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2-day In-person Seminar:

The A to Z's of Microbial Control, Monitoring and Validation of Water Systems for Pharmaceuticals, Biologics, Medical Devices, Cosmetics, and Personal Care Products

By: **T.C. Soli**, President of Soli Pharma Solutions, Inc

Location 1: San Francisco, CA | March 8-9, 2018

SPEAKER

T.C. Soli, President of Soli Pharma Solutions, Inc

T.C. Soli, Ph.D., is President of Soli Pharma Solutions, Inc, with training, auditing, and troubleshooting expertise covering water systems, sterilization, aseptic processing, contamination control, and microbiological laboratories. He has over 34 years of combined pharmaceutical experience as a consultant and with operating companies (DSM Pharmaceuticals, Glaxo Wellcome, Burroughs Wellcome, and Pfizer). Dr. Soli's career-long water system and manufacturing contamination troubleshooting expertise, coupled with water-related USP, ISPE, PhRMA, and PDA committee and guide creation involvements, afford him practical knowledge about process and contamination control and mitigation; cleaning, sterilization, process, and microbiological testing validation; and all aspects of high purity water systems.

Dr. Soli is in his third 5 year term on USP Expert Committees responsible for Pharmaceutical Water, previously served 5 years on the Advisory Panel to the USP Microbiology Subcommittee, and helped develop the Water Conductivity and TOC specifications used by USP and adopted world-wide. He has authored many articles and chapters in books and industry guides published by PDA and ISPE and is the author of USP's Chapter <1231>.

LEARNING OBJECTIVES

At the completion of the course, attendees will be able to:

- Understand the role of system design, maintenance and sanitization in controlling microbial levels in pharmaceutical water systems.
- Successfully troubleshoot problems resulting from poor design/maintenance versus sampling or testing problems.
- Devise water system validation protocols that truly validate microbial control.
- Validate their water microbial test method.
- Develop sound Alert and Action Levels and Water Specifications.
- Defend their test method, in-process control levels and specifications to FDA.

COURSE DESCRIPTION

All facilities manufacturing pharmaceuticals, biologics, medical devices, cosmetics, and personal care products are likely to have high purity water systems. In spite of this purity, microorganisms can flourish within these systems and lead to undesirable contamination of facility processes and their products. Of all the individuals at the facility, it is site's microbiologists who should understand the microorganisms in water systems and how best to monitor and control them. Sadly, this is often not the case due to the lack of familiarity with biofilm and its impact on water system sampling, testing, sanitization, and routine maintenance. This lack of understanding of microbial control often leads to poor system designs, poor system sampling, poor system maintenance and poor sanitization practices, and as a result, ongoing microbial problems with the water.

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, since this training is for everyone involved with water systems, from the lab to utility room operations. The instructor will provide the necessary background needed to understand this very important subject matter. This understanding is essential for the proper design, validation, operation, monitoring, and maintenance of a high purity water system. Without this understanding, water system control and monitoring consists of a set of rules that often don't work or result in erroneous monitoring data and can cause everything from very costly and unnecessary system downtime to patient injury and product recalls.

AGENDA

DAY ONE (8:30 AM – 4:30 PM)

Registration Process: 8:30 AM – 9:00 AM
Session Start Time: 9:00 AM

1. **Basics of Water System Biofilm Control by Design & Operation**
   - 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
2. **Successful Water System Sanitization**
   - Material and construction limitations
   - Continuous vs intermittent sanitization
   - The importance of biofilm removal
   - How sanitants work (or don't work)
   - When to sanitize
   - Common causes for sanitization failures and troubleshooting sanitization problems
3. **Common Sense Water System Validation**
   - Why validate a water system?
   - Basic ground rules for water systems before you validate them
   - Minimum validation expectations
   - Making changes to a validated water system
   - Special considerations for lab water systems
   - Are packaged waters a viable option?
4. **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?
5. **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

AGENDA

DAY TWO (8:30 AM – 4:30 PM)

6. **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
7. **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
8. **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
9. **Leadership in Mfg Contamination Control: The Microbiology Lab**
   - How contamination is controlled
   - Why the microbiology lab should lead in contamination control
   - Routine contamination evaluation activities
   - Microbiological training
   - Root cause and impact investigations
   - Impediments to leadership
   - Doing the right thing
10. **USP Chapter <1231> : What USP Says about PW, WFI, Pure Steam & 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 pharmacopeias
    - New water initiatives – need your input/feedback
11. **Guarding Against Common Pharmaceutical 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

WHO WILL BENEFIT

This 2-day course is particularly relevant to managers, supervisors, and operatives taking on new responsibilities related to water, but also for experienced water personnel to learn the "true" whys behind what they do and perhaps better ways of doing things. Specific positions that will benefit:

- Microbiology Laboratory supervisors and analysts responsible for water sampling and testing
- Quality Assurance personnel responsible for water system deviation management and change control
- Regulatory and Compliance professionals responsible for FDA interactions
- Process and Utility Engineers responsible for water system maintenance, troubleshooting, and excursion mitigation
- Facility Engineers responsible for water system design or renovation
- Validation personnel for water system qualification

Registration Form

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Seminar Topic: The A to Z's of Microbial Control, Monitoring and Validation of Water Systems for Pharmaceuticals, Biologics, Medical Devices, Cosmetics, and Personal Care Products

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