



ISPE

San Francisco |
Bay Area Chapter



ISPE

Greater Los Angeles
Area Chapter



TWO-PART WEBINAR ON CLEANING VALIDATION

COMPLIMENTARY FOR MEMBERS AND NON-MEMBERS

This webinar will address strategies, approaches and challenges to improving cleaning processes. Learn about the latest topics in regulatory enforcement, best practices and designs for CIP, and SIP technologies in cleaning validation.



Part 1: Developing and Implementing a Robust Cleaning Process

**Tuesday, September 15, 2020
Noon - 1:30 PM**



Part 2: Automated Cleaning Procedures and Validation of Automated Cycles

**Wednesday, September 16, 2020
Noon - 1:30 PM**

Register [Here](#) Today!

Format: GoToWebinar

(Instructions to join will be emailed one day prior)

Program Managers:

Ian Bruns, Sales Engineer, Biotechnical Solutions
Paul Crissman, Principal, Biotechnical Solutions

Speakers:

Part 1: Chris McNulty,
Director of Business Dev - Bio-Pharm, Sani Matic

Moderator:

Justin Cantor, Chief Strategy Officer, PSC Biotech

Part 2: Rebecca Brewer,
VP Strategic Practices, Quality Executive Partners

CLEANING VALIDATION

Part 1: Developing and Implementing a Robust Cleaning Process

Chris McNulty, Director of Business Development - Bio-Pharm, Sani-Matic



Chris is an instructor for the ISPE Clean-In-Place course and has co-instructed with Becky Brewer on numerous occasions. He is responsible for leading Sani-Matic's sales team and their customers through the complex BioPharm regulatory landscape and generating detailed system cleaning approaches to meet industry standards and customer-specific processes. He is driven by the desire to solve problems for customers and ensure they meet regulatory requirements. His experience spans more than 30 years including field commissioning and program development while also serving as an electrical project engineer and technical services manager.

Topics to be Covered:

- CIP Technologies – Examination of the current state of the art for CIP design and management
- Spray Device Technologies – Overview of spray device technologies and spray device limitations when integrating them into CIP processes
- Integrating CIP into a Process – Examination of the challenges of integrating CIP into various processes and ensuring an effective cleaning program

Part 2: Automated Cleaning Procedures and Validation of Automated Cycles

Rebecca "Becky" Brewer, VP Strategic Practices, Quality Executive Partners

Becky is the course instructor for the ISPE Cleaning Fundamentals class, and co-instructor with Chris McNulty for the ISPE Clean-In-Place course. She also teaches the PDA course on Cleaning Validation for Biotechnology. As VP Strategic Practices for Quality Executive Partners Becky works with customers to develop sustainable, compliant cleaning validation programs across various manufacturing environments, including biotech, traditional pharma, API production, medical device and in-vitro diagnostics. Becky has more than 30 years in the industry. She previously worked for Dober Chemical Corporation, Raytheon Engineers & Constructors and Bristol-Myers Squibb.



Topics to be Covered:

- Cleaning Validation Limits – Overview of the current industry guidance on cleaning validation limits and practical tips on incorporating the new limits into existing programs
- Sampling Methods and Limitations – Take a fresh look at what the limitations are for swab and rinse sampling along with lessons learned on recovery studies
- Cleaning Validation Considerations for Automated Equipment – Points to consider when validating cleaning processes for automated equipment; the considerations from equipment qualification to process validation
- Cleaning Agent Selection, Product / Process Grouping, and Scale-Up Studies – Consideration of Quality by Design elements from the outset of cleaning agent selection, product and process grouping through scale-up and eventual validation

Complimentary Webinar for ISPE Members and Non-Members

Two Part Cleaning Webinars

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Moderator: Justin Cantor, Chief Strategy Officer, PSC Biotech

Speakers:



Part 1:
Chris McNulty
Director of Business Development - Bio-Pharm
Sani-Matic



Part 2:
Rebecca Brewer
VP Strategic Practices
Quality Executive Partners

Background:

This webinar will address the challenges and strategic approaches to improve your cleaning processes. Learn about current cleaning topics in regulatory enforcement as well as best practices and design for CIP, CIP technologies and points to consider for cleaning validation.

ISPE Cleaning Validation Principles and Additional ISPE Training Courses:

ISPE offers in-depth training on a variety of technical topics. A four-day training by Rebecca Brewer, “Cleaning Validation Principles”, will be held online September 21-24, 2020. Here is the link for more information:

<https://ispe.org/training/course/cleaning-validation>

Visit ISPE’s website for additional training courses: <https://ispe.org/training/course>

Two Part Cleaning Webinars

About the Speakers and Topics To Be Covered:

Part 1: Developing and Implementing a Robust Cleaning Process Tuesday, September 15, 2020



Chris McNulty, Director of Business Development - Bio-Pharm, Sani-Matic

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Part 2: Automated Cleaning Procedures and the Validation of Automated Cycles Wednesday September 16, 2020



Rebecca "Becky" Brewer, VP Strategic Practices, Quality Executive Partners

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ISPE San Francisco/Bay Area Chapter

<http://www.atdevents.net/register.php>

Registration Instructions

Please note that our system does not email confirmations for complimentary events, however, you will receive a link to join the day before the webinar.

- 1) Click on the link then log on using your username and password: <http://www.atdevents.net/register.php>
- 2) Click on the appropriate event. Here is where you can download the event flyer also.
- 3) Scroll through the list of registration options and find the one that applies to you then complete the registration. Our site does not send confirmation emails for complimentary events, however, the link to join the webinar will be emailed to you the day before the webinar.

ISPE California Chapter Members:

If you are an ISPE Member in California, please do not set up a new account, as you should already be in our system (takes a few days after joining). You will need your username and password to log on.

How To Find Your ISPE Member Number or Update Your Account to a Member Account:

To update your existing account to a Member account, or to add your new ISPE Member account to our website, please forward your confirmation email from ISPE or your ISPE Membership information to Rob Fleming (rob.fleming@yahoo.com). We need your Chapter name, your ISPE Member number and expiration date. To retrieve this information, log onto the ISPE website. Click on "Account" on the top right side, then "My Account". Your Membership information (not including your chapter affiliation) is on the left side. Please take a screen shot or make a pdf of the page, then email it along with the name of your chapter to Rob Fleming to update your profile on the atdevents.net site.

ISPE Members of Other Chapters:

You will not be in our system unless you have previously set up an account. Please follow instructions for Non Members below then follow the instructions to update your account to a member account (see above).

Non Members:

If you do not have an account, you can set one up on the site using letters (not numbers) as your username.

HELP: Please email Rob Fleming (rob.fleming@yahoo.com) for assistance with registration.

ISPE San Francisco and Los Angeles Chapters
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