




2-day In-person Seminar:

The A to Z's of Microbial Control, Monitoring, Validation and Troubleshooting of Pharmaceutical Water Systems for Bio-pharma, Medical Devices and Cosmetics Industries

-  Washington, DC
-  June 7th & 8th, 2018
-  9:00 AM to 6:00 PM



Teri C. Soli

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T.C. Soli is a Ph.D. Microbiologist and President of Soli Pharma Solutions, Inc. offering troubleshooting and training expertise covering water systems, sterilization, sterile and non-sterile manufacturing, microbiological laboratories, and microbial and beta-lactam contamination control. He has 39 years of pharmaceutical experience as a consultant and with operating companies including DSM Pharmaceuticals, Glaxo Wellcome, Burroughs Wellcome, and Pfizer.

His career-long water systems and contamination troubleshooting experience, coupled with water-related USP, ISPE, PhRMA, and PDA committee involvements, afford him practical knowledge about contamination control; cleaning, sterilization and process validation; and all aspects of high purity water systems.

Overview :

This course is designed to provide a microbiology-focused education about all aspects of water systems and how biofilm manages to thrive there. Prior microbiological education or training, though a plus, is not a requirement because engineers and other non-biologists also need this training if they are involved with any aspect of water systems. The instructor will provide the necessary background needed to understand this very important subject matter. This understanding is essential to the proper design, validation, operation, monitoring, maintenance, troubleshooting, and excursion investigations of a high purity water system. Without this understanding, water system control consists of a set of rules that often don't work and can cause very costly system downtime or even product recalls, and leaves the user without a clue as to what went wrong or how to effectively fix it so it doesn't recur.

Price

Price: **\$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **\$4,485.00** You Save: \$2,990.0 (40%)*
~~\$7,475.00~~

Register for 10 attendees

Price: **\$8,222.00** You Save: \$6,728.0 (45%)*
~~\$14,950.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Agenda:

Day One

Lecture 1. 3 hrs:

Controlling Water System Biofilm Through Design & Operation

- Microbial control - where and why it matters
- Biofilm basics and how it develops
- Biofilm impact on "active" surfaces
- Environmental resistances of biofilm
- Biofilm impact on purification unit operations and how to control it
- Good design practices to control biofilm
- Good maintenance practices to control biofilm

Lecture 2. 90 min:

Successful Sanitization Approaches for Trouble-Free Water Quality

- Material and construction limitations
- Continuous vs intermittent sanitization
- The importance of biofilm removal
- How sanitants work (or don't work)
- When to sanitize
- Common sanitization failure causes and troubleshooting sanitization problems

Lecture 3. 90 min:

Water System Validation by Logic Instead of Tradition

- Why validate a water system?
- Basic ground rules for water systems before you validate them
- Minimum validation expectations
- What happens after the honeymoon is over
- Making changes to a validated water system
- Special considerations for lab water systems
- Are packaged waters a viable option?

Lecture 4. 60 min:

Understanding and Controlling Endotoxin

- Where does endotoxin come from?
- What are the properties of endotoxin ?
- How do you get rid of it?
- How do you detect it?
- What assay controls are used?
- What are the endotoxin specs for water?
- How do you control it?

Day One

Lecture 5. 60 min:

Harmonizing vs Optimizing Water Microbial Testing for System Quality Control

- Water harmonization that has occurred
- Water Micro TM "Dis-Harmonization"
- Biofilm diversity in water systems
- The good and bad of Micro harmonization
- Where RMMs can fit in

Day Two

Lecture 6. 90 min:

Microbial Enumeration Issues with High Purity Water Systems

- Biofilm enumeration issues (planktonic vs surface)
- Purpose of sampling and testing (PC vs QC)
- Traditional cultivative approach issues
- Validation of your test method
- Alternative RMM choices (advantages/disadvantages)
- Significance of water isolates

Lecture 7. 90 min:

Reducing Water Microbial Excursions & Improving Investigations

- What are excursions?
- Water system dilemma: process control or quality control (utility or raw material), or both
- Intended roles of Alert/Action Levels and Specifications
- Investigation, necessary and often fruitless
- Excursion responses and impact
- Criticality of valves, hoses, & outlet flushing
- Diagnosing the source of the problem
- Minimizing unnecessary excursion responses through best practices

Lecture 8. 90 min:

Water System Investigation "How-To's" and Example Case Studies

- Early information; user opinions
- Investigation approach elements
- Water system contamination case studies
 - The Beige Puddle
 - "TNTC"
 - High TOC
 - The Sloppy Lab
 - Flanged PolyPro System
 - The Stealthy Dead Leg
- Parting kernels of water system wisdom

Agenda:

Day Two

Lecture 9. 90 min:

Myths of Water System Biofilm Control and Microbial Monitoring

- Why water myths develop
 - Impact of c-GMPs
 - Well-meaning but misguided precedents
 - Scientifically unchallenged traditions
 - Rule-hungry culture
- Water System Microbial Control Myths (Just a few)
 - WFI from RO
 - Turbulent Flow and Flow Rate
 - Dead Leg Rules
 - Smooth Surfaces
 - Periodic Sanitization of 80°C Systems
 - In-Line Sterilizing Filters
 - Ozone as an Added Substance
- Water Microbial Testing Myths (Just a few)
 - Referee Methods
 - Thermophiles in Hot Systems
 - R2A, 35°C, 5 days
 - Test Filter Membrane Rating
 - Compendial Action Levels
 - USP <62> Tests for Specified Microorganisms in Purified Water
 - TOC and Endotoxin as Microbial Count Correlates

Lecture 10. 60 min:

Avoiding Common Water System Inspection Pitfalls

- Initial Deficiencies Usually Lead to Others
- Design and Construction Issues
- Source Water Issues
- Sampling Issues
- Validation Issues
- Change Control Issues
- Procedure Issues
- Specification Issues
- Excursion Investigation Issues
- Training Issues

Why you should attend:

Much fear and hype exists with pharmaceutical biofilms, especially those in water systems. Long term biofilm control cannot be achieved from a blind set of hand-me-down rules for design and operation. One must truly understand biofilm to be able to control it. And because every water system is unique, understanding how biofilm is trying to grow in your system, which could be different than any other system. This course will give you that understanding that is translatable to any system, so that uneventful microbial control is possible. Without this understanding you will quickly find that blind rules for operation (and design) eventually fail to work, and the consequences of failure will far exceed the educational costs that could have prevented it.



Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

- 1 Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
- 2 Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
- 3 PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
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What You will get

- 1 Learning Objectives
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- 9 Networking with industry's top notch professionals

Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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