

2-day In-person Seminar:

## The A to Z's of Microbial Control, Monitoring, Validation and Troubleshooting of Pharmaceutical Water Systems



Philadelphia, PA



April 23rd & 24th, 2019



9:00 AM to 6:00 PM



### Teri C. Soli

Principal Consultant, Soli Pharma Solutions

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: **\$2,000.00**

*(Seminar for One Delegate)*

Register now and save \$200. (Early Bird)

Register for 5 attendees

Price: **\$10,000.00**

Register for 10 attendees

Price: **\$20,000.00**

**ENROLL**

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

## Agenda:

### Day One

#### Lecture 1: **What Makes Water Systems Have Microbial Quality Problems**

- Understand biofilm basics and how it develops
- Understand the impact of biofilm on the commonly used purification unit operations
- Understand how various commonly used microbial control strategies work (or don't work) to control biofilm development
- Understand the how, where, and why of microbial monitoring, action levels, etc.
- Debunk a few water system myths
- Get answers to your own water system questions

#### Lecture 2: **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
- Troubleshooting sanitization problems

#### Lecture 3: **Water System Validation by Logic Instead of Tradition**

- Why validate a water system?
- Basic ground rules for water systems before you validate them
- Micro Test Method "validation"
- Minimum validation expectations
- How to figure out what you should validate
- What happens after the honeymoon is over
- Is validation ever really over?
- Special considerations for lab water systems
- Are packaged waters a viable option?

#### Lecture 4: **Implementing Changes to a Validated System**

- Purpose of a Change Control program - a help, not a hindrance
- When is a change major vs minor, requiring full vs limited re-qualification?
- What about water use during re-qualifications?
- FDA validation expectations
- Reliance on logic and common sense and the disservice of precedent and paradigms
- Additional useful tips

#### Lecture 5: **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

### Day Two

#### Lecture 6: **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?

#### Lecture 7: **Harmonizing vs Optimizing Water Microbial Testing for System Quality Control**

- Water harmonization that has occurred
- Water Micro TM "Dis-Harmonization"
- A little about Biofilm
- Biofilm diversity in water systems
- Micro TM options and evaluation protocol
- The good and bad of Micro harmonization
- Where RMMs can fit in
- Parting wisdom

#### Lecture 8: **Microbial Enumeration Issues with High Purity Water Systems**

- Microbial Enumeration Issues with High Purity Water Systems
- Biofilm enumeration issues (planktonic vs surface)
- Traditional cultivative approach issues
- Validation of your test method
- Alternative TM choices (advantages/disadvantages)
- Significance of water isolates
- Sampling issues
- Establishing Alert/Action Levels and Water Specs and defending them to FDA

#### Lecture 9: **Water System Investigation "How-To's" and Example Case Studies**

- Gathering and assessing existing data and symptoms
- Considering user opinions
- Investigation approach elements
- Recognizing red herrings/false positives
- Recognizing possible root causes
- Water system contamination case studies
- Parting kernels of water system wisdom

#### Lecture 10: **What USP Does and Doesn't Say about PW, WFI, Pure Steam and Micro Issues**

- PW, WFI, Pure Steam micro specifications?
- <1231> Starting water issues
- <1231> Misunderstood issues clarified
- <1231> Microbiological test issues clarified
- <1231> Suggested micro test method
- <1231> Micro Specifications
- <1231> Alert and Action Levels and max's
- Recent/Upcoming USP water changes
- Discrepancies between pharmacopeia's

### 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
- 4 Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

### What You will get

- 1 Learning Objectives
- 2 Participation certificates
- 3 Interactive sessions with the US expert
- 4 Post event email assistance to your queries.
- 5 Special price on future purchase of web based trainings.
- 6 Special price on future consulting or expertise services.
- 7 Special price on future seminars by GlobalCompliancePanel.
- 8 Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
- 9 Networking with industry's top notch professionals

### Contact Information: Event Coordinator

NetZealous LLC, DBA GlobalCompliancePanel  
161 Mission Falls Lane, Suite 216,  
Fremont, CA 94539, USA  
Toll free: +1-800-447-9407  
Fax: 302 288 6884  
Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

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

Look forward to meeting you at the seminar

**GlobalCompliancePanel**