



Soli Pharma Solutions, Inc.  
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## *Résumé for Teri C. Soli*

### **EDUCATION:**

**Ph.D. Major: Microbiology [& Immunology] Minor: Biochemistry (1980)**

University of Arizona, Tucson, AZ

**M.S. Major: Microbiology (1974)**

Texas A&M University, College Station, TX

**B.S. Major: Microbiology (1971)**

Texas A&M University, College Station, TX

### **CONSULTING EXPERIENCE:**

**Soli Pharma Solutions Inc. (formerly Soli Pharmaceutical Consulting), Stokes, NC**

11/95 – present Principal Consultant and President (Full-Time 11/04 - present)

Principal Consultant (Part-Time 11/95 – 10/04 during operating company employment listed below)

#### *Areas of Expertise:*

- High purity water systems design, operation, maintenance, sampling, Chem & Micro testing, & validation
- Current & emerging water GMPs, RM & Product micro test methods & compendial requirements (USP/PhEur/JP)
- Current & emerging water purification technologies & applications
- Current & emerging sterilization technologies and aseptic biopharmaceutical & medical device processes
- Aseptic and Non-aseptic process contamination control for biopharmaceuticals & medical devices
- Microbiological laboratory operations, method adaptation/development & validation
- Troubleshooting of all the above
- Compliance auditing of bulk chemical, aseptic and non-aseptic manufacturing, packaging, utilities, and laboratories
- Industry training on the above through presentations, workshops & customized on-site programs
- Participation & interaction with expert working committees with organizations such as USP, PDA, RAPS & ISPE

#### *Examples of Past Projects/Accomplishments:*

- Expert witness in TOC instrument patent infringement and contract water system maintenance malpractice litigations
- Evaluated/Oversaw 3<sup>rd</sup> party WFI system redesign/installation for chloramine removal and client validation
- Evaluated/Oversaw client PW system redesigns for emergency and permanent interconnections and extensions
- Evaluated water monitoring sampling and testing procedures and recommend changes
- Provided application and market ideas for water ozone treatment to an R&D company
- Evaluated impact of water system design changes on existing water system PQ
- Developed protocol to determine optimal microbial enumeration test conditions for water system monitoring
- Prepared rationale documents justifying microbial enumeration test conditions used for water system monitoring
- Prepared rationale documents for the significance of specific water system microbial isolates
- Developed data-driven microbial and chemical Alert and Action Levels and Specifications for a water system
- Evaluated water system maintenance and monitoring SOPs and audited compliance therewith
- Performed successful troubleshooting of causes of high TOC and high microbial counts in clients' water systems
- Performed successful troubleshooting of premature DI failure in client's water system
- Performed successful troubleshooting of SIP system failure during PQ
- Developed unique  $F_{BIO}$  vs  $F_o$  validation approach for minimal terminal sterilization cycle validation
- Performed successful troubleshooting of causes of non-sterile solid and liquid product contaminations
- Execute validation (IQ, OQ, PQ) of lab instruments, environmental chambers, and manufacturing equipment
- Performed compliance audit of an API (fermentation) facility, incl utilities, laboratory, fermentation, and purification
- Performed compliance audit of drug repackaging facility
- Performed successful troubleshooting of trace beta lactam product and facility cross-contamination
- Routinely highest rated presenter at PDA, IIR, Barnett, IQPC, CfPA, IVT, and other private water conferences

**OPERATING COMPANY EXPERIENCE:****DSM Pharmaceuticals Inc., Greenville, NC**

5/04 – 10/04 *Senior Principal Quality Associate, Quality Assurance Dept.*

- Investigate Customer Complaints as assigned, including medical complaints and manufacturing defects
- Determine root cause of all assigned complaints and appropriate corrective actions as needed
- Prepare written report of all complaint investigation findings and corrective actions
- Communicate appropriate investigational findings to customer
- Serve as site regulatory, technical, and scientific expert on all matters related to microbiological troubleshooting, aseptic processing and sterilization validation, pharmaceutical water systems, and raw material microbiology (incl. viral safety/clearance for biologicals, TSE contamination, microbiological attributes, etc.)
- Assist international DSM sites as a corporate regulatory, technical, and scientific expert as above

2/02 – 5/04 *SAP Implementation Specialist, Information Technology Dept.*

- Interact with SAP implementation team members and all Department stakeholders to determine current and future business needs for Timesheets, Proposal Preparation (Bidding), Project Management, and Resource Management
- Develop short term SAP alternative to legacy Timesheet Program for easy transition for current site users
- Develop long term SAP Timesheet module to be compatible with SAP Project Systems module, enhance time accounting ease, accuracy and thoroughness, and expand applicability to all site functions
- Develop SAP--Project Systems module to include bidding, project planning, and capacity planning functions
- Serve as site regulatory, technical, and scientific expert on all matters related to microbiological troubleshooting, aseptic processing and sterilization validation, pharmaceutical water systems, and raw material microbiology (incl. viral safety/clearance for biologicals, TSE contamination, microbiological attributes, etc.)

1/01 – 1/02 *Customer Development Specialist, Pharm R&D – Regulatory Affairs Dept.*

- Develop programs and lead multidisciplined teams to implement site-wide initiatives for Quality Leadership, Analytical Reporting Standardization, Laboratory Notebook Entry Standardization, Viral Safety/Clearance Expectations for development stage biological projects, and other initiatives as they arise
- Create FDA/MCA regulatory submission templates for sterile/aseptic process validation information
- Serve as primary author or reviewer (if not preparer) for all regulatory submission documents related to sterile/aseptic processes and microbiology and respond to related client and FDA/MCA reviewer questions
- Plus same responsibilities as Manager of Technical Business Development under Catalytica Pharmaceuticals Inc.

**Catalytica Pharmaceuticals Inc., Greenville, NC**

1/98 – 1/01 *Manager of Technical Business Development, Pharm Marketing & Sales Dept./Quality Operations Dept.*

8/97 - 12/97 *Manager of Analytical Development and Senior Contract Technical Liaison*

- Interact with potential contract manufacturing customers to describe Analytical R&D, QA/QC, Validation, and Regulatory Affairs services and develop a detailed project scope for accurate tech transfer project bid preparation
- Assess technical, clinical, and strategic business merits of potential contract manufacturing relationship
- Prepare project cost estimates, timelines, resource commitments, and assumption lists for above services
- Develop regulatory rationale for all activities that lead to rapid and defensible application approvals
- Create and utilize bid element checklists and project plan/cost templates to streamline the bid preparation process
- Train/mentor backup personnel on effective use of bidding tools and analytical bid preparation process
- Serve as site regulatory, technical, and scientific expert on all matters related to microbiological troubleshooting, aseptic processing and sterilization validation, pharmaceutical water systems, and raw material microbiology (incl. viral safety/clearance for biologicals, TSE contamination, microbiological attributes, etc.)
- (8/97-12/97 only) Plus same responsibilities as Manager of QC Technical Services under Glaxo Wellcome Inc.

**Glaxo Wellcome Inc.(and Burroughs Wellcome Co.), Greenville, NC**

3/95 - 7/97 *Manager of QC Technical Services, Quality Assurance Div. (under GW)*

7/88 - 2/95 *Department Head of Microbiological Validation and Development Support (under BW)*

- Manage staff of 23 people: 3 supervisors, 16 degreed analysts (incl. 2 PhD's & 2 MS's), 3 co-ops, and 1 admin.)
- Coordinate all micro & chem method development/validation/troubleshooting for dev. & commercial products
- Coordinate micro and chem lab support for sterilization, depyrogenation and cleaning validation
- Coordinate all inbound and outbound method transfers for chem and micro QC methods & contract lab qualification
- Coordinate frozen inoculum and microbial identification programs
- Coordinate all departmental instrument repair and calibration services
- Establish microbiological specifications for new products
- Prepare company position papers/memos/official correspondence on complex issues
- Author or final review all regulatory documents involving microbiological and sterilization issues

- Interact with FDA investigators and application reviewers on site inspection and NDA issues
- Troubleshoot water system, sterile and non-sterile manufacturing, and validation problems
- Serve on project teams supporting development and launch of new products and international harmonization

### **Pfizer Inc., Groton, CT**

1986 – 1988 *Senior Development Scientist and Microbiology Lab Supervisor, Quality Control Division*

1982 – 1986 *Senior Development Scientist, Quality Control Division*

1979 – 1982 *Development Scientist, Quality Control Division*

- Supervise QC microbiology laboratory staff of 10 people (1 M.S., 4 B.S., 2 A.A.S., 3 non-deg)
- Coordination of all microbiological special testing
- Validation of all routine and non-routine microbiological test methods
- Validation of manufacturing sterilization processes
- Investigation/troubleshooting of complex analytical and manufacturing problems

### **University of Arizona, Tucson, AZ**

1974 - 1979 *Research and Teaching Associate, Department of Microbiology & Immunology*

- Technical assistant for study of toxicity of oil digesting bacterium on intertidal fauna
- Technical assistant for NIH grant to study the potential use of immune lymphocyte and urine extracts (containing transfer factor) in IV and PO intra- and interspecies passive transfer of cellular immune responses to tuberculin, dinitrochlorobenzene, coccidioidin, skin grafts, and bovine shipping fever
- Prepared and taught laboratories for introductory and advanced level microbiology courses.

### **Texas A&M University, College Station, TX**

1971 - 1974 *Research and Teaching Assistant, Department of Biology*

- Technical assistant for NASA grant to study the effect of spacecraft and EVA environments on potentially pathogenic exoenzyme systems of normal astronaut flora.
- Prepared and taught laboratories for introductory and advanced level microbiology courses

## ***PROFESSIONAL TASK FORCE MEMBERSHIPS AND ACCOMPLISHMENTS:***

### **USP Pharmaceutical Waters Expert Committee**

*Working member 2000-2005 and V.Chair 2005-2010 Revision Cycles*

- Developed strategy and educational approach for pharmaceutical water harmonization in USP, EP, and JP.
- Significant progress in updating and harmonizing attribute tests for packaged waters
- New chapter pending for <1232> Instrumentation for Analysis of High Purity Pharmaceutical Water
- Created Water for Hemodialysis monograph
- Created <1230> Water for Health Applications
- Created Pure Steam monograph
- Revised monographs for Purified Water & Water for Injection for source water & production methods
- Complete rewrite (primary author) of <1231> Water for Pharmaceutical Purposes to expand/contemporize discussion

### **USP Expert Advisory Panel on Microbiological Control and Process Validation**

*Working member from 1995-2000*

- Developed/evaluated data affecting adoption of USP/NF standards for strength, quality, purity, bioavailability, packaging and labeling.
- Developed/evaluated information affecting adoption/modification of USP standards for pharmaceutical and medical product microbiological quality and for validation of microbiological control processes for products

### **Pharmaceutical Research and Manufacturers of America -- Water Quality Group**

*Working member from 1982 -1998*

- Coauthored many publications in Pharmaceutical Technology on water system design, operation, validation and troubleshooting
- Concept originator (and author of proposed text) of the USP-23 changes for Purified Water and Water for Injection monographs relative to Conductivity, TOC, and pH
- Coauthored many publications in Pharmacopeial Forum detailing conceptual background and rationale to Conductivity, TOC, pH and other water test changes
- Frequent conference presenter on all above topics to notify industry of impending changes

***PERSONAL TECHNICAL AND PRACTICAL EXPERTISE:***

- Validation of all sterilization technologies, including steam (autoclaves and SIP), ethylene oxide, hydrogen peroxide vapor/fog/liquid, peracetic acid vapor/fog, gamma irradiation, UV irradiation, electron beam irradiation, & filtration.
- Biological indicators (types, uses, preparation, characterization, qualification).
- Pharmaceutical water system design, maintenance, monitoring, troubleshooting, and validation.
- Utility system troubleshooting and validation (Compressed Air, Nitrogen, Chilled Water, Municipal Water, Pharmaceutical Water, Pure Steam, HVAC).
- Microbial testing techniques for pharmaceutical water, including various culture techniques and epifluorescent microscopy.
- Microbial test method validation for pharmaceutical products and raw materials.
- TOC analysis technologies and applicability to water testing and cleaning validation.
- Conductivity analysis and applicability to water testing and cleaning validation.
- Antibiotic agar diffusion and turbidimetric bioassays.
- LAL testing theory, practice, and validation.
- Container/closure integrity assurance testing (physical and microbiological challenges).
- Beta Lactam cross-contamination control and assessment for products and facilities.
- Environmental microbiology and microbial ecology.
- Immunology and immunotherapy.
- Molecular biology and biotechnology theory and techniques.
- Laboratory and large animal handling and care experience.
- Experimental design and statistical applications.
- Microbiological process troubleshooting of equipment trains and aseptic processing.
- Microbiological QC specification establishment for new products.
- Pharmaceutical QA/QC laboratory GMPs.
- FDA interactions on microbiological/sterilization validation/sterility assurance issues.
- NDA CMC Section preparation, including Sterilization Process Validation Volume (a.k.a. "White Binder").
- Cleaning validation limit rationale establishment.
- GMP auditing of laboratories and manufacturing/distribution areas.
- Site advance preparation for and hosting of FDA Inspection (PAI and general GMP).

***PERSONAL MANAGERIAL AND ADMINISTRATIVE EXPERTISE:***

- Project planning and execution/management skills using both MS Project and SAP Project Systems
- Presentation and training skills.
- Familiarity with various mainframe, PC, and Macintosh software for communications, word processing, spreadsheets, databases, project planning, audio/visual presentations, etc.
- Familiarity with SAP Project Systems software (and related integrated modules).
- Familiarity with SAP Master Recipe software (and related integrated modules).
- Familiarity with SAP Cross Application Timesheet software (and related integrated modules).

***PROFESSIONAL AFFILIATIONS AND MEMBERSHIPS:***

- PDA
- RAPS
- ISPE
- AAAS, American Association for the Advancement of Science (past member)
- ASQ, American Society for Quality (past member)
- SIM, Society for Industrial Microbiology (past member)

***HONORS AND HONOR SOCIETIES:***

- Phi Kappa Phi, Phi Sigma, Sigma Xi, Phi Eta Sigma,
- University of Arizona Foundation Award for Meritorious Performance in Teaching (1977),
- Texas A&M University Bachelor of Science Degree conferred "With Honors" (1971),
- Bay City High School American Legion Award (1967)

**PUBLICATIONS:**

- Transfer of Delayed Hypersensitivity to Tuberculin in the Dog with Dialyzable Leucocyte Extracts**, coauthored with W. S. Jeter and R. E. Reed, *Abst. Ann. Mtng. A.S.M.* 1976:81 (1976).
- Transfer of Tuberculin Hypersensitivity in Cattle with Dialysates of Leucocytic Extracts**, coauthors W. S. Cozine, W. S. Jeter, R. N. Ferebee, and R. E. Reed, *Fed. Proc.* 35:338 (1976).
- Passive Transfer of Coccidioidin Hypersensitivity in Guinea Pigs and Rabbits with Transfer Factor**, coauthors W. S. Jeter, R. E. Reed and J. D. Cramer, in *Coccidioidomycosis*, L. Ajello, ed., *Symposia Specialists*, Miami, p. 359 (1977).
- Interspecies Transfer of Delayed Hypersensitivity by Purified Transfer Factor Preparations**, coauthored with D. E. Lewis, M. E. Stafford, R. Kibler, and W. S. Jeter, *Fed. Proc.* 37:1365 (1978).
- Oral Administration of Bovine and Human Dialyzable Transfer Factor to Human Volunteers**, coauthors W. S. Jeter, R. Kibler, and C. A. L. Stephens, in *Immune Regulation in Transfer Factor*, A. Khan, C. H. Kirkpatrick, and N. O. Hill, eds., Academic Press, New York, p. 451 (1979).
- Protection of Water Treatment Systems, Part I: The Problem**, coauthor with PMA Water Quality Committee, *Pharm. Tech.* 7(5):48-57 (May 1983).
- Protection of Water Treatment Systems, Part IIA: Potential Solutions**, coauthor with PMA Water Quality Committee, *Pharmaceutical Technology* 7(9):86-92 (September 1983).
- Protection of Water Treatment Systems, Part IIB: Potential Solutions**, coauthor with PMA Water Quality Committee, *Pharmaceutical Technology* 7(10):38-48 (October 1983).
- Protection of Water Treatment Systems, Part III: Validation and Control**, coauthor with PMA Water Quality Committee, *Pharmaceutical Technology* 8(9):54-68 (September 1984).
- Validation and Control Concepts for Water Treatment Systems**, coauthor with the PMA Water Quality Committee, *Pharmaceutical Technology* 9(11):50-56 (November 1985).
- Updating Requirements for Pharmaceutical Grades of Water**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 16(6):1283-1285 (Nov.-Dec. 1990).
- Updating Requirements for Pharmaceutical Grades of Water: Conductivity**, principal author with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 17(6):2669-2675 (Nov.-Dec. 1991).
- Water Conductivity Test Method**, principal author with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 18(6):4388-4391 (Nov.-Dec. 1992).
- Updating Requirements for Pharmaceutical Grades of Water: Aluminum**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 18(6):4392-4394 (Nov.-Dec. 1992).
- Updating Requirements for Pharmaceutical Grades of Water: Heavy Metals**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 18(6):4395-4396 (Nov.-Dec. 1992).
- Updating Requirements for Pharmaceutical Grades of Water: Microbial Considerations**, principal author with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 18(6):4397-4399 (Nov.-Dec. 1992).
- <645> Water Conductivity**, principal author with PMA Water Quality Committee, in *Pharmacoepial Preview of General Tests and Assays*, *Pharmacoepial Forum* 19(1):4480--4483 (Jan.-Feb. 1993).
- Updating Requirements for Pharmaceutical Grades of Water: Total Organic Carbon**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 19(4):5858-5862 (July-Aug. 1993).
- Updating Requirements for Pharmaceutical Grades of Water: Total Solids**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 19(4):5863-5865 (July-Aug. 1993).
- Updating Requirements for Pharmaceutical Grades of Water: General Notices and Monographs**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 19(5):6179-6182 (Sept.-Oct. 1993).
- Updating Requirements for Pharmaceutical Grades of Water: <1235> Microbiological Aspects of Pharmaceutical Water**, principal author with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 19(5):6183-6187 (Sept.-Oct. 1993).
- Updating Requirements for Pharmaceutical Grades of Water: Validation and Technology Section**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 19(6):6633-6645 (Nov.-Dec. 1993).
- Updating Requirements for Pharmaceutical Grades of Water: Proposed Revisions**, coauthor with PMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 20(3):7526-7544 (May-June 1994).
- Updating Requirements for Pharmaceutical Grades of Water: Rationale for Changes to Conductivity, pH, and TOC Test Proposals**, principal author with PhRMA Water Quality Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 22(1):1934-1939 (Jan.-Feb. 1996).
- Harmonisation of Pharmaceutical Water Testing**, sole author, *Pharmaceutical Manufacturing International* (July-Sept issue, 1999).
- Water for Hemodialysis\_ The Case for Compendial Standards**, coauthor with USP Pharmaceutical Water Expert Committee, *Stimuli to the Revision Process*, *Pharmacoepial Forum* 28(5):1684-1686 (Sept.-Oct. 2002).
- <1231> Water for Pharmaceutical Purposes**, Proposed completely rewritten General Information Chapter, sole author, *In-Process Revision*, *Pharmacoepial Forum* 29(5):1641-1681 (Sept-Oct, 2003).

- <1230> **Water for Health Applications**, New General Information Chapter, coauthor with USP Pharmaceutical Water Expert Committee, New USP Informational Chapter in USP 27 (2004).  
**Water for Hemodialysis**, New USP Monograph in USP 27 (2004).  
**Pure Steam**, New USP Monograph, coauthor with USP Pharmaceutical Water Expert Committee, In-Process Revision, Pharmacopeial Forum 30(5):1651 (Sept-Oct, 2004).  
<643> **Total Organic Carbon**, Proposed major revisions to General .Test Chapter, coauthor with USP Pharmaceutical Water Expert Committee, In-Process Revision, Pharmacopeial Forum 30(5):1700-1702 (Sept-Oct, 2004).  
<1231> **Water for Pharmaceutical Purposes**, Major rewrite of General Information Chapter, principal author with USP Pharmaceutical Water Expert Committee, In-Process Revision, Pharmacopeial Forum 30(5):1745-1806 (Sept-Oct, 2004).  
<1232> **Instrumentation for Analysis of High Purity Pharmaceutical Waters**, Proposed new General Information Chapter, coauthor with USP Pharmaceutical Water Expert Committee, In-Process Revision, Pharmacopeial Forum 30(5):1807-1817 (Sept-Oct, 2004).  
**Pure Steam**, New USP Monograph, coauthor with USP Pharmaceutical Water Expert Committee, In-Process Revision, Pharmacopeial Forum 31(2):467-468 (Mar-Apr, 2005).  
<1231> **Water for Pharmaceutical Purposes**, Major rewrite of General Information Chapter in USP 28, Supplement 2.  
**Pure Steam**, New USP Monograph in USP 29, Supplement 1.

### **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, Compendial 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, 4<sup>th</sup> 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)
- 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 source for “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)
- 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)
- 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> : Author’s Perspective on 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**