentation will provide an overview of one company's approach for interpreting and implementing the Annex 1 CCS requirements, including updating existing CCS global guidance and implementing tools such as a template for sites to create local CCS and global contamination risk assessment with recommended risk questions, appropriate risk assessment tools/methods for each risk question, and guidance on how to group risk assessments for efficient management.

From this presentation, the attendees will learn:

- How to build a compliant CCS that is commensurate with risk.
- How to leverage existing contamination controls and identify/mitigate gaps for a holistic approach to CCS.
- A practical and pragmatic approach to implementing the over 50 requirements for risk assessment in Annex 1 that can be applied within a company.

2:55 *Afternoon Networking Break*

3:25 **Introduction to Annex 1: Disinfectant, Contamination Control, and Environmental Monitoring**

Dr. David Vincent, Chief Scientific Officer, VTI Life Sciences

With the recent revisions to Annex 1, regulatory expectations around contamination control and environmental monitoring have evolved, emphasizing proactive strategies and continuous improvement. Annex 1 provides guidance for manufacturers of sterile products, with detailed requirements on disinfectant use, contamination prevention, and maintaining control in cleanroom environments. This presentation aims to clarify the new requirements, outline best practices, and equip participants with the tools necessary for compliance in these critical areas.

Key Learning Objectives:

- Understand the updates to Annex 1 and their implications for contamination control and environmental monitoring programs.
- Learn about the regulatory expectations for disinfectant efficacy, rotation, and usage in sterile manufacturing settings.
- Explore strategies for establishing and maintaining contamination control plans that align with Annex 1 guidelines.
- Review best practices for environmental monitoring to ensure early detection and mitigation of potential contamination risks.
- Discuss practical approaches for implementing an effective environmental monitoring program that meets regulatory standards.

4:10 **Introduction and Overview of ASTM Cleaning Standards**

Andrew Walsh, President, Center for Pharmaceutical Cleaning Innovation

This presentation will discuss the movement to "science-based" and "risk-based" cleaning validation and the ongoing development of ASTM Standards on cleaning and cleaning validation.

4:55 ***Happy Hour Mixer***

Join your colleagues in the lounge for informal networking. Complimentary appetizers provided.

Thursday, January 30

7:45 ***Complimentary Breakfast***

Spotlight On Quality Risk Management

8:45 **Case Study: A Risk-Based Approach to Material Transfer Validation**

Liz Brockson, Aseptic Processing and Sterility Assurance Lead, Takeda

Transfer of equipment and materials is identified as "one of the greatest potential sources of contamination" in cleanrooms as per EU Annex 1 (Aug 2022); therefore, the process of transferring materials and equipment within classified and critical areas plays a key role in the safety and quality of products. This presentation will describe one firm's approach to material transfer, including evaluation of the critical factors associated with the process and a roadmap to robust validation execution. The result is a QRM-informed material transfer process which is easily defendable in a contamination control strategy.

At the conclusion of this presentation, attendees will:

- **Understand the importance of a material transfer process in controlling contamination in cleanrooms.**
- **Learn about critical factors associated with the material transfer process and how**

to objectively analyze the hazards to determine the risk each factor presents.

- **Be able to implement a robust, QRM-based approach to material transfer validation at their own facility.**

9:30 **Quantitative Measurement of Risk in the Cleaning of Pharmaceuticals and Medical Devices**

Andrew Walsh, President, Center for Pharmaceutical Cleaning Innovation

This presentation will review the implementation of ICH Q9 Quality Risk Management principles and their application to Cleaning. The concept of a Cleaning Assurance Level (CAL) will also be discussed. The Shirokizawa Matrix as a risk tool and its use in Risk Reduction/Mitigation and determining Cleaning Control Strategies will be discussed.

10:15 ***Midmorning Coffee & Networking Break***

10:45 **Lean Approach to Analytical Methods to Support Cleaning Validation**

Brian Bosso, Technical Services Manager, STERIS Life Sciences

Routine cleaning validation programs rely heavily on quality control labs to analyze samples and report results in minimal time, leading to resource constraints and delayed product or equipment release. Biopharmaceutical manufacturing cleaning validation programs utilize specialized assays, instruments and reagents to demonstrate the presence, degradation or activity of residual product on cleaned equipment. These assays can be costly and time-consuming. A lean analytical panel at each stage of the cleaning validation lifecycle can build upon previous stages, minimizing risk of surface contamination and optimizing lab resources. Continuous, in-line monitoring, such as conductivity, TOC and UV, in addition to a robust visual inspection program, shift the testing from the lab to automated processes. This presentation will include applied laboratory models as well as case studies to better understand and incorporate a lean analytical panel to your cleaning vali-dation program.

Objectives

- **Demonstrate the use of in-line analytical techniques as a lean approach to monitoring surface cleanliness in biopharmaceutical manufacturing.**
- **Discuss strategies for implementing a lean analytical panel to support cleaning validation lifecycle.**
- **Share case studies utilizing in-line analytical techniques and savings in terms of time, cost and personnel hours.**

11:30 **Optimizing Your Validation Program**

Jenna Carlson, President & Quality Consultant, Mindful Quality

This presentation will demonstrate how to optimize your cleaning validation program without sacrificing quality. Key takeaways include:

- Effectual analytical method qualification
- Optimizing cleaning processes
- Product and Equipment grouping strategies
- Consolidating validation activities

12:15 *Complimentary Lunch*

1:30 **Creeping Residue on Medical Devices and Pharmaceutical Contact Surfaces—Managing the Unknown**

Barbara Kanegsberg, President, BFK Solutions & Ed Kanegsberg, Vice President, BFK Solutions

Because creeping residues are both future and currently observed product hazards, we have reached the age of the never-ending validation. Ideally, once a cleaning process has been validated and limits established, nothing changes – not the metal working fluids, not the cleaning chemicals, not the cleaning processes. In the real world, changes happen. These changes can result in undesirable and unknown residue on medical devices and on vessels and product contact surfaces. We will discuss factors that can result in undesirable, and sometimes undetected, residue. Examples include recent and impending nationwide worker safety and environmental rules, market decisions by chemical suppliers, and costs to components manufacturers/job shops. One particular concern is that, if a cleaning agent in a validated process becomes costly or unavailable, substitute products and modified processes may be adopted. These substitutes often have very different molecular structures than the original cleaning chemical(s). The more the molecule structure differs from the original, the greater the potential for undesirable residue. The new process may be determined to be "essential the same" based on the toxicity or biocompatibility profile of the cleaning agent. However, an unsuspected, reacted combination of cleaning agent and soil may result in residue with potential catastrophic impact to product performance; and analytical tests used for the original validation may not be appropriate for the new process. We will discuss practical strategies for testing, for supply chain monitoring, and for spotting early warning signs of problems.

2:15 **Hygienic Design Excellence for Enhanced Cleaning Validation**

Sharif Uddin, Principal Engineer, Process Cleaning, Rockline Industries, Inc.

Hygienic design excellence plays a crucial role in cleaning validation. With the right design and materials, cleaning can become more effective and efficient, leading to better health outcomes and reduced risk of contamination. Cleaning is a life cycle event that starts with equipment design and the selection of cleaning parameters. To perform a successful cleaning validation, equipment, and piping systems need to be designed to be cleanable and to an acceptable level. The right combination of materials, surface finishes, and accessibility will drive the design and evaluation of equipment and associated systems. The design and quality engineers need to completely understand the equipment design before developing a protocol for cleaning validation. The presentation will focus on three key areas each facility needs to understand to perform enhanced validation: the importance of training required in hygienic design, understanding and practice of sanitary design principles, and continuous monitoring.

3:00 *Afternoon Coffee & Networking Break*

3:15 **Maintain that CV Program After All the Hard Work**

Fred Ohsiek, Principal Cleaning Process Consultant, Validation Resolution

- Fix the shutdown woes
- What do the guidelines say?
- Here is a way to do CPV efficiently and compliantly
- Routine monitoring case study

4:00 *Close of Program*

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About your conference destination:

La Jolla, California, has enchanted generations of travelers. Follow in their footsteps and embark on an adventure like no other with a stay at Sheraton La Jolla Hotel. Famous attractions like Torrey Pines Golf Course, the San Diego Zoo, Balboa Park, LEGOLAND and the USS Midway are all nearby. Visit celebrated academic institutions such as Birch Aquarium and the University of California San Diego. Our La Jolla hotel also places you near local restaurants, breweries, distilleries and shops. If you prefer to relax at our hotel, we offer an oasis filled with palm trees, manicured gardens, cascading waterfalls and tranquil koi ponds. Stay fit in our hotel gym and heated outdoor pool. At night, savor tasty cuisine, inventive cocktails and live entertainment at our two on-site restaurants before you retire to your peaceful accommodations. See why La Jolla is called the "Jewel of San Diego."

Registration Information

Register for the conference using one of three options:
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VENUE INFORMATION:

Dates:	January 29-30, 2025
Venue:	Sheraton La Jolla
Venue Address:	3299 Holiday Court La Jolla CA 92037
Venue Phone:	1(858)-453-5500

Please register me for:

Cleaning Validation Summit 2025

Standard Registration	$1,895
Early Bird Registration (by December 10)	$1,695
Call for government, academic, or non-profit rate	

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