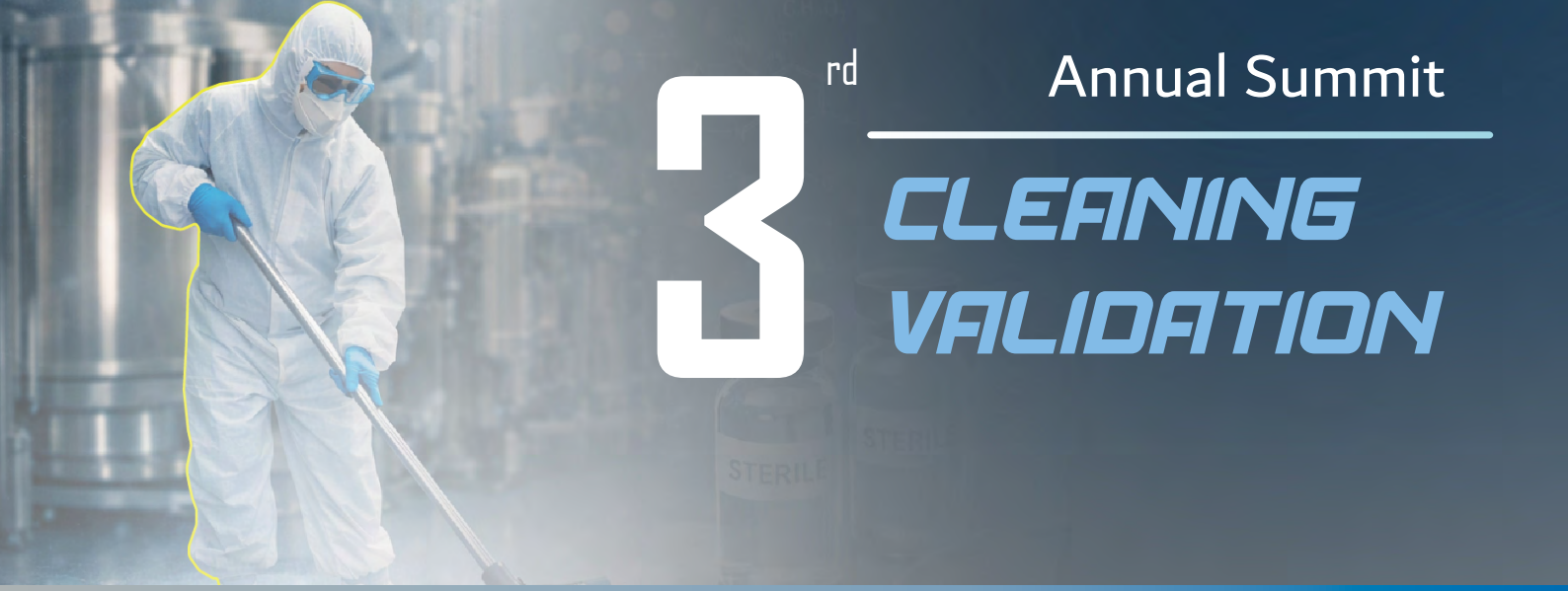

3rd Annual Summit

CLEANING VALIDATION

virtual | May 28th - 29th, 2026

Key Speakers:

3:30pm IST / 12:00pm CET / 6:00am EST

Thomas Altmann, DE
Global Technical Consultant
Ecolab Deutschland GmbH

Joe Cagnassola, USA
Sr Technology Transfer Leader
Fresenius Kabi, LLC

Ram Kouda, USA
Scientific Associate Director
Amgen

Jenna Carlson, USA
President & Quality Consultant
Mindful Quality

Elizabeth Dallison, UK
Analytical Chemist
Pfizer (Retired)

Brian Bosso, USA
Technical Service Manager
STERIS

Fred Ohsiek, USA
Associate Director of Cleaning Validation
Eliquent Life Sciences

Andrew Walsh, USA
President
Center for Pharmaceutical Cleaning Innovation (CPCI™)

Michael Moussourakis, USA
Vice President of Strategy
Alconox, LLC

Ester Lovsin Barle, CH
Global Head PSS
Takeda

Mariann Neverovitch, USA
Sr. Manager Logistics Operations
Bristol-Myers Squibb

Virginie Breugnon, CH
Cleaning Validation Lead
Biogen

Rizwan Sharnez, USA
Founder and Owner
Cleaning Validation Solutions

Susan Malkin, USA
Vice President, AI/ML Compliance platforms
Global Financial Institution

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3rd Annual Summit
CLEANING VALIDATION

virtual May 28TH - 29TH, 2026

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Antoinette Ryan, USA
Vice President Quality Assurance
Controlled Contamination Services

Antoinette Ryan is a Quality Assurance executive with 20+ years of experience in GMP-regulated industries, including biopharma, medical devices, and nuclear medicine. She currently serves as Vice President of Quality Assurance at Controlled Contamination Services, where she leads enterprise-wide QMS, compliance, and audit readiness programs. She has led successful FDA PAIs, implemented enterprise eQMS systems, and consistently driven improvements in training compliance, audit performance, and organizational effectiveness. Antoinette is particularly passionate about strengthening quality culture and developing high-performing teams in complex, regulated environments.

CONFERENCE OVERVIEW

From Fundamentals to Lifecycle Control in a High-Scrutiny Environment

Join us for the 3rd Annual Cleaning Validation Summit, a two-day virtual event dedicated to the latest regulatory expectations, best practices and real-world challenges in pharmaceutical cleaning validation. Building on the success of the 2025 edition, the 2026 summit reflects how the industry has evolved in response to increased regulatory scrutiny, Annex 1 implementation, digital transformation and more complex product portfolios.

Day 1 reinforces core principles and regulatory alignment, incorporating inspection trends observed in 2025.
Day 2 focuses on advanced lifecycle management, risk-based decision-making, automation and complex case studies, supporting sustainable, inspection-ready cleaning validation programs.

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12:00 - 12:05 Registration

12:05 - 12:10 Opening Address from the Organizer

Fundamentals & Regulatory Expectations (Updated for 2026)

12:10 - 12:40

Virginie Breugnon, CH
Cleaning Validation Lead
Biogen

Cleaning Validation Lifecycle Approach

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12:40 - 12:50 Short Break

12:50 - 13:20

Elizabeth Dallison, UK
Analytical Chemist
Pfizer (Retired)

Analytical & Microbiological Methods for Cleaning Validation

- Analytical techniques (HPLC, TOC, UV-Vis) and rapid methods.
- Validation of analytical methods.
- Recovery studies.
- Microbiological testing.

13:20 - 13:30 Short Break

13:30 - 14:00

Ester Lovsin Barle, CH
Global Head PSS
Takeda

Alignment of limits set for cross-over contamination and occupational exposure

- Clarifying two safety paradigms: Explain how PDE and OELs are derived.
- Understanding why limits diverge: Highlight how differences can lead to large PDE–OEL mismatches.
- Equipping experts for inspections: Provide inspection-ready guidance on articulating the scientific rationale behind both limit types.

14:00 - 14:10 Short Break

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14:10 - 14:40

Fred Ohsiek, USA
Associate Director of Cleaning Validation
Eliquent Life Sciences

ELIQUENT LIFE SCIENCES

Cleaning Validation Documents, including Protocols and Inspection-Readiness

- Minimum regulatory expected cleaning validation documents.
- Essential elements of modern cleaning validation protocol.
- Aligning acceptance criteria with toxicology and analytical capability.
- Common documentation gaps identified during inspections.

14:40 - 15:00 Break

15:00 - 15:30

Fred Ohsiek, USA
Associate Director of Cleaning Validation
Eliquent Life Sciences

ELIQUENT LIFE SCIENCES

Product and Equipment Grouping

- Quick review of regulatory expectations.
- Spray coverage equipment grouping.
- Product bracketing.
- Equipment grouping.
- Equipment grouping case study.

15:30 - 15:40 Short Break

15:40 - 16:10

Jenna Carlson, USA
President & Quality Consultant
Mindful Quality

MINDFULQUALITY

Regulatory & Inspections Trends Update

- FDA, EMA and PIC/S expectations for cleaning validation in 2026.
- Key inspection observations and deficiencies seen in 2025.
- How to proactively address recurring regulatory findings.

16:10 - 16:20 Short Break

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16:20 - 16:50

Michael Moussourakis, USA
Vice President of Strategy
Alconox, LLC

CIP Detergents and pH: To Hazmat or not to Hazmat

A review of general cleaning gen¬eral cleaning concepts, chemistry, and detergency. Aqueous detergent cleaning will be reviewed with a detailed focus on automated CIP (Clean-In-Place) cleaning methods, associated pros and cons, and the nature of such detergents. The types of surfactants, and related chemistries being used. The necessary pre and post cleaning steps, vital to any cleaning application are presented as a lifestyle ap¬proach. 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 prac¬tice in post cleaning—long after the final rinse has been completed. Finally, a recent automated cleaning validation of a dermatological 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.

16:50 - 17:00 Short Break

17:00 - 17:30

Andrew Walsh, USA
President
CPCI™

Qualification of Operators and Inspectors for Visual Inspection following ASTM E3263

- What is ASTM E3263.
- EMA requirements for justifying Visual Inspection.
- Selection of Products and Materials of Construction for Visual Inspection studies.
- Using Attribute Agreement Analysis for Qualification.
- Automation of Qualification using Cell Phone APP.

17:30 - 17:40 Short Break

17:40 - 18:10

Mariann Neverovitch, USA
Sr. Manager Logistics Operations
Bristol-Myers Squibb

Analytical Approach for Implementation of Visual Inspection

- Visual inspection following equipment cleaning is a mandatory step in the cleaning verification workflow for pharmaceutical equipment. Equipment must pass visual inspection before swab sampling for analysis can be performed.
- Since a significant number of low-risk compounds are visible well below established safety levels, it is possible to justify equipment as “visually clean” without performing swabbing analysis. Internal studies performed at BMS showed that over 90% of participants could identify residual product at a level of ~2 ppm without preliminary training.
- The implementation of a robust visual inspection qualification program and clear “Visually Clean” inspection parameters can enable visual inspection to be used to qualify equipment in lieu of swab analysis for low-risk products.

18:10 - 18:20 Organizer’s closing remarks and end of day one

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12:00 - 12:05 Registration

12:05 - 12:10 Opening Address from the Organizer

Advanced Topics, Lifecycle Management & Case Studies

12:10 - 12:40

Thomas Altmann, DE
Global Technical Consultant
Ecolab Deutschland GmbH

Cleaning process development and cleaning agent selection

- Regulatory expectations.
- Laboratory bench scale studies / cleanability trials.
- Implementation of cleaning process on-site.
- Levels of cleaning and level of documentation requiered.

12:40 - 12:50 Short Break

12:50 - 13:20

Thomas Altmann, DE
Global Technical Consultant
Ecolab Deutschland GmbH

Limit setting and visual clean – how does this fit together?

- Limit calculation for cleaning validation (HBEL, fixed limits, TTC).
- Points to consider for limit setting.
- Visual clean - regulatory requirements.
- Determination of visual residues limit (VRL).
- Case study Paracetamol and visual clean.

13:20 - 13:30 Short Break

13:30 - 14:00

Joe Cagnassola, USA
Sr Technology Transfer Leader
Fresenius Kabi, LLC

Risk-Based Cleaning Validation in Complex Facilities

- Applying FMEA and other risk assessment tools.
- Risk ranking, control strategies and justification.
- Managing shared equipment and multiproduct facilities.
- Case study: defending risk-based decisions during inspections.

14:00 - 14:10 Short Break

14:10 - 14:40

Brian Bosso, USA
Technical Service Manager
STERIS

Process Analytical Technology (PAT) in Cleaning Validation

- Real-time monitoring techniques.
- Analytical methods in PAT for in-line, on-line and at-line testing.
- Bridging lab scale and full-scale testing.
- Case Studies for PAT in Cleaning Validation.

14:40 - 15:00 Break

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15:00 - 15:30

Antoinette Ryan, USA
Vice President Quality Assurance
Controlled Contamination Services

The Human Factor in Cleaning Validation

- Why the human factor matters.
- Training does not equal competency.
- Behavioral Drift.
- Engineering controls.
- Annex 1 tie-in.

15:30 - 15:40 Short Break

15:40 - 16:10

Rizwan Sharnez, USA
Founder and Owner
Cleaning Validation Solutions

Degradation of therapeutic proteins during cleaning: Implications for setting acceptance limits for cleaning validation

-

16:10 - 16:20 Short Break

16:20 - 16:50

Ram Kouda, USA
Scientific Associate Director
Amgen

Extending Visible Residue Limits to Potent Therapeutic Proteins: Replacing TOC Swab Testing with a Scientifically Justified Visual Approach

- Assessed whether VRL-based visual inspection can replace TOC swab testing for protein cleaning validation.
- Tested mAbs, fusion proteins, and BiTEs under controlled worst-case viewing conditions.
- Native vs Degraded protein Visual residue limit assessment.
- Demonstrated VRLs translate to TOC values within current acceptance limits, supporting VRL as a viable alternative.

16:50 - 17:00 Short Break

17:00 - 17:30

Susan Malkin, USA
Vice President, AI/ML Compliance platforms
Global Financial Institution

Use of computer vision models to assist with cleaning validations

- Overview of computer vision models.
- How to build a model for cleaning validation.
- How computer vision models can help with cleaning validation.

17:30 - 17:40 Organizer's closing remarks and end of day two

Speakers Biographies

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Thomas Altmann

Global Technical Consultant

Ecolab Deutschland GmbH

Thomas has 27 years' experience in cleaning chemistry, cleaning process, cleaning validation and regulatory compliance. As Strategic Global Technical Consultant, he provides technical consultation on cleaning and sanitization processes optimization for pharmaceutical, API, biotechnology and personal care manufacturers globally. In his role Thomas is a subject matter expert in cleaning validation for product contact surfaces across all types of pharmaceutical and personal care production equipment.
Thomas is a member of ASTM E55 WK15778 Cleaning Process Development & Validation Team and worked on ASTM E3106 Risk-based Cleaning Validation Process Standard what was published 2018 and updated 2022. Additionally he is an active member of Parenteral Drug Association (PDA) and currently working on Cleaning Validation Process updates like the Technical Report 29.
Based on the participation in variouse working groups he is a co-author of different publications. Especially the series „Cleaning Validation for the 21st Century" series on Pharmaceutical online and he published lately in journals like PharmInd in Germany, Bioprocess online and Biopharma International.

Elizabeth Dallison

Analytical Chemist

Pfizer (Retired)

Liz Dallison has over 20 years experience in Cleaning Validation for the Pharmaceutical industry. She holds a BSc in Analytical Sciences from the University of Greenwich. Her expertise in cleaning validation was gained in Pfizers investigational medicinal products facility at Sandwich. Liz has a breadth of knowledge on the subject with particular expertise in the analysis of cleaning validation samples and the validation of the methods required.
Liz led a team providing analytical support for residue testing following both solid and liquid dosage manufacturing.
Liz has spoken at previous conferences and was one of the contributors to the ISPE Cleaning Validation Lifecycle – Application, Methods and Controls guidance. After over 30 years service, Liz retired from Pfizer in 2024.

Brian Bosso

Technical Service Manager

STERIS

Brian Bosso is a Technical Services Manager for STERIS Life Sciences. He has responsibility for providing global technical support for pharmaceutical detergents and critical environment products and their application and validation. Brian has over 15 years of experience in the pharmaceutical and biopharmaceutical industries in North America, Europe and Asia. He has held supervisory and management positions with responsibilities in areas including developing and implementing cleaning validation process lifecycle, process design, analytical method development and validation, GMP quality and regulatory remediation. Brian also managed the Technical Services Analytical team based in St. Louis, MO. He earned a Bachelor of Science degree in chemistry from the Colorado School of Mines.

Joe Cagnassola

Sr Tech Transfer Leader

Fresenius Kabi, LLC

Joe Cagnassola currently holds the position of a Tech Transfer Leader with Fresenius-Kabi.
In this position, Joe participates in the validation of cleaning, , tech transfers and processes qualifications.
He is active in performing qualifications protocols, writing Master Plans and remediation and optimization efforts of process related activities.
During his career, Joe has held validation position of increasing responsibility with, Cardinal , Mallinckrodt, Pfizer, Merck and Alcon.
Joe has professional interests in ASQ, he obtained his Certified Quality Engineer and Auditor Certifications and has been trained in Six Sigma and Lean. His work supporting various Quality initiatives has provided him a unique experience and insight into the challenges in today's fast paced pharma environment. Joe earned his Bachelor's of Science in Biology from Arizona State University.

Jenna Carlson

President & Quality Consultant

Mindful Quality

Jenna Carlson is a Cleaning Validation Subject Matter Expert (SME) with over 27 years of experience working in corporate, site, and external manufacturing roles throughout the US, Europe, & Asia. While working in various Validation and Quality Assurance roles, Jenna has gained extensive knowledge of global cGMP requirements and best practices. Jenna has a proven track record, including development of Corporate and Site Cleaning Programs, supporting Regulatory Inspections, Observations, Untitled Letters, Complete Response Letters, and Warning Letters. She has also been instrumental in developing and remediating cleaning programs throughout her career. Jenna has co-authored PDA Technical Reports #29 and #49, Cleaning & Cleaning Validation Volume 1, and various other articles.

Fred Ohsiek

Associate Director of Cleaning Validation

Eliquent Life Sciences

Fred Ohsiek who earned his BS in Chemistry from University of South Florida, resides in the NC RDU area. He has 25 plus years of validation experience as an FTE and Consultant, while specializing in cleaning validation.
He has been fortunate to work for 7 major pharmaceuticals (Catalent, AstraZeneca, Boehringer Ingelheim, Teva, Astellas, Bayer, and Novo Nordisk) where he was considered the cleaning validation SME in most of his roles. Working with various routes of administration (OSD, parenteral, topical, and softgels) in green and brown field small and large molecule manufacturing projects has provided Fred with a very broad range of experience.
Fred also obtained "cleaning chemistry" experience while working as a Sr Global Technical Manager at Ecolab (Life Science division).
As Associate Director of Cleaning Validation at Eliquent Life Sciences, he and his team support industry by authoring tailored justifications, reducing the validation footprint via risk assessments, creating startup CV programs, remediating legacy processes, and increasing manufacturing capability.
He was one of the authors of the ISPE Cleaning Validation Lifecycle – Application, Methods, and Controls guidance, and he regularly presents at conferences nationally and globally.

Speakers Biographies

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Ram Kouda

Scientific Associate Director

Amgen

Ram Kouda has more than 10 years of experience of leading Validation and engineering teams in Pharmaceutical/Biopharmaceutical and Medical Device industries. Ram holds PhD in Chemical Engineering.

As an Associate Scientific Director in Amgen, Ram is leading Amgen Cleaning program as an SME, his team is supporting the assessment of Amgen clinical and Commercial Biological Molecules prior to manufacturing in Multiproduct facility. He has experience of successfully defending Validation programs as SME of different regulatory agencies in Biopharmaceutical and Medical Device industry.

Ram led several scientific initiatives supporting multiproduct manufacturing in same facility, it resulted in several industry-first scientific data and multiple Manuscripts.

Andrew Walsh

President

CPCI™

Andrew Walsh is President of the Center for Pharmaceutical Cleaning Innovation (CPCI™) a not-for-profit research and educational organization and laboratory whose purpose is to support companies in the implementation of new ASTM Pharmaceutical Cleaning Standards. CPCI™ supports companies through research into new technologies (2 patents), educational offerings and internship opportunities for students. Andrew teaches a week long “hands-on” Cleaning SME class at CPCI™ and published a 400+ page textbook «Cleaning Validation: Science, Risk and Statistics-based Approaches» in 2022 to accompany the course.

Andrew has taught Cleaning Validation at the Temple University School of Pharmacy Regulatory Affairs and Quality Assurance Program since 2019. Andrew was also an Industry Professor from 2008 - 2015 in the Pharmaceutical Manufacturing and Engineering Graduate Program at Stevens Institute of Technology where he created and taught courses in Pharmaceutical Validation and Lean Six Sigma. While at Stevens, Andrew also founded and directed the Stevens Pharmaceutical Research Center (SPRC) from 2009 - 2015 which focused on Cleaning and Cleaning Validation topics.

Andrew is very active in developing industry consensus standards with ASTM International and has led teams that have written 9 Pharmaceutical cleaning standards.

Andrew has an M.S. in Biology (Microbiology) and is a certified Lean Six Sigma Black Belt and an Accredited Trainer.

Susan Malkin

Vice President, AI/ML Compliance platforms

Global Financial Institution

Susan Malkin is a senior technology leader with over 20 years of experience delivering innovative solutions across the financial services industry. She has built and led high-performing engineering and AI teams, focusing on developing scalable, data-driven systems in complex, regulated environments.

In addition to her work in financial services, Susan has applied advanced machine learning techniques to industrial and scientific challenges. She developed a computer vision model for residue detection.

Currently, Susan leads AI/ML initiatives in market surveillance, building advanced systems to detect market manipulation and enhance compliance through machine learning, LLMs, and agentic AI workflows.

Ester Lovsin Barle

Global Head PSS

Takeda

Ester Lovsin Barle is a global leader in product sustainability and stewardship, work experience to over 30 years, including 19 years in the pharmaceutical industry. She holds a DVM, MSc, PhD, and MScTox degrees, and has extensive expertise in toxicology, occupational health, and environmental sustainability. Ester is the chair of ISPE Sustainability CoP.

Michael Moussourakis

Vice President of Strategy

Alconox, LLC

Michael Moussourakis is Vice President of Strategy at Alconox, LLC headquartered in White Plains, NY, responsible for Marketing and Technical Support, and Corporate Strategy. The Marketing and Technical Support teams provide cleaning related support, guidance, and product leadership to Alconox, LLC customers for their critical cleaning needs. They take great pride in ensuring Alconox, LLC’s products, procedures and information meet and exceed cleaning market requirements. He has over 25 years of experience in the biotech, pharmaceutical, medical device, and laboratory industries.

Through various and progressive roles in hands-on technical services, marketing, product management, commercial development, and corporate strategy, he has contributed to industry via publications, training, talks, and committee participation. Michael’s technical expertise covers critical cleaning, filtration, and process troubleshooting. Michael holds a BS and MS in Biomedical Engineering from the Columbia University School of Engineering and Applied Science.

Mariann Neverovitch

Sr. Manager Logistics Operations

Bristol Myers Squibb

Mariann Neverovitch, MS Pharmacy

Research Scientist at Bristol-Myers Squibb with over 20 years of experience in HPLC method development and validation for drug product, API and intermediates.

Cleaning Validation Subject Matter Expert with 15+ years of experience in cleaning verification method development and support. Since 2010 leading cleaning verification program in Support of Clinical Supply Operations

Presented a number of papers on integrated approach in method development, analytical support, and challenges in life cycle management of analytical methods for determination of residual product on the equipment, and development and implementation of visual inspection program.

Co-Author of ASTM WK15778 «Standard Guide For Science-based and Risk-based Cleaning Process Development and Validation» and number of articles for Cleaning Validation For the 21 Century series

Member of Eastern Analytical Symposium (EAS) Governing Board

Member of United States Pharmacopoeia (USP) Expert Committee

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