



Soli Pharma Solutions, Inc.
3520 Post Oak Road
Stokes, NC 27884

Office&Fax: (252) 795-4779
Mobile: (252) 902-5097
tcsoli@solipharmasol.com
www.solipharmasol.com

CONFERENCE & WORKSHOP PRESENTATIONS:

- 1989 Pittsburgh Conference** (Atlanta) – High Purity Water Analysis in the Pharm. Industry
- 1992 Interphex Conference** (New York) – Impact of Proposed USP Monograph Changes on Pharmaceutical Water System Validation
- 1992 FDA Investigator Training** (Raleigh) – Pharmaceutical Compressed Gas Systems
– Pharmaceutical Water Systems
- 1992 ASQC-FDC/FDA Conference** (New Brunswick, NJ) – Impact of Proposed USP Monograph Changes on Pharmaceutical Water System Validation
- 1993 Pharm Tech Conference** (Atlantic City) – Industry Views on New Test Methods [for WFI and PW]
- 1994 ISPE Conference on WFI and Pure Steam** (Raleigh) – Revising the Chemical Specifications and Microbial Discussion in the USP
- 1994 Pharm Tech Conference PR** (San Juan, PR) – Revising the Chemical Specifications and Microbial Discussion in the USP
- 1994 Pharm Tech Conference** (Atlantic City) – Revising the Chemical Specifications and Microbial Discussion in the USP
- 1994 FDA Investigator Training** (Raleigh) – Pharmaceutical Compressed Gas Systems
– Pharmaceutical Water Systems
- 1995 ASQC/FDA Conference** (Raleigh) – Compendial Water Requirements: An Industry Perspective
- 1995 PhRMA Water Conference** (Arlington, VA) – Updating USP Pharmaceutical Grades of Water
– Impact of USP Changes
– Development of USP Conductivity Method
– Overview/History of USP TOC Method
– Workshop: Conductivity Method
– Workshop: TOC Method
- 1995 Pharm Tech Conference** (New Brunswick, NJ) – Impact of New USP Water Monographs
– Instrument Selection Considerations
- 1996 PhRMA Water Conference** (Arlington, VA) – Impact of USP Changes
– Conductivity Test Details and Considerations
– Workshop: Conductivity Method
– Workshop: Microbiological Method/Sampling
- 1996 Pharm Tech Conference PR** (San Juan) – Chair of Workshop and General Session
Workshop – Water Systems: Laboratory & Manufacturing Preparations for the USP Water Changes
General Session – Water Systems: Impact of USP Water Changes
- 1996 Royal Society for Chemistry Symposium** (London) -- Conductivity & TOC as Adjunct Tests for USP Waters
- 1996 FDA Investigator Training** (Raleigh) – Overview of USP23 Water Monograph Changes
– Impact of USP23 Water Changes
– Pharmaceutical Water System Microbiology Primer
- 1996 Pharm Tech Conference** (Meadowlands) – Overview of USP23 Water Monograph Changes
– Impact of USP23 Water Changes
– "To Do" List Preparations for USP23 Water Changes
- 1997 USP Conference on Water and Microbiology** (San Juan) -- TOC and Conductivity in USP Water Testing
- 1997 Compliance South Conference** (Raleigh) – Workshop on Latest Developments in Water System Technology
- 1997 Pharm Tech Conference** (Philadelphia) – Pharmaceutical Water Paradigms, Myths, and Reality: Implementation and Laboratory Issues
- 1997 USP Conference on Water and Microbiology** (Buenos Aires) – TOC and Conductivity in USP Water Testing
- 1997 Microbiological Control Conference** (Islamorada, FL) – Pharmaceutical Water:
USP Monographs, Microbiological and Chemical Tests, System Validation

- 1998 USP Open Conference on Microbiology for the 21st Century (New Orleans) – Session Moderator
- 1998 Center for Professional Advancement -- **Pharmaceutical Water Systems Course** (New Brunswick, NJ)
 - Water System Microbiology
- 1998 Institute For International Research – **High Purity Water Conference** (Arlington, VA) – Complying with USP/EP/JP Water Attribute Tests Cost-Effectively
- 1998 Microbiological Control Conference (Islamorada, FL) – Pharmaceutical Water Production and Testing, Aseptic Processing Guidelines, USP Changes in Microbiological Tests
- 1999 IBC Conference on International Harmonization of Water (Washington, DC) – Pre-Harmonization Options for Pharmaceutical Water Testing
- 1999 Center for Professional Advancement: **Pharmaceutical Water Systems Course** (New Brunswick, NJ)
 - Water System Microbiology
- 1999 Institute For International Research – **High Purity Water Conference** (San Francisco)
 - Complying with USP/EP/JP Water Attribute Tests Cost-Effectively
 - Control the Enemy by Knowing the Enemy: A Pharmaceutical Water System Microbiology Primer
- 1999 Microbiological Control Conference (Islamorada, FL) – Pharmaceutical Water Production and Testing, Aseptic Processing Guidelines, USP Changes in Microbiological Tests
- 2000 Southeast Chapter Parenteral Drug Association Meeting (Raleigh) – Pharmaceutical Water System Microbiology Primer
- 2000 Center for Professional Advancement: **Pharmaceutical Water Systems Course** (New Brunswick, NJ)
 - Water System Microbiology
- 2000 Barnett Conference on Pharmaceutical Grade Water (Philadelphia) – Pre-Harmonization Testing Approaches to Comply with USP/EP/JP Pharmaceutical Water Attributes
- 2000 Institute For International Research – **High Purity Water Conference** (San Francisco)
 - Complying with USP/EP/JP Water Attribute Tests Cost-Effectively
 - Pharmaceutical Water Microbiology: Understand the Science So You Can Monitor and Control the Bugs!
- 2000 USFilter Winter 2000-2001 City Seminars (Raleigh) – Microbiology of Pharmaceutical Waters
- 2001 Barnett Conference on Pharmaceutical Water Purification Systems (Washington, DC)
 - Cost Effective and Defensible PreHarmonization Water Testing Approaches
- 2001 Center for Professional Advancement: **Pharmaceutical Water Systems Course** (New Brunswick, NJ)
 - Control the Enemy by Knowing the Enemy: A Pharmaceutical Water System Microbiology Primer
 - Practical Pharmaceutical Water System Design and Operation Issues Related to Microbiology
- 2001 Institute For International Research – **Validating Utilities Conference** (Philadelphia)
 - Pharmaceutical Water Microbiology: Understand the Science So You Can Effectively Validate Your System
- 2001 Center for Professional Advancement: **Pharmaceutical Water Systems Course** (New Brunswick, NJ)
 - Control the Enemy by Knowing the Enemy: A Pharmaceutical Water System Microbiology Primer
 - Practical Pharmaceutical Water System Design and Operation Issues Related to Microbiology
- 2001 Microbiological Control Conference (Islamorada, FL) – Pharmaceutical Water Production and Testing, Aseptic Processing Guidelines, USP Changes in Microbiological Tests, Compdial Harmonization
- 2002 Institute For International Research – **Validating Utilities Conference** (Princeton, NJ)
 - Conference and Roundtable Moderator and Presenter
 - Achieve Better Water System Validation through Better Water Microbiology Understanding
- 2002 2nd Annual GlaxoSmithKline Global Quality Assurance Conference on FDA Inspections (Athens, Greece)
 - Pharmaceutical Water System Microbiology: A Very Short Course on Biofilm
- 2002 Center for Professional Advancement: **Pharmaceutical Water Systems Course** (North Chicago, IL)
 - Control the Enemy by Knowing the Enemy: A Pharmaceutical Water System Microbiology Primer
 - Practical Pharmaceutical Water System Design and Operation Issues Related to Microbiology
- 2002 Institute For International Research – **High Purity Water Conference** (San Francisco)
 - Conference Advisory Board member
 - Fundamentals of Pharmaceutical Water System Microbiology
- 2002 Pureflow, Inc: **High Purity Water Conference** (Greensboro, NC)
 - Fundamentals of Industrial High Purity Water System Microbiology
- 2002 Institute For International Research – **Validating Utilities Conference** (Princeton, NJ)
 - Conference Advisory Board member
 - Fundamentals of Pharmaceutical Water System Microbiology

2003 Center for Pharmaceutical Training (IQPC) – Pharmaceutical Water Systems Summit 2003 (Philadelphia)

- Conference Moderator
- Panel Discussion Moderator
- Essentials of Pharmaceutical Water System Microbiology
- Practical Pharmaceutical Water System Design and Operation Issues
- Pharmaceutical Water System Excursion Issues

2003 Pureflow, Inc: High Purity Water Conference (Cary, NC)

- Conference Advisory Board member
- Water System Microbiology – Understanding, Controlling, Monitoring

2003 Center for Pharmaceutical Training (IQPC) – Pharmaceutical Water Systems Conference (Boston)

- Essentials of Pharmaceutical Water System Microbiology
- Practical Pharmaceutical Water System Design and Operation Issues

February 2004, Center for Pharmaceutical Training (IQPC) – Best Practices for Pharmaceutical Water Systems: Current Trends, Concern and Development (San Francisco)

- Pharmaceutical Water System Microbiology – Understanding, Controlling, Monitoring
- Practical Pharmaceutical Water System Design and Operation Issues
- Pharmaceutical Water System Excursion Issues

May 2004, Center for Pharmaceutical Training (IQPC) – Pharmaceutical Water Systems: Optimizing Strategies and Guidance for Efficient Operations and Compliance (Philadelphia)

- Conference Advisory Board member
- Conference Moderator
- Panel Discussion Moderator
- Pharmaceutical Water System Microbiology – Understanding, Controlling, Monitoring
- Practical Pharmaceutical Water System Design and Operation Issues

September 2004, Barnett International – Water Summit & Utilities Validation Conference (Philadelphia)

- Conference Advisory Board member
- Panel Discussion Member
- Workshop -- Understanding Water System Microbiology: \$\$ Now or \$\$\$\$ Later

October 2004, US Filter City Seminars – Pharmaceutical Water System Training (Raleigh)

- Featured Speaker: New USP Developments in Pharmaceutical Water

October 2004, Southeast Chapter PDA Meeting (Raleigh) – Recent USP Developments in Pharmaceutical Water

January 2005, 4th Annual IQPC Pharmaceutical Water Systems: Current and Emerging Technologies Addressing Design, Implementation, Operation and Validation Issues (Philadelphia)

- Keynote Address: Update on the Latest USP Pharmaceutical Water Developments
- Tutorial: Pharmaceutical Water Microbiology: Good Decisions from Good Understanding

April 2005, Pureflow Spring Seminar – High Purity Water System Piping (Durham, NC)

- Understanding Biofilm in High Purity Water Systems
- Practical Water System Design and Operation Issues Affecting Microbial Control

June 2005, Microbiology Network and High Peaks Associates present – 2005 Spring Course Series (Chicago, IL)

- Water System Microbiological Test Validation

October 2005, PMF and High Peaks Associates’ Pharmaceutical Microbiology Fall Forum (Rochester, NY)

- What’s Up with USP <1231> Water for Pharmaceutical Purposes
- Practical Pharmaceutical Water System Microbiology Workshop

October 2005, Bioprocessing & Process Development – Applying USP in a Biotech/Biomfg Environment (RTP)

- Information contributor to “The Challenge to Conform to Multi-Compendial Requirements for Purified Water & WFI”

- USP Pharmaceutical Water Expert Committee representative for Panel Discussion

November 2005, Pureflow Fall Seminar – High Purity Water Conference (Greensboro, NC)

- Understanding Biofilm in High Purity Water Systems
- The Logic of Water System Validation – Start Well, Stay Well

December 2005, IVT’s Microbiology Event of the Year (Baltimore, MD)

- Understanding Biofilm in High Purity Water Systems Workshop
- Practical System Design and Operation Issues Affecting Microbial Control
- USP Pharmaceutical Water Expert Committee Update – What’s New & What’s Coming

February 2006, Mettler-Toledo Thornton’s Pharmaceutical Water Update (Boston, MA)

- Optimizing Microbial Monitoring of Water

Systems

AVAILABLE CLIENT SITE PRESENTATIONS:

Understanding Biofilm in High Purity Water Systems (1.5 – 4 hr)

Practical Water System Design and Operation Issues Impacting Microbial Control (1 – 4 hr)

Validation of Microbial Enumeration Methods for Water: A Very Different Sort of Beast (3 – 5 hr)

Optimizing Microbial Monitoring of Water Systems (1 – 3 hr)

Pharmaceutical Water System Excursions: Types, Impact, and Response (0.75 – 1.5 hr)

The Logic of Water System Validation (0.75 – 1.5 hr)

Update on Latest USP Pharmaceutical Water Developments (0.75 – 2 hr)

USP-ology: Understanding the “Big Red Book” (0.75 hr)

USP <1231> : What USP’s Informational Chapter Really Says About Water (1 – 3 hr)

Water System Microbiology 101: The essential course for everyone who tests & maintains water systems (7 – 10 hr)

Customized presentations: TBD by client