KENX
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ADVANCED

CLEANING VALIDATION & CRITICAL CLEANING PROCESSES

May 12, 2021 | The Dana Mission Bay | San Diego, CA

TOP REASONS TO ATTEND

Cleaning Validation & Critical Cleaning Processes

- Discover Risk-based Approaches to Cleaning Monitoring and Manufacturing Equipment
- Advanced Cleaning Validation – How Much Validation is Enough and Green Your Clean
- Cleaning Process Development from Lab Bench to Full Scale – Lean Six Sigma Case Study
- Validation of Analytical Methods Used in Cleaning
- Selection of Cleaning Agents and Parameters

ELITE FACULTY

Keith Bader
VP of Cleaning Science and Technical Services
Hyde Engineering + Consulting

Cindy Duhigg
Global Validation Steward
Alcon Laboratories

Beth Kroeger
Technical Services Manager
STERIS Life Sciences

Charlie Maher
Senior Director, Capital Projects Validation and Operational Readiness, **Resilience**

Dawn Marshall (Tavalsky)
Senior Director of Global Quality
Sanofi

Kenneth Pierce, Ph.D.
Cleaning Validation SME
Hyde Engineering + Consulting

Jim Polarine, Jr.
Senior Technical Services Manager
STERIS Life Sciences

Ruijin Song
Senior Cleaning Validation Specialist
Center for Pharmaceutical Cleaning Innovation

Andrew Walsh, MS, CLSBB
President
Center for Pharmaceutical Cleaning Innovation

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TEAM DISCOUNT: REGISTER 3 AND THE 4TH ATTENDS FREE

Register Online | kenx.org/conferences/cleanroom-2021

May 12, 2021

7:30 PST **Exhibitor Showroom and Virtual Platform Open House**

8:00 PST **Chairperson's Opening Remarks**

8:15 - 8:45 PST — EU GMP Annex I – The Impact on Cleaning and Disinfection Development and Validation of Disinfectant Efficacy

Jim Polarine Jr., MA., Senior Technical Service Manager, **STERIS Corporation**

- Define the current sections of Draft version 12 of Annex I directly related to cleaning and disinfection, and validation of disinfectants
- Learn how to rotate disinfectants and access residues and rinse on a periodic basis
- Discover how to address bioburden in isolators and RABS
- Interpret how to address sterility is Grade A cleanrooms

Takeaway Tools

- *Template covering cleaning and disinfection frequencies*
- *Risk assessment strategy for rinsing frequencies*
- *Risk based strategy for pass through decon into the cleanroom*

8:45 - 9:15 PST — A Roadmap to ISPE Cleaning Validation and PDA TR 49 Biotechnology Guides

Beth Kroeger, Technical Services Manager, **STERIS Life Sciences**

- Review PDA TR 49 guidance and explore how cleaning validation has adapted in the past 10 years
- Understand the key concepts from the ISPE Cleaning Validation Guide and how you can implement best practices at your site
- Equipment and plant design considerations
- Global trends and how they relate to the cleaning process design and development
- Understand what "clean" means so you can better defend your process to inspectors, auditors, and investors

Takeaway Tools

- *Worksheet on implementation of health-based exposure limits for cleaning agents*

9:15 - 9:45 PST — Microbial Control – 5 Things You Need to Know

Cindy Duhigg, Global Validation Steward, **Alcon Laboratories**

- Define the fundamental elements of microbial control
- Prevent process and product variability through engineering controls
- Reduce variability through effective cleaning, sanitization and maintenance
- Recognize variability with effective monitoring

Takeaway Tools

- *Example FMEA for microbial control*
- *Case studies from pharmaceutical, medical device and biopharmaceuticals*

9:50 - 10:20 PST **Exhibitor Showroom & Think Tank Sessions**

10:30 - 11:00 PST — Human Behavior – Know the Impact and Reduce Risk Risk

Dawn Marshall, Senior Director Global Quality, **Sanofi Pasteur**

Part 1 – The Human Microbiome

- Understand the microbiology basics behind the human microbiome
- The "why" behind the "what" for personnel behavior
- Bacteria – Types and how they thrive and survive
- Virus – How they thrive, survive and reproduce
- Molds – How they thrive, survive and reproduce

Part 2 – Protecting Products from People

- Environmental requirements of the cleanroom
- Behaviors prior to gowning
- Gowning procedures
- Behaviors in the clean rooms
- Tracking and Trending performance through environmental monitoring
- A link to personnel qualification

Knowledge Exchange

Attendees take part in a hand cleaning exercise using Glow-Germ® to demonstrate the effectiveness and difficulty in getting completely cleaned hands.

Takeaway Tools

- *Generic personnel and gowning flows*
- *Process risk assessment template*

11:00 - 11:30 PST — Operational Readiness – Fast Track to Vertical Start Up

Charlie Maher, Senior Director, Capital Projects, Validation and Operational Readiness, **Resilience**

Coming Soon

11:30 - 12:00 PST — Qualification of Visual Inspection – Introduction to the ASTM E3263 Standard Practice

Andrew Walsh, MS, CLSSBB, President,
Center for Pharmaceutical Cleaning Innovation

- Historical background on visual inspection
- Regulatory perspectives on visual inspection
- EMA's Q&A 7 & 8 on HBEL Guidance
- ASTM E55 and F04 committee collaboration
- Goals Of ASTM E3263
- Scope Of ASTM E3263
- The E3263 Standard Practice Guide Procedure
- The critical significance of HBELs for visual inspection

Takeaway Tools

- *"Toxicity Scale"*

8:00 - 9:30 PST Knowledge Exchange Session

Discover Risk-based Approaches to Cleaning Monitoring and Manufacturing Equipment

Dawn Marshall, Senior Director Global Quality, **Sanofi Pasteur**

Part 1 – How Did We Get Where We Are With Respect to Cleaning Monitoring?

- Historical review – Tragedies that have brought us to where we are
- Explore similarities and difference between product contact cleaning and environmental cleaning
- Explore equipment types, different materials of product contact, and cleaning methodologies and their unique cleaning challenges
- Understand the regulations and observations with respect to cleaning and cleaning monitoring
- Understand the expectations for a cleaning monitoring program
- Discuss the pitfalls and traps that have been encountered in cleaning monitoring programs

Part 2 – Successful Implementation of Risk-Based Approaches to Cleaning Monitoring

- Understand the application of a Risk-Based Approach
- Ensure the acceptance of risk does not become an excuse for not doing cleaning monitoring
- Understand tools and decision trees utilized to group, bracket and assess different types of equipment
- Review examples of implemented cleaning monitoring programs
- Learning from the cleaning monitoring exercise
- Discuss how to respond to a cleaning monitoring failure
- Discuss a vision for the future for cleaning monitoring and the use of PAT

Knowledge Exchange

Attendees take part in a round-the-room survey of your company's cleaning and cleaning monitoring challenges and strategies and evaluate the current industry baseline versus the future of where the industry is headed.

Takeaway Tools

- *Decision Trees associated with cleaning and cleaning monitoring*
- *Example cleaning monitoring programs*
- *Templates for cleaning monitoring execution exercises*

9:45 - 10:15 PST Exhibitor Showroom & Think Tank Sessions

10:30 - 12:00 PST Knowledge Exchange Session

Advanced Cleaning Validation – How Much Validation is Enough and Green Your Clean

Kenneth Pierce, Ph.D., Cleaning Validation SME,
Hyde Engineering + Consulting

Part 1 – How Much Cleaning Validation is Enough? Maximise the Power of Grouping Strategies

- Start-Up and NPI dead-weight or validation team badge of honor
- Cleaning validation – Bottom of the list? Understand why, and drive out of that space
- Understand what the primary grouping strategy opportunities are
- Learn the key drivers that enable grouping strategy success – Avoid mediocrity!
- Make the business case to achieve and leverage your inputs – Find your champion
- Merge the different strategies into a cohesive validation plan
- Supercharge validation program efficiency

Part 2 – Greening Your Cleaning – Strategies and Opportunities

- Global business imperative and site badge of honor
- Process for reviewing and identifying current operations
- ROI evaluation and business case development to drive resource allocation
- Design a multi-stage process setup, build in stage-gate monitoring and reporting – ensuring continued sponsor support
- Understand the importance of setting realistic goals
- Improve outcomes by driving empowerment of your team and giving them runway to maximize their skills, while applying correct oversight
- Realizable value; reduce changeover time by 66%, reduce water consumption by >25%, reduce cleaning agent consumption by 30%, reduce solvent usage, reduce electricity consumption

Takeaway Tools

- *Process workflows*
- *Goal prioritisation model*
- *Know the real-world value achievable – find your sponsor!*
- *Input -> impact shortlist*
- *Real-world Examples of workload multipliers*

12:15 - 1:00 PST Knowledge Exchange Session

Cleaning Process Development from Lab Bench to Full Scale – Lean Six Sigma Case Study

Ruijin Song, MS, Senior Cleaning Validation Scientist, **Center for Pharmaceutical Cleaning Innovation**

- Cleanability studies and ASTM Standards G121 and G122
- Development of automated cleanability testing
- Determination of "hardest-to-clean" compounds/products
- Cleaning agent selection
- Design of Experiments
- Critical Cleaning Process Parameter identification
- Time-To-Clean" studies and analysis
- Cleaning process development case study

1:15 - 2:45 PST Knowledge Exchange Session

Validation of Analytical Methods Used in Cleaning

Cindy Duhigg, Global Validation Steward, **Alcon Laboratories**

Part 1 – The Rapidly Changing Landscape of Cleaning Validation Methods

- Regulations – FDA, EU, PIC/S, APIC, WHO
- Cleaning process development
- Cleaning methods
- Cleaning residues
- "Limits" and the new EMA guide
- Sampling methods

Part 2 – Systematic Validation of Analytical Methods for Cleaning Residues

- Common and uncommon methods for cleaning residues
- Limit tests vs. quantitative
- Specific vs non-specific methods
- Performance characteristics

Knowledge Exchange

Attendees take part in interactive design of a method validation protocol.

Takeaway Tools

- *Example analytical method protocol*

3:00 - 3:30 PST Exhibitor Showroom & Think Tank Sessions

3:45 - 5:15 PST Knowledge Exchange Session

Selection of Cleaning Agents and Parameters

Keith Bader, VP of Cleaning Science and Technical Services, **Hyde Engineering + Consulting**

Coming Soon

5:30 PST Close of Conference

REGISTRATION: $595.00

TEAM DISCOUNT: Register 3 & receive the 4TH free!

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