

Curtailing Microbial Excursions and Investigations in Pharmaceutical Water Systems

Date: Tuesday, July 8, 2014

Time: 10:00 AM PDT | 01:00 PM EDT

Duration : 90 Minutes

Location : **Online**

Instructor: Teri C. Soli

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Overview:

Water system microbial excursions are the bane of laboratories, utility operations, and production, often causing huge expenditures of labor for system sanitization and additional testing and quarantines of whole systems or specific outlets while fruitless investigations are mounted, not to mention the potential cost of product rejections when root causes are not definitive.

Area Covered In the session:

What are excursions?

Water system dilemma: process control or quality control (utility or raw material), or both

Intended functions 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

Who will benefit:

- 1 QA managers and personnel involved in investigations of excursions and preparing CAPAs
- 1 QC managers and personnel involved in sampling, testing, and trending chem and micro data from water systems
- 1 Utility operators and their managers involved in maintaining and sanitizing water systems
- 1 Validation managers and personnel
- 1 QA managers and other personnel involved in Change Control programs
- 1 QA managers and Regulatory Affairs personnel involved in defending water system operations and quality data to FDA and EMEA inspectors and outside auditors
- 1 Consultants and Troubleshooters

Instructor:

T.C. Soli *Principal Consultant, Soli Pharma Solutions*

T.C. Soli, is a Ph.D. Microbiologist and President of Soli Pharma Solutions, Inc. (www.solipharmasol.com), and is a consultant serving consumer products and FDA-regulated industries with training and contamination troubleshooting expertise covering water systems, sterile and non-sterile products and processes, and microbiological laboratory operations.

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