Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

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

Zurich, Switzerland

October 13th & 14th, 2016

9:00 AM to 6:00 PM

Price

(Without Stay) Price: **$1,695.00**

(Seminar for One Delegate)

(With Stay) Price: **$2,095.00**

(Seminar for One Delegate)

Register now and save $200

Register for 5 attendees (With stay)

Price: **$5,343.00**

~~$1,0475.00~~ You Save: $5,132.00 (49%)*

ENROLL

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

Dr. Teri C. Soli

Principal Consultant, Soli Pharma Solutions

Teri C. ("T.C.") Soli, Ph.D. is President of Soli Pharma Solutions, Inc, serving the Pharmaceutical, Biotech, Medical Device, Dialysis, Cosmetics and Personal Care Products and related equipment and instrument manufacturing industries with training, auditing, and troubleshooting expertise. He has over 32 years of combined pharmaceutical experience as a consultant as well as with operating companies such as DSM Pharmaceuticals, Glaxo Wellcome, Burroughs Wellcome, and Pfizer. Dr. Soli's career-long experience with water systems and product and process contamination troubleshooting, coupled with USP, ISPE, PhRMA, and PDA committee involvements.

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.

Seminar Pricing Includes (With Stay)

- 2 Days Stay
- Pick-up and Drop Facility (Nearest Airport)
- Break-Fast and Lunch
- High Tea
- Pack of 3 Webinars will be provided which has been done in the past on similar subject

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
- 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