PharmaED RESOURCES, Inc.

Cleaning Validation Summit 2022

December 1–2, 2022, La Jolla, CA

Featuring Lessons Learned and Case Studies from Industry Experts:

Walid El Azab
STERIS

Beth Kroeger-Fahnestock
Avantor

Fred Ohsiek
Ecolab

Mariann Neverovitch
BMS

Dushyant Varshney
Arcturus Therapeutics

Manix Eluhu
Native Resource Group, Inc.

Joe Cagnassola
Pfizer

Paul Lopolito
STERIS

David Vincent
VTI Life Sciences

Ralph Basile
Healthmark

Maria Ramirez-Marrero
Lonza

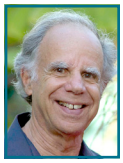
Koshy George
Koshy & Assoc.

Sharif Uddin
Rockline Industries

Michael Moussourakis
Alconox

Stephen Spiegelberg
Cambridge Polymer Group

Barbara Kanegsberg
BFK Solutions



Ed Kanegsberg
BFK Solutions

Can you implement the best science-, risk-, and statistics-based approaches to cleaning validation? Today's regulators are now expecting ADE monographs and comprehensive risk assessments of your organization's cleaning validation protocols. 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:

- Creating a Robust Cleaning Protocol and Report
- Global Validation and Transfers of mRNA Vaccines
- Lifecycle Management Challenges in Cleaning Verification Analytical Methods
- How to Validate the Manual Cleaning Process
- Manual Cleaning: Best Practices to Optimize the Process and Qualify Your Operators
- Addressing Concerns with Validated Legacy Cleaning Processes
- Answering Frequently Asked Questions from Cleaning Validation Teams
- Risk-based Approaches to Cleaning Validation
- Meeting the New Cleaning Standards for Drugs and Med Devices
- How to Develop a Cleaning Program Based on Hygienic Design and Gap Analysis, Training and Continuous Monitoring
- Maintaining the Cleaning Validated State
- And More!

With Representation From:

STERIS · avantor · Pfizer · Bristol Myers Squibb · Cambridge Polymer Group · ALCONOX CRITICAL CLEANING EXPERTS

microsize Particle Size Reduction Specialists · ECOLAB Everywhere It Matters. · KOSHY ASSOCIATES · healthmark · ARCTURUS therapeutics · VTI LIFE SCIENCES · rockline people who make it right · BFK Solutions LLC Critical Cleaning Consulting

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Thursday, December 1, 2022

7:00 *Sign-in & Complimentary Breakfast*

7:55

Chairperson Beth Kroeger-Fahnestock's Welcome & Opening Remarks

8:00 **Presentation Title Forthcoming**

Beth Kroeger-Fahnestock, Director, New Biopharma Product Introduction, Avantor

Abstract forthcoming

Critical Issues—Validating Your Cleaning Processes

8:40 **Creating a Robust Cleaning Protocol and Report**

Joe Cagnassola, Senior Validation Consultant, Pfizer

The key to success in any cleaning program is having a cleaning protocol and report that captures the critical steps and provides audit ready documentation. Understanding the cleaning process/program helps the users write polished documentation that stands up to the scrutiny of auditors. This presentation will go step by step through the inception of the cleaning project through the completion of the report. Understanding the process flow will help expedite the Validation time and ensure compliance to internal and external requirements. Learning Goals for this presentation include:

- User Requirements
- Pre-Requisites to get started writing
- Understanding the Writing Process
- Execution and Report Writing

9:20 **Why Validate the Manual Cleaning Process?**

Koshy George, President, Koshy & Associates Consulting Services

At least some manual steps are involved in almost all cleaning processes. At some pharmaceutical facilities all cleaning processes are manual. Manual cleaning processes involves human intervention. This involvement can be intentionally systematic or at random. Manual cleaning processes are almost always fully operator controlled, while semi-automatic processes involve operator intervention at different stages of the process. The outcome of the manual cleaning processes, the success or failure of the process, depends upon the operator input. For a successful outcome, a deliberate and systematic approach by the operator to the cleaning process is required.

Operators must be trained and their training documented, which is a compliance requirement. Operators must follow a written standard operating procedure. SOPs for manual processes must be written in detail with no ambiguity so that any operator can follow the instructions without getting confused. The cleaning process must be repeatable with a consistent outcome. For manual cleaning process the main variable is the human input. Critical Cleaning Parameters (CCPs) such as TACT (Time, Action, Concentration, Temperature) must be monitored during manual cleaning processes also. It is a regulatory expectation that all processes in the pharmaceutical industry are validated and the processes are repeatable, consistent and meets certain predetermined limits. Manual cleaning processes are validatable despite claims from some people that manual cleaning processes are not validatable. This presentation will cover points to consider for successful manual cleaning processes and explain why manual cleaning processes must be validated.

10:00 *Midmorning Coffee and Networking Break*

10:30 **Improving Cleaning Performance and Prospective Future Performance**

Walid El Azab, Senior Manager, Technical Services, STERIS Corporation

Through some examples, the presentation discusses the elements to consider in improving cleaning performance, such as laboratory studies to design cleaning cycles, on-site observation, and data analysis to identify the drivers for cleaning improvement. Finally, how to use statistical analysis to confirm if the improvements made were successful.

Key takeaways:

- Understand the elements to analyze or monitor to be able to improve cleaning performance
- Understand basic statistics to analyze retrospectively and prospective potential cleaning performance
- Share some case studies

11:10 **Designing a Cleaning Process for Medical Devices that Can be Validated and Stays Validated**

Barbara Kanegsberg and Ed Kanegsberg, BFK Solutions LLC

The key to relatively stress-free cleaning validation is to treat validation an open-book test. Preparation is the key. Further, particularly with complex devices containing many materials of construction and devices where fabrication and assembly involves a multi-step supply chain, monitoring and even partial revalidation may be required. Topics include

- The 3-stage lifecycle approach for medical devices
- Four Ds: Design, Develop, Document, Defend
- Pre-validation to fine-tune the process
- Maintaining validation for complex designs, 3D printing
- Planning for emergencies, including cleaning agent availability

11:50 *Complimentary Lunch*

Spotlight on Manual Cleaning Methods

1:05 **Manual/COP Cleaning: Methods and Validation**

Michael Moussourakis, Senior Director, Strategic Affairs, Alconox

A brief introduction will be presented reinforcing general cleaning concepts, chemistry and detergency. Aqueous detergent cleaning methods will be reviewed with a detailed focus on manual and clean-out-of-place cleaning methods, associated pros and cons, and equipment. The necessary pre and post cleaning steps, vital to any cleaning application are presented as a lifestyle approach. Their goal being to facilitate cleaning validation programs. This includes needs for focus on set up and procedures before cleaning steps are introduced, during the cleaning process itself, and methods for good practice in post cleaning—long after the final rinse has been completed. Finally, a recent manual cleaning validation of a pharmaceutical product is presented as a case study and reviewed. The requirements, results and procedure followed. The residue detection methods chosen for both residual product and detergent will be discussed.

1:45 **Manual Cleaning: Best Practices to Optimize the Process and Qualify Your Operators**

Maria E. Ramirez-Marrero, Quality Assurance Specialist, Microsize, Inc.

Manual cleaning is a variable process that requires detailed steps to guarantee a successful validation. Once the process is validated you need to qualify your operators in order to obtain acceptable results that compare to the ones obtained during the validation process.

Spotlight on Visual Inspection

2:25 **Application and Qualification of Visual Inspection**

Ralph J. Basile, Vice President of Marketing & Regulatory Affairs, Healthmark

Failure to properly and effectively visually inspect clinically-used medical devices, prior to their use on the next patient, has been directly linked to poor patient outcomes, including death. A summary of these events, as documented in the FDA Maude Database, will be reviewed. Measures that can and should be taken to avoid these unfortunate events will then be presented. This will include discussion of industry standards and research that supports these measures

3:05 ***Afternoon Networking Break***

3:35 **What is That Residue? When Visual Assessment and TOC is Not Enough in Cleaning Testing**

Stephen Spiegelberg, President, Cambridge Polymer Group

Cleaning validation activities often involve nonspecific qualitative and quantitative assessment of residues using total organic carbon, weighing of residue, and visual assessment. In most cases, these levels of analysis are sufficient to establish consistency in cleaning operations. When cleaning operations drift out of control, or a downstream failure occurs, specificity in residue identification and quantitation is sometimes needed to determine the source of the issue. In this presentation, case studies of cleaning operations that required additional analysis are presented, with analytical techniques selected to help identify issues with cleaning operations as part of a root cause investigation.

Critical Issues—Validated Legacy Cleaning Processes: Challenges and Opportunities

4:05 **Concerns with Validated Legacy Cleaning Processes**

Fred Ohsiek, Senior Global Technical Manager, Life Science (Cleaning Validation), Ecolab

Dated cleaning validation packages can have hidden or known compliance risks. In this presentation, different areas of the validation process will be dissected (dated practices and rationales, documentation practices, product and equipment grouping, and use of risk-based decision). Even newer validations (5 years or less) may have compliance risks. In this presentation, we will examine:

- Quick review of regulatory guidelines for cleaning validation
- Legacy cleaning validation concerns and pitfalls
- Explore the benefits for revalidating legacy cleaning processes
- Tour and examine the revalidation process

4:45 ***Happy Hour Mixer***

Join us in the lounge for informal networking. Complimentary appetizers provided.

Friday, December 2

7:30 ***Complimentary Breakfast***

8:30 **Global Validation and Transfers of mRNA Vaccines**

Dushyant Varshney, CTO, Arcturus Therapeutics

Abstract forthcoming

Spotlight on Lifecycle Management & Analytical Methods

9:10 **Analytical Methods: Frequently Asked Questions**

Paul Lopolito, Senior Technical Services Manager, STERIS Corp.

Asking the right question, at the right time, and to the right person is the core of the scientific method. This

is no different when selecting and validating analytical methods used in designing, qualifying, and continuously monitoring a cleaning process.

Common questions may include …

- Why was the method selected?
- Are we detecting the most difficult to rinse or the most toxic analyte?
- What should we do if the analyte has been degraded?
- How do we increase the limit of detection of the analyte?
- When is a low recovery acceptable?
- What are the options and benefits of in-line and direct surface methods?

These are just a few of the questions asked by pharma and biopharma manufacturers around the world. This presentation will review these common questions and others through a series of examples. The goal of the presentation is a better understanding of the analytical method used and how to leverage this information throughout the cleaning life cycle.

9:50 *Midmorning Coffee & Networking Break*

10:20 **Lifecycle Management Challenges in Cleaning Verification Analytical Methods**

Mariann Neverovitch, Senior Manager, Bristol-Myers Squibb

Equipment Cleaning is a critical GMP element of the Manufacturing Process. It ensures quality and safety of future batches. 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 nonspecific analytical methods based on risk assessment of the residual product.

Case studies, training and qualification programs will also be discussed.

11:00 **Steps to a Successful Cleaning Cycle Development Program**

Manix Eluhu, Validation Engineer, Native Resource Group, Inc.

I'll outline the cleaning validation needs and strategy for product contact manufacturing equipment and parts used to formulate, transfer, and fill products for those who are just getting started with cleaning validation. This presentation will provide a framework for validating product contact equipment cleaning operations. I'll also go through the processes necessary to guarantee that the product contact equipment and parts used in manufacturing are properly cleaned in order to comply with current Good Manufacturing Practices (cGMP).

11:40 *Complimentary Lunch*

12:55 **Steps to a Successful Cleaning Cycle Development and Validation Applying a Life Cycle Approach**

David Vincent, CSO, VTI Life Sciences

Participants will benefit from surveying a hands-on approach to support the life science industry in the development and establishment of compliant cleaning programs that meet or exceed regulatory expectations. Key topics to be covered include:

- Current Regulatory Expectations
- Life Cycle Approach to Cleaning Validation (FDA 3 Stage Approach)
- How to Gain Cleaning Process Understanding by utilizing Risk Based Approach
- CIP and Automated Systems Design and Qualification of Equipment
- Sprayball Coverage Studies
- Washout Curve
- Holdup Volume, Acceptable Flow
- Dead legs
- Cleaning Equipment Characterization Report
- Cleaning Cycle Development and Validation
- Sampling and Testing Requirements (Bioburden/ Endotoxin)
- Continued/Ongoing Cleaning Process Verification
- Tools That Enable Effective and Efficient Validation
- Change Management/Process Monitoring Stage

Regulatory Spotlight—Meeting the New Cleaning Standards for Drugs and Med Devices

1:35 **Cleaning Standards Covering Both Drugs and Devices**

Ralph J. Basile, Vice President of Marketing & Regulatory Affairs, Healthmark

This year, 1 new AAMI Standard, 1 new ISO standard and 1 updated ISO standard on processing of clinical medical devices have published. ANSI/AAMI ST98 is the first standard to establish requirements for validation of cleaning instructions supplied by manufacturers of medical devices to their healthcare customers. The standard sets very clear requirements for how to develop and test the steps for cleaning their medical device prior to use on the next patient. An overview of this important new U.S. national standard will be provided. Also of significance, ISO 17664, has been broken into two parts. Part 1 is a slight update to the original document published in 2017, and provides requirements for the information on processing critical and semicritical medical devices that medical device manufacturers are to provide to healthcare facilities. Part 2 is brand new and provides similar requirements for noncritical devices that are not intended to be sterilized. A brief review of both documents will be presented.

2:05 *Afternoon Break*

2:20 **Develop a Cleaning Program Based on Hygienic Design and Gap Analysis, Training and Continuous Monitoring**

Sharif Uddin, Senior Engineer, Process Cleaning, Rockline Industries

To perform a successful cleaning and sanitation program, equipment and piping systems need to be designed in such a way, so it could be cleanable to an acceptable level. It is important for the design and quality engineers to have complete understanding of the equipment design before making any decision on the cleaning. The presentation will focus on three key areas which each facility needs to understand to perform robust cleaning and validation: importance of training required in hygienic design, understanding and practice of hygienic design principles during equipment and CIP systems design and continuous monitoring of CIP systems.

3:00 **Maintaining the Cleaning Validated State**

Fred Ohsiek, Senior Global Technical Manager, Life Science (Cleaning Validation), Ecolab

The frequency and the type of testing needed for routine monitoring is not easily determined. Once the monitoring program is established, determining the best rationale for reducing the frequency is also difficult. In this presentation, a robust science and risk-based method will not only determine the frequency, but also how to reduce it.

- Quick review of FDA 2011 Continued Process Verification (CPV) regulatory guidelines
- In-depth discussion on periodic review, CPV, and dated validation packages
- Risk-Based approach to Continued Process Verification
- Determining and reducing routine monitoring frequency
- Routine monitoring risk assessment case study

3:40 **Impact of non-FDA Activities on Cleaning Validation of Medical Devices**

Ed Kanegsberg and Barbara Kanegsberg, BFK Solutions LLC

Use the term "regulatory," and medical device manufacturers immediately think of the FDA. However, other government agencies, notably the EPA, as well as other business and market forces can directly impact cleaning agent availability as well as the ruggedness of cleaning validation. The reason is that even if cleaning during final assembly does not involve using cleaning agents subject to impending regulations, those regulatory activities and business decisions can have a ripple effect in the supply chain and jeopardize a validated cleaning process. Emphasis in this presentation is on the EPA amended TSCA (2016 Lautenberg amendment to the Clean Air Act). Regulation of PFAS and global regulatory restrictions will also be discussed. Before any proposed EPA regulations, there are already shortages of trichloroethylene prompted by business decisions of cleaning agent suppliers to leave the U.S. market. Even where production phaseout is not an immediate issue, regulatory activities have resulted in short-term unavailability of fluorinated products.

4:20 ***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."

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VENUE INFORMATION:

Dates:	December 1–2, 2022
Venue:	Sheraton La Jolla Hotel
Venue Address:	3299 Holiday Court La Jolla, CA 92037
Venue Phone:	1 (858)-453-5500

Please register me for:

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Early Bird (by September 1)	$1,395
Standard Registration	$1,595
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