

# **CLEANING UNIVERSITY**

## **CLEANROOM OPERATIONS & DISINFECTION**

## **ENVIRONMENTAL MONITORING & QUALIFICATION**

## **CLEANING VALIDATION & CRITICAL PROCESSES**

May 11 - 12, 2021 | The Dana Mission Bay | San Diego, CA

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## ELITE FACULTY



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



Chip Bennett,  
Associate Director,  
Global C&Q, SME, CQV Program  
Development, QRM, **CAI**



Joscelyn Bowersock  
Customer Success Manager  
**L7 Informatics**



Elizabeth Brockson  
Senior Validation Scientist  
**CAI**



Javier Cardenas, Ph.D.  
Senior Consultant, Technical Lead  
**Azzur Group**



Susan B. Cleary, B.Cs, M.B.A.  
Director of Product  
Development  
**NOVATEK INTERNATIONAL**



Cindy Duhigg  
Global Validation Steward  
**Alcon Laboratories**



Madison Hoal  
Global Technical Consultant  
**Ecolab Life Sciences**



Jason Kelly  
VP of Services  
**Lighthouse Worldwide  
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Beth Kroeger  
Technical Services Manager  
**STERIS Life Sciences**



Fred Ohsiek  
Senior Cleaning Validation  
Specialist  
**Novo Nordisk**



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



Shelley Preslar  
President & COO  
**Azzur Training Center**



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



Ravi Samavedam  
President  
**Azzur Cleanrooms on Demand  
LLC**



Ruijin Song  
Senior Cleaning Validation  
Specialist  
**Center for Pharmaceutical  
Cleaning Innovation**



David W. Vincent, MPH, Ph.D.  
CEO  
**VTI Life Sciences**



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



TJ Woody  
Director of Cleaning Validation  
**Azzur Group**



Charlie Maher  
Senior Director, Capital Projects  
C&Q and OR,  
**National Resilience, Inc.**

DAY ONE		MAY 11, 2021
7:00 PT		Exhibitor Showroom and Virtual Platform Open House
7:30 PT		Chairperson's Opening Remarks
7:45 - 8:15 PT	COMPLIANCE INTELLIGENCE	 <b>EU GMP Annex 1 – The Impact on Cleaning and Disinfection</b> Jim Polarine Jr., MA., Senior Technical Service Manager, <b>STERIS Corporation</b>
8:15 - 8:45 PT	COMPLIANCE INTELLIGENCE	 <b>A Roadmap to ISPE Cleaning Validation and PDA TR 49 Biotechnology Guides</b> Beth Kroeger, Technical Services Manager, <b>STERIS Life Sciences</b>
8:45 - 9:15 PT	COMPLIANCE INTELLIGENCE	 <b>Microbial Control – 5 Things You Need to Know</b> Cindy Duhigg, Global Validation Steward, <b>Alcon Laboratories</b>
9:15 - 9:45 PT	AUTOMATION & MACO LIMITS	<b>Risk Based Cleaning Validation, Automation, &amp; How to Develop and Apply the MACO Limits</b> Susan B. Cleary, B.Cs, M.B.A., Director of Product Development, <b>NOVATEK INTERNATIONAL</b> ; Javier Cardenas, Ph.D., Senior Consultant, Technical Lead, <b>Azzur Group</b>
9:50 - 10:20 PT		Exhibitor Showroom and Think Tank Sessions
10:30 - 11:00 PT	HUMAN BEHAVIOR	 <b>Human Behavior - Know the Impact and Reduce Risk</b> Chip Bennett, Associate Director, Global C&Q, SME, CQV Program Development, <b>CAI</b>
11:00 - 11:30 PT	CLEAN BY DESIGN	 <b>Risk-Based Cleanroom Validation - Fast Track to Vertical Start Up</b> Charlie Maher, Senior Director, Capital Projects, C&Q and OR, <b>National Resilience, Inc.</b>
11:30 - 12:00 PT	VISUAL INSPECTIONS	 <b>Qualification of Visual Inspection – Introduction to the ASTM E3263 Standard Practice</b> Andrew Walsh, MS, CLSSBB President, <b>Center for Pharmaceutical Cleaning Innovation</b>
12:30 - 1:15 PT		Select Between Knowledge Exchange Sessions (1-3)
1	CLEANROOM OPERATIONS	 <b>Cleanroom Disinfection – 5 Things You Need to Know</b> Beth Kroeger, Technical Services Manager, <b>STERIS Life Sciences</b>
2	ENVIRONMENTAL MONITORING	 <b>Investigations of Alert/Action Level Excursions</b> Elizabeth Brockson, Senior Validation Specialist, <b>CAI</b>
3	CLEANING VALIDATION	<b>Common Gaps in Cleaning Validation and Their Solutions – From Pain to Optimization</b> TJ Woody, Director of Cleaning Validation, <b>Azzur Group</b>
1:30 - 2:00 PT		Exhibitor Showroom and Think Tank Sessions
2:15 - 3:45 PT		Select Between Knowledge Exchange Sessions (4-6)
4	CLEANROOM OPERATIONS	<b>Clean By Design – Successful Implementation of a Holistic, Risk-based Program for Cleanroom Design, Cleaning and Monitoring</b> Ravi Samavedam, President, <b>Azzur Cleanrooms on Demand™</b>

5	ENVIRONMENTAL MONITORING	 <b>Commission and Qualification of Clean Utilities</b> David W. Vincent, MPH, Ph.D., CEO, <b>VTI Life Sciences</b>
6	CLEANING VALIDATION	 <b>Science, Risk and Statistics-based Cleaning Process Development and Validation – The Key Elements for Success</b> Andrew Walsh, MS, CLSSBB, President, <b>Center for Pharmaceutical Cleaning Innovation</b>
4:00 - 4:30 PT		Exhibitor Showroom and Think Tank Sessions
4:45 - 6:15 PT		Select Between Knowledge Exchange Sessions (7-9)
7	CLEANROOM OPERATIONS	 <b>Design and Construction of Cleanrooms – Optimize Performance and Compliance</b> David W. Vincent, MPH, Ph.D., CEO, <b>VTI Life Sciences</b>
8	ENVIRONMENTAL MONITORING	<b>Design of an Environmental Monitoring Performance Qualification Program</b> Chip Bennett, Associate Director, Global C&Q, SME, CQV Program Development, QRM, and Elizabeth Brockson, Senior Validation Specialist, <b>CAI</b>
9	CLEANING VALIDATION	 <b>Establish Acceptance Criteria and Set Health Limits</b> Fred Ohsiek, Senior Cleaning Validation Specialist, <b>Novo Nordisk</b>
6:15 - 7:00 PT		Game Night - Trivia Welcome Reception
<b>DAY TWO</b>		
<b>MAY 12, 2021</b>		
7:30 PT		Exhibitor Showroom Opens
8:00 - 9:30 PT		Select Between Knowledge Exchange Sessions (10-12)
10	CLEANROOM OPERATIONS	<b>Microbial Control – Develop a Proactive Approach to Reduce Risk</b> Elizabeth Brockson, Senior Validation Specialist, <b>CAI</b>
11	ENVIRONMENTAL MONITORING	 <b>Analyze and Organize Trending Data</b> David W. Vincent, MPH, Ph.D., CEO, <b>VTI Life Sciences</b>
12	CLEANING VALIDATION	<b>Discover Risk-based Approaches to Cleaning Monitoring and Manufacturing Equipment</b> Fred Ohsiek, Senior Cleaning Validation Specialist, <b>Novo Nordisk</b>
9:45 - 10:15 PT		Exhibitor Showroom and Think Tank Sessions
10:30 - 12:00 PT		Select Between Knowledge Exchange Sessions (13-15)
13	CLEANROOM OPERATIONS	 <b>Development and Validation of Disinfectant Efficacy</b> Madison Hoal, Global Technical Consultant, <b>Ecolab Life Sciences</b>
14	ENVIRONMENTAL MONITORING	 <b>Establish Sampling Sites and Execute Plans Based on Risk</b> Joscelyn Bowersock, Customer Success Manager, <b>L7 Informatics</b>
15	CLEANING VALIDATION	<b>Advanced Cleaning Validation – How Much Validation is Enough and Green Your Clean</b> Kenneth Pierce, Ph.D., Cleaning Validation SME, <b>Hyde Engineering + Consulting</b>
12:15 - 1:00 PT		Select Between Knowledge Exchange Sessions (16-18)

16	CLEANROOM OPERATIONS	 <b>Cleaning and Disinfection – Create a Training Strategy Playbook for Operators</b> Jim Polarine Jr., MA., Senior Technical Service Manager, <b>STERIS Corporation</b>
17	ENVIRONMENTAL MONITORING	<b>Best Documentation Strategies for Critical Information</b> Joscelyn Bowersock, Customer Success Manager, <b>L7 Informatics</b>
18	CLEANING VALIDATION	 <b>Cleaning Process Development from Lab Bench to Full Scale – Lean Six Sigma Case Study</b> Ruijin Song, MS, Senior Cleaning Validation Scientist, <b>Center for Pharmaceutical Cleaning Innovation</b>
1:15 - 2:45 PT		<b>Select Between Knowledge Exchange Sessions (19-21)</b>
19	CLEANROOM OPERATIONS	 <b>Reduce Deviations and Contamination Events through Effective Training</b> Shelley Preslar, President, <b>Azzur Training Center</b>
20	ENVIRONMENTAL MONITORING	 <b>Risk-Based EM Sampling Strategy - Using the Process Risk Control Strategy to Determine EM Sampling Strategy</b> Chip Bennett, Associate Director, Global C&Q, SME, CQV Program Development, QRM, <b>CAI</b>
21	CLEANING VALIDATION	<b>Validation of Analytical Methods Used in Cleaning</b> Cindy Duhigg, Global Validation Steward, <b>Alcon Laboratories</b>
3:00 - 3:30 PT		<b>Exhibitor Showroom and Think Tank Sessions</b>
3:45 - 5:15 PT		<b>Select Between Knowledge Exchange Sessions (22-23)</b>
22	ENVIRONMENTAL MONITORING	<b>Digitalize Your EM Contamination Control Strategy</b> Jason Kelly, Vice President of Services, <b>Lighthouse Worldwide Solutions</b>
23	CLEANING VALIDATION	 <b>Using Design of Experiments for Cleaning Process Development - Cleaning Agent Selection to Cleaning Parameter Determination</b> Keith Bader, VP of Cleaning Science and Technical Services, <b>Hyde Engineering + Consulting</b>
5:30 PT		<b>Close of Conference</b>