

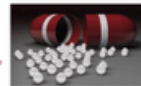


**Cleanroom Contamination Control  
Environmental Monitoring  
Cleaning Validation**

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Sheba Zaman  
Head of Product  
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Sharif Uddin, Ph.D.  
Principal Engineer  
Process Cleaning  
**Rockline Industries**




David W. Vincent  
MPH, Ph.D.  
Chief Scientific Officer  
**VTI Life Sciences**

12:00 - 1:00 PM	Registration - Coffee & Tea
1:00 - 1:15 PM	Chairperson's Opening Remarks
1:15 - 2:15 PM	<p><b>Panel: Annex 1 &amp; the Impact on Cleanroom Management, Environmental Monitoring, &amp; Cleaning Validation</b></p> <p>Moderator: Sheba Zaman, Head of Product Specialists and Training Services, <b>Novatek International</b></p> <p>Panelists: Cindy Duhigg, Global Process Validation Steward, <b>Alcon</b></p> <p>Joscelyn Bowersock, Senior Director Quality Assurance and Regulatory, <b>Precision for Medicine</b></p> <p>Liz Brockson, Aseptic Processing &amp; Sterility Assurance Lead, <b>Takeda</b></p> <p>Sharif Uddin, Ph.D., Principal Engineer Process Cleaning, <b>Rockline Industries</b></p>
2:15 - 3:00 PM	<p><b>Advancements in Cleanroom Technology: Explore Emerging Trends</b></p> <p>Cindy Duhigg, Global Process Validation Steward, <b>Alcon</b></p>
3:00 - 3:30 PM	Networking Refreshment Break and Exhibit Showroom
3:30 - 4:00 PM	<p><b>Bridging the Gap - Aligning Your Processes to the Annex 1 Update</b></p> <p>Amy Bradford, Principal Consultant-Quality/Micro, <b>CAI</b></p>
4:00 - 4:30 PM	<p><b>Harness Generative AI for Enhanced Cleanroom Validation, Disinfection, and Environmental Monitoring</b></p> <p>Arielle Musa, Microbiology Specialist, <b>Johnson &amp; Johnson</b></p>
4:30 - 5:00 PM	<p><b>Annex 1 &amp; Rapid Microbiological Methods</b></p> <p>Joscelyn Bowersock, Senior Director Quality Assurance and Regulatory <b>Precision for Medicine</b></p>
5:00 PM	Networking Cocktail Reception

8:00 - 9:00 AM	<b>Exhibitor Showroom Opens and Lite Breakfast</b>
9:10 - 10:00 AM	<b>Select Between Knowledge Exchange Sessions</b>
<b>Cleanroom Contamination Control</b>	<b>Celsis ATP Bioluminescence Technology for Rapid Sterility Testing</b> Nathan Wasilko, Ph.D, Scientist II, <b>Charles River Laboratories</b>
<b>Environmental Monitoring</b>	<b>Environmental Monitoring: Process Performance Qualification</b> Thomas Walker, Sr Principal Quality Engineer, <b>Alcon</b>
 <b>Cleaning Validation</b>	<b>Cleaning Validation Program Design - A Risk-based Lifecycle Approach</b> David W. Vincent MPH, Ph.D, Chief Scientific Officer, <b>VTI Life Sciences</b>
10:05 - 10:45 AM	<b>Select Between Knowledge Exchange Sessions</b>
 <b>Cleanroom Contamination Control</b>	<b>Performing Facility Annex 1 Compliance GAP Analysis</b> David W. Vincent MPH, Ph.D, Chief Scientific Officer, <b>VTI Life Sciences</b>
<b>Environmental Monitoring</b>	<b>Case Study: Machine Learning in Microbiology</b> Arielle Musa, Microbiology Specialist, <b>Johnson &amp; Johnson</b>
<b>Cleaning Validation</b>	<b>Unlocking 20 Years of Digital Cleaning Validation Wisdom: Key Lessons and Insights</b> Ravi Moorthy, President, <b>Quascenta</b>
10:45 - 11:00 AM	<b>Exhibitor Showroom and Refreshment Break</b>
11:10 - 12:00 PM	<b>Select Between Knowledge Exchange Sessions</b>
<b>Cleanroom Contamination Control</b>	<b>Disinfectant Efficacy Testing: A Critical Component of a Valid Contamination Control Strategy</b> Anthony Grilli, CEO & Owner, <b>FOCUS Laboratories</b>
<b>Environmental Monitoring</b>	<b>New ASTM Standards for Environmental Controls and Monitoring for ATPMs</b> David W. Vincent MPH, Ph.D, Chief Scientific Officer, <b>VTI Life Sciences</b>
 <b>Cleaning Validation</b>	<b>Hygienic Design Mastery: Elevate Your Cleaning Validation Standards</b> Sharif Uddin, Ph.D., Principal Engineer Process Cleaning, <b>Rockline Industries</b>
12:00 - 1:00 PM	<b>Lunch and Learn</b>


1:10 - 1:50 PM	Select Between Knowledge Exchange Sessions
Cleanroom Contamination Control	<p><b>Case Study: Global Implementation of Annex 1-Compliant Contamination Control Strategy</b></p> <p>Liz Brockson, Aseptic Processing &amp; Sterility Assurance Lead, <b>Takeda</b></p>
 Environmental Monitoring	<p><b>Automation in Environmental Monitoring</b></p> <p>Alexandra Bezilla, Project Manager, Technical Specialist, <b>SherpaPharma</b></p>
Cleaning Validation	<p><b>Hot Topics in Cleaning - Stainless Steel Equipment Maintenance and Air</b></p> <p><b>TBD</b></p>
2:00 - 3:00 PM	Liquid Interface Rings
3:10 - 3:50 PM	Select Between Knowledge Exchange Sessions
Cleanroom Contamination Control	<p><b>Navigating the Barriers Associated with Implementing Alternative Microbiological Methods</b></p> <p>Nathan Wasilko, Ph.D, Scientist II, <b>Charles River Laboratories</b></p>
Environmental Monitoring	<p><b>Perfecting Your Environmental Monitoring Program</b></p> <p>Alexandra Bezilla, Project Manager, Technical Specialist, <b>SherpaPharma</b></p>
Cleaning Validation	<p><b>From Surface to Success: Craft a Comprehensive Cleaning Validation Program</b></p> <p>Christiana Ellis, Cleaning Validation Manager, <b>Vertex Pharmaceuticals</b></p>
4:00 - 4:40 PM	Select Between Knowledge Exchange Sessions
 Cleanroom Contamination Control	<p><b>Contamination Control Strategy for Aseptic Environments - Program Development, Validation, Maintenance</b></p> <p>Liz Brockson, Aseptic Processing &amp; Sterility Assurance Lead, <b>Takeda</b></p>
Environmental Monitoring	<p><b>Qualifying Your Disinfection Program Using Environmental Monitoring</b></p> <p>Donald Singer, Senior Microbiology Technical Consultant, <b>Ecolab Life Sciences</b></p>
Cleaning Validation	<p><b>Revolutionize Cleaning Validation: Embrace the Modern Era</b></p> <p>Cindy Duhigg, Global Process Validation Steward, <b>Alcon</b></p>

4:50 - 5:00 PM	Exhibitor Showroom and Refreshment Break
5:00 - 5:30 PM	Select Between Knowledge Exchange Sessions
<p>Cleanroom Contamination Control</p>	<p><b>Mold and Microbial Contamination and Remediation</b>                  Daniel Klein, Senior Manager Microbiology and Clinical Affairs, <b>STERIS Corporation</b></p>
<p>Environmental Monitoring</p>	<p><b>Develop and Implement a Risk-based Non-sterile Program</b>                  Cindy Duhigg, Global Process Validation Steward, <b>Alcon</b></p>
<p> Cleaning Validation</p>	<p><b>Conduct a Gap Analysis of Your Cleaning Validation Program</b>                  Sunil Patel, Freelancer, <b>Industry Expert</b></p>
	<p>Close of Day Two</p>

8:00 - 9:00 AM	<b>Exhibitor Showroom Opens and Lite Breakfast</b>
9:10 - 9:50 AM	<b>Select Between Knowledge Exchange Sessions</b>
 <b>Cleanroom Contamination Control</b>	<b>Cross Contamination &amp; Smoke Studies</b> Dawn Marshall, Global Quality - Site Support, <b>Sanofi</b>
<b>Environmental Monitoring</b>	<b>Creating an Environmental Monitoring Program for Isolator Units</b> Thomas Walker, Sr Principal Quality Engineer, <b>Alcon</b>
<b>Cleaning Validation</b>	<b>Efficiency Unleashed: Strategies for Streamlining Cleaning Validation Processes</b> Christiana Ellis, Cleaning Validation Manager, <b>Vertex Pharmaceuticals</b>
10:00 - 10:40 AM	<b>Select Between Knowledge Exchange Sessions</b>
<b>Cleanroom Contamination Control</b>	<b>Fungi and Challenging Contamination</b> Daniel Klein, Senior Manager Microbiology and Clinical Affairs, <b>STERIS Corporation</b>
<b>Environmental Monitoring</b>	<b>Qualifying Critical Utility Systems</b> Mike Westerman, VP of CQV and Compliance Services, <b>IPS-Integrated Project Services</b>
 <b>Cleaning Validation</b>	<b>Don't Miss a Spot! – Documentation Best Practices in Cleaning Validation</b> Christiana Ellis, Cleaning Validation Manager, <b>Vertex Pharmaceuticals</b>
10:45 - 11:00 AM	<b>Exhibitor Showroom and Refreshment Break</b>
11:10 - 12:00 PM	<b>Select Between Knowledge Exchange Sessions</b>
<b>Cleanroom Contamination Control</b>	<b>Overview of Rapid Microbiological Method Groups: Advantages and Drawbacks</b> Anthony Grilli, CEO & Owner, <b>FOCUS Laboratories</b>
 <b>Environmental Monitoring</b>	<b>Craft an Effective Environmental Monitoring and Contamination Control Strategy</b> Liz Brockson, Aseptic Processing & Sterility Assurance Lead, <b>Takeda</b>
<b>Cleaning Validation</b>	<b>Decode Disinfectants and Cleaning Materials: A Comprehensive Exploration</b> Dawn Marshall, Global Quality - Site Support, <b>Sanofi</b>
12:00 - 1:00 PM	<b>Lunch and Learn</b>



1:10 - 1:50 PM		Select Between Knowledge Exchange Sessions
Cleanroom Contamination Control	<b>Establish a Contamination Control Strategy</b> Marsha Steed, Sr. Consultant, JYA and Founder & President, <b>Steed MicroBio LLC</b> Sheba Zaman, Head of Product Specialists and Training Services, <b>Novatek International</b>	
 Environmental Monitoring	<b>Analyzing Environmental Monitoring Data</b> Arielle Musa, Microbiology Specialist, <b>Johnson &amp; Johnson</b>	
Cleaning Validation	<b>Optimizing Spray Coverage and Routine Monitoring: Insights for Enhanced Validation</b> Sharif Uddin, Ph.D., Principal Engineer Process Cleaning, <b>Rockline Industries</b>	
2:00 - 3:00 PM		Select Between Knowledge Exchange Sessions
 Cleanroom Contamination Control	<b>Management of Contamination Risks</b> Cindy Duhigg, Global Process Validation Steward, <b>Alcon</b>	
Environmental Monitoring	<b>Conduct an Audit of Your Environmental Monitoring Program</b> Joscelyn Bowersock, Senior Director Quality Assurance and Regulatory, <b>Precision for Medicine</b>	
Cleaning Validation	<b>Handling In-Direct &amp; Non-Product Contact Surfaces</b> Ravi Moorthy, President, <b>Quascenta</b>	
3:10 - 3:20 PM		Exhibitor Showroom and Refreshment Break
3:30 - 4:10 PM		Select Between Knowledge Exchange Sessions
 Cleanroom Contamination Control	<b>Current Regulatory Inspection and Enforcement Trends for Cleaning &amp; Disinfection</b> Donald Singer, Senior Microbiology Technical Consultant, <b>Ecolab Life Sciences</b>	
Environmental Monitoring	<b>Navigate the Challenge of Accurate Microbial Identification</b> Ratul Saha Ph.D., Director, Global Sterility Assurance Programs, <b>Bausch &amp; Lomb</b>	
Cleaning Validation	<b>Controlling Aseptic Simulation (Media Fill) Processes as Part of Your Master Plan</b> Neal Schmidt MS PMP, Senior Manager of Validation, <b>Resilience</b>	

4:20 - 5:00 PM	Select Between Knowledge Exchange Sessions
Cleanroom Contamination Control	<p><b>Cleanroom Chemistries – What and why?</b>                  Daniel Klein, Senior Manager Microbiology and Clinical Affairs, <b>STERIS Corporation</b></p>
 Environmental Monitoring	<p><b>Techniques for Monitoring Passivation and Derouging</b>                  Ratul Saha Ph.D., Director, Global Sterility Assurance Programs, <b>Bausch &amp; Lomb</b></p>
Cleaning Validation	<p><b>Cleaning Efficiency: Reduce Costs and Environmental Impact for a Greener Future</b>                  TBD</p>
	Close of Day Three

Conference Schedule

# 2024

March 5 -6	<p><b>Validation University</b>                  Singapore</p>	
April 23 - 25	<p><b>Validation University</b>                  San Diego, CA</p>	September 25 <b>Validation Statistics Summit</b> Virtual
June 4 - 6	<p><b>Laboratory University</b>                  Philadelphia, PA</p>	October 17 <b>PSDG Stability Testing Special Focus Training</b> Virtual
June 26 - 27	<p><b>Lean Validation</b>  <b>Computer Software Assurance Implementation</b>  <b>Digitalization Implementation &amp; Validation</b>                  Philadelphia, PA</p>	October 22 - 24 <b>GMP University</b> RTP, North Carolina
August 6 -8	<p><b>Cleanroom Contamination Control</b>  <b>Environmental Monitoring</b>  <b>Cleaning Validation</b>                  San Diego, CA</p>	November 12 - 14 <b>Validation University Europe</b> Dublin, Ireland
September 17 - 19	<p><b>Validation &amp; Verification</b>  <b>Medical Device</b>                  Chicago, IL</p>	December 10 - 12 <b>CSV &amp; CSA University AI Implementation &amp; Validation</b> Washington D.C



# REGISTRATION

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