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Consulting Services - Scott Sutton, Ph.D.

[Consultation Services](#), [Resume](#), [Publications](#) and [In-house Courses](#) are described in detail below.

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Quality Control Microbiology is a specialized discipline, frequently difficult to manage from both a compliance and a scientific perspective without relevant training and experience. It is also a laboratory discipline central to **successful manufacturing by aseptic processing and manufacture of non-sterile products free of "objectionable organisms."**

This discipline becomes especially demanding when things go wrong. The need for expert assistance is never more keenly felt than when **investigating a microbiological data deviation (MDD, a.k.a OOS)**. However, the time to prepare for the investigation is in your normal activities. Let's make sure that everything is in order ahead of time, and also call on us for assistance in need to establish the root cause, determine appropriate corrective action and evaluate the effectiveness of that action.

Mentoring is the Focus

Rather than investing in the hiring expense of high-level personnel, consider outsourcing the expertise to train existing personnel to execute and maintain the systems and processes needed to ensure success. We can design practical systems to meet your specific needs, and then mentor the staff on-site in the execution of the systems and in problem-solving skills to meet the demands of the future ***without immediate increase in headcount directed at managerial and technical expertise.***

Scott Sutton , Ph.D.

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Dr. Sutton's Areas of Interest:

In-house Training

- cGMP
 - Manufacturing Issues
 - Aseptic Production
 - Environmental Monitoring of Controlled Environments
 - Non-sterile Manufacturing Operations
 - API Production
 - Laboratory Issues
 - Lab Practice vs Regulatory Expectations (International Guidances and FDA 483 observations)
 - Lab Audits
 - Preparation for regulatory audits
 - Qualification of external contract labs
 - Training exercises

- Test Method Validation
- Laboratory Design and Leadership
 - Lab design review to minimize laboratory-induced OOS
 - SOP review and consultation
 - Lab Practices training
 - Management consultation on Best Practices and metrics to assure efficient operation
 - Training and proficiency documentation
- Project Management
- Rapid Microbiological Methods
- Expert Witness
- In-house training



[Contact Scott Sutton for Consultation](#)

[Review White Papers on Topics of Interest](#)

Details Below

[Consultation Services](#) [Resume](#) [Publications](#) [Presentations](#) [In-house Courses](#)

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Also see our [White Papers](#) and the [QC Microbiology Bibliography](#)

Services



cGMP - Manufacturing

- Guidance and assistance in meeting the new requirements of FDA's **Aseptic Processing** Guidance.
- Consulting on **manufacture of non-sterile product dosage forms and API** with particular emphasis on the requirements of the newly harmonized Microbial Limits Tests.
- Consultation on modernizing, or on "greening" established API production processes.
- Assistance in **responding effectively to FDA observations** and warning letters.
- cGMP audits of facilities and associated control systems for both sterile and non-sterile finished dosage forms.
- **Project management services.**
- Process development for contamination control
- Sterilization sciences

Training

Training on critical knowledge and skills brought to your site from recognized and experienced experts in the field. Courses can be developed to meet your needs, or can be chosen from a selection of prepared units including:

- Manufacturing Focus
 - GMP for Manufacturing
 - Environmental Monitoring (both for sterile and non-sterile processes)
 - Aseptic Processing
 - Contamination Control
 - Microbiology for Aseptic Manufacturing
 - Microbiology for cosmetics and non-sterile manufacturing
 - What is the FDA and its role?
 - PAT and Rapid Microbiological Methods in Manufacturing Support
- Microbiology Lab Focus
 - The United States Pharmacopeia & Microbiology
 - Auditing the Microbiology Lab (contract lab or QC support)
 - GMP for the QC Microbiology Lab (suitable for annual training requirement)
 - Understanding the USP Tests
 - Investigations of Microbiological Data Deviations (OOS)
 - USP Chapter <1117> Best Microbiological Lab Practices
 - Validation of Alternate Microbiological Methods

cGMP - Laboratory

- Design of **microbial identification strategy** to assist in **investigations** while maintaining operating expenses.
- Review of documentation and assistance in compliance.
- Management of change to establish and maintain a **compliant laboratory culture**.
- **Design and evaluation of a SOP system** to support compliance and training.
- **Auditing** of Pharmaceutical laboratories in preparation for regulatory inspections and also as an aid to benchmarking and training.
- **Laboratory investigation support**, e.g., sterility test failure and media fill failure investigations, evaluation of aseptic processing procedures
- **Training** on critical knowledge and skills brought to your site from recognized and experienced experts in the field. Courses can be developed to meet your needs, or can be chosen from a selection of prepared units including:
 - Microbiology and the USP

- Validation of microbiological methods
- Microbiology validation - theory and practice
- Auditing a Microbiology Lab (and preparing for the audit)
- Techniques in effective laboratory organization, leadership and management
- Project management services.

Lab Management

- **Design of the laboratory** to assist in workflow and efficiency
- Assistance in **equipment** acquisition, documentation and validation to maximize efficiency.
- **Training** in all aspects of microbiology in the pharmaceutical, medical device and consumer products industries.
- **Optimization** of laboratory operations and procedures.
- Development of **environmental control** procedures
- Quality engineering and quality management evaluation of your laboratory
- Laboratory automation.
- Project management services.

Project Management

- Assistance in developing project strategy for process change, product development where circumstances require significant microbiological expertise
- Assistance in technical documentation to support NDA/ANDA/CTD filing.
- Skilled manager in all aspects of microbiological testing to meet product development or process change needs.
- Assistance with regulatory submissions and interactions.
- Assistance in development of metrics to reflect laboratory operations

Rapid Microbiological Methods and PAT

- Application of Rapid Microbiological Methods to support manufacturing within the Process Analytical Technology Initiative.
- Recommendation and validation of appropriate alternate microbiological technology to maximize efficiency.
- Evaluation of your current manual growth-based systems with recommendations and implementation of a rapid system that suits your user requirements.
- Comprehensive Installation Qualification, Operational Qualification, and Performance Qualification validation protocols and execution, as well as process development and validation study services for the

new rapid technology.

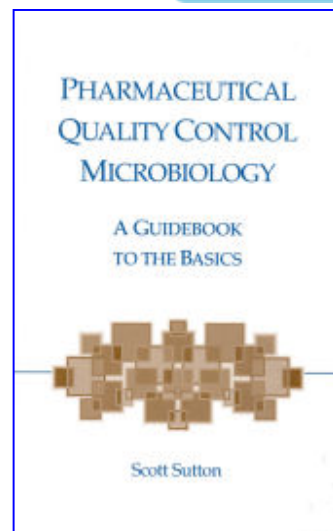
Consultation Inquiry

Expert Witness

- Aseptic manufacturing and environmental monitoring
- Microbiological control
- Product adulteration through contamination
- Contact Lens Care Products

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2008 PDA Distinguished Author
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Resume: Scott V.W. Sutton

Education:

- Ph.D. (microbiology) 1987 University of Rochester
 - Advisor: Dr. Robert E. Marquis
 - Thesis: Proton-translocating, Fluoride sensitive ATPases of *Streptococcus mutans*, *Streptococcus sanguis*, and *Lactobacillus casei*.
- M.S. (microbiology) 1984 University of Rochester; Rochester, NY
- B.S. (genetics) 1978 University of California at Davis

Experience:

- The Microbiology Network (<http://www.microbiol.org>) 2/95 to present

- Own, operate and maintain the Internet information service for microbiologists. This service provides information, links, mail lists, and web pages for individuals and user's groups in microbiology.
- Own and Moderate the [PMFList](#) since 7/95 – an Email list devoted to pharmaceutical microbiology.
- Own and Moderate the [PSDGList](#) since 9/2005 - an Email list devoted to pharmaceutical stability programs.
- Vectech Pharmaceutical Consultants
 - 3/06 - Present: Senior Director, Microbiology Services
 - 3/04 – 3/06: Pharma Consultant, Microbiology

Recent Projects:

- Many training programs for international pharmaceutical, medical device and personal products companies
- Expert Witness for FDA in legal action involving a Medical Device Manufacturer
- Redesign and re-equipped a microbiology laboratory to eliminate persistent contamination issues. Job involved training, rewriting the entire SOP system, re-hiring technicians and lab management, and facility redesign to optimize work-flow. This laboratory supported environmental monitoring for an aseptic manufacturing facility and conducted finished product testing.
- Market review of available rapid microbiological methods with focus on consumer Return on Investment (ROI). Study conducted for vendor.
- Laboratory review for start-up focusing on microbiology laboratory control and data integrity. Included training, SOP generation and benchmarking studies as well as input on product design.
- Project management for changes to legacy API manufacturing process to "green" the process and eliminate costs associated with toxic preservative in raw material. Project planning, project management (coordination of work at three separate locations during the 12 month project) and regulatory submission.
- Generation of technology benchmarking reports for microbiology in pharmaceutical and personal care industries.
- [Publications](#)
- [Presentations](#)

- In-house Courses

- The Pharmaceutical Microbiology Forum (<http://www.microbiologyforum.org>)
 - 5/05 – Present: President; Editor - PMF Newsletter; this newsletter designed to provide a source of information and training for the professional microbiologist in regulated industries. Archives available at <http://www.microbiologyforum.org/news.htm>.
- Scientific Advisory Boards
 - Genomic Profiling Systems 4/02 – Present
 - MODA Technology Partners 12/06 – Present
- Editorial Boards
 - *Controlled Environments Magazine* 10/05 – Present
 - *PDA Letter* 12/05 – Present
 - *PMF Newsletter* 1/06 – Present
- Alcon Laboratories, Inc., Fort Worth, TX
 - 3/01 – 3/04: Director, R&D Microbiology
 - 1/98 – 3/01: Associate Director of R&D Microbiology
 - 6/94 – 12/97: Assistant Director of R&D Microbiology
- Bausch & Lomb Research Center, Rochester, NY
 - 9/92 - 6/94: R&D Manager, Product Development Microbiology
 - 10/91 – 9/92: R&D Manager, Healthcare Products
 - 9/88-10/91: Senior Research Specialist; Lab Leader, Microbiology Research
- Monroe Community College, Rochester, NY
 - 1992 - 6/94: Adjunct Faculty, Dept. of Biology Taught course (lecture and lab) "Medical Microbiology for Nurses" for four semesters.
- Medical College of Virginia, Richmond, VA
 - NIH Postdoctoral Fellowship under Dr. Francis Macrina in the Department of Microbiology, 1/86 - 7/88.

Memberships:

- United States Pharmacopeia (USP)
 - 1993 - Named to advisory panel (Preservation Efficacy and

- Aseptic Processing) to Microbiology Subcommittee of USP
 - Elected to serve the 1995-2000 revision cycle on the USP Subcommittee of Revision, Microbiology
 - Elected Vice-chairman of the USP Committee of Experts, Analytical Microbiology, for the 2000-2005 revision cycle
 - Elected Vice-chairman of the USP Committee of Experts, Microbiology and Sterility Assurance, for the 2005-2010 revision cycle
 - Member Project Team 18 (PAT); Working Group 6 (Rapid Microbiology Methods) from 2003 to present
- Association for the Advancement of Medical Instrumentation (AAMI)
 - USP representative to the Association for the Advancement of Medical Instrumentation (AAMI) 1995-2000.
 - Alcon representative to WG 8-Microbiological Methods; and WG 4-Biological Indicators, from 1999 to 2004.
- Parenteral Drug Association (PDA)
 - Member of Task Force on "Microbiological Data Deviations"
 - Member of Task Force on "Validation of Alternate Microbiological Test Methods" 1998 – 2000 (completion)
 - Member of Task Force on "Isolator Technologies"
 - Served on Conference Planning Boards:
 - 1997 Annual Conference (3/97 in Philadelphia, PA)
 - Basel 2000 Meeting (2/00 in Basel, Switzerland)
 - 2001 Spring Conference (3/00 in Las Vegas, NV)
 - Program Chair of "BSE/TSE Issues Forum" (December 5-6, 2001 in Washington, DC)
 - Faculty for TRI (Training Research Institute) 2004 to present
 - Editorial Board for *PDA Newsletter*
- American Society for Microbiology (ASM)
 - Board of Education and Training
 - Auditor/Reviewer for Workshops
 - Faculty and convener in national workshops 1990, 1992, 1994, 2004
 - Vice President of Central NY chapter 1991-1993
 - President of Central New York Chapter 1993-1994
 - Planning Committee, Texas Branch Fall Meeting, 1999

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[Publications](#)

1. [Correlation of the Genetic Map and the Endonuclease Site Map of Bacillus subtilis Bacteriophage SPO2](#); with S. Graham, Y. Yoneda, and F.E. Young. *Journal of Virology* 42: 131 134 1982.
2. [Acid Tolerance, Proton Permeabilities, and Membrane ATPases of Oral Streptococci](#); with G.R. Bender and R.E. Marquis. *Infection and Immunity* 53: 331 338 1986.
3. [Membrane associated and Solubilized ATPases of Streptococcus mutans and Streptococcus sanguis](#); with R.E. Marquis. *Journal of Dental Research* 66: 1095 1098 1987.
4. [Fluoride Inhibition of Proton Translocating ATPases of Oral Bacteria](#); with Gary R. Bender and Robert E. Marquis. *Infection and Immunity* 55: 2597-2603 1987.
5. [A Spreadsheet for the Quantitative Validation of Direct Transfer Sterility Testing](#). *Binary: Computers in Microbiology*. 2: 191-194. 1990.
6. [Neutralization Efficacy of Dey-Engley Media in Testing of Contact Lens Disinfecting Solutions](#); with Thomas Wrzosek and David W. Proud. *Journal of Applied Bacteriology* 70: 351-354. 1991.
7. [D-value Determinations Are an Inappropriate Measure of Disinfecting Activity of Common Contact Lens Disinfecting Solutions](#); with R.J. Franco, M.F. Mowrey McKee, S.C. Busschaert, J. Hamberger, and D.W. Proud. *Applied and Environmental Microbiology* 57: 2021-2026. 1991.
8. [Ophthalmological Preparations](#); with T.M. Dolak, O.W. Lever, D. Marsh, and I. Moran. *IN Ullman's Encyclopedia of Industrial Chemistry* vol. A 18 VCH Publ, Germany. pp. 127-151 1991.
9. [Development of a Universal Diluting Fluid for Membrane Filtration Sterility Testing](#); with David W. Proud. *Applied and Environmental Microbiology*. 58: 1035-1038. 1992.
10. [A Critical Evaluation of the Multi-item Microbial Challenge Test in Ophthalmic Disinfectant Testing](#); with D.W. Proud, H. Proskin and D.A. Keister. *The CLAO Journal*. 18: 155-160. 1992.
11. [The Importance of Neutralizer Evaluations in the Microbicidal Testing of Preservatives and Disinfecting Solutions](#). *International Contact Lens Clinics*. 19: 167-173. 1992.
12. [The Relation Between Oral Pain and Ethanol Concentration in Mouthrinses](#); with S.J. Bolanowski and G.A. Gerscheider. *Journal of Periodontal Research* 30: 192-197. 1995.

13. **Neutralizer Evaluations as Control Experiments for Biocidal Efficacy Tests** *IN Handbook of Disinfectants and Antiseptics*, J.M. Ascenzi (ed.) Marcel Dekker, Inc., NY. pp. 43 - 62. 1996.
14. **Antimicrobial Effects of Hydrogen Peroxide as an Antiseptic and Disinfectant**; with Andrea Lance, *IN Handbook of Disinfectants and Antiseptics*, J.M. Ascenzi (ed.) Marcel Dekker, Inc., NY. pp159 - 176. 1996.
15. **Preservative Efficacy, Microbial Content, and Disinfectant Testing**; with Mary Anne Magee and Daniel K. Brannan, *IN Cosmetic Microbiology*, D.K. Brannan (ed.) Marcel Dekker, Inc., NY. 1997. p.95.
16. **In-use Shelf-Life Testing – What Data are Required and When?**; with Brian Matthews and Danny Dunn. *Regulatory Affairs Journal* 9:728-733. 1998.
17. **Activities of the USP Microbiology Subcommittee of Revision During the 1995 – 2000 Revision Cycle**; with Joseph E. Knapp and Roger Dabbah *PDA Journal of Science and Technology* 55(1):33-48. 2001
18. **The Role of USP in the Assessment of Microbiological Quality of Pharmaceuticals: A Five-Year Retrospective Leading to the Future**; with Roger Dabbah and Joseph E. Knapp *Pharmaceutical Technology North America* 25(7):54-61 2001
19. **Review of Standard for Evaluating the Effectiveness of Contact Lens Disinfectants** with Ruth A. Rosenthal and Barry A. Schlech. *PDA Journal of Science and Technology* 56(1):37-52. 2002
20. **Developing an Information Chapter in the USP to Demonstrate Equivalency in Microbiological Methods** with Joseph Knapp, Roger Dabbah and David Porter *American Pharmaceutical Review* 5 (2):14-19 2002
21. **Validation of Microbial Recovery from Disinfectants**; with David W. Proud, Stephen Rachui, and Daniel K. Brannan *PDA J of Science and Technology* 56(5):255-266. 2002
22. **Development of the Antimicrobial Effectiveness Test as USP Chapter <51>**; with David Porter. *PDA J of Science and Technology*. 56(6):300-311. 2002
23. **The USP Perspective to Minimize the Potential Risk of TSE-infectivity in Bovine-derived Articles Used in the Manufacture of Medical Products**; with Ian DeVeau and Roger Dabbah. *Pharmacopeial Forum*. 30(5):1911-1921. 2004

24. [Microbial Identification in the Pharmaceutical Industry](#); with Anthony Cundell. *Pharmaceutical Forum*. 30(5):1884-1894. 2004
25. [Towards an Improved Sterility Test](#); with Jeanne Moldenhauer. *PDA J of Science and Technology* 58(6):284-286. 2004
26. [Validation of Alternate Microbiology Methods for Product Testing - Quantitative and Qualitative Assays](#). *Pharmaceutical Technology*. 29(4):118-122 Jan/Feb 2005.
27. [Activities of the USP Analytical Microbiology Committee of Experts During the 2000 - 2005 Revision Cycle](#); with Joseph E. Knapp and David Porter *PDA Journal of Science and Technology* 59 (3):157-176. 2005.
28. [Disinfectant Rotation – A Microbiologist’s View](#). *Controlled Environments* (formerly *A2C2*). 8(7):9-14. July, 2005
29. [Cleanroom Microbiology](#). *IN Environmental Monitoring: A Comprehensive Handbook - Volume 1*, J Moldenhauer (ed.) DHI Publications, Washington, DC. pp 97-118. 2005
30. [Opportunities for the Pharmaceutical Industry](#). *IN Encyclopedia of Rapid Microbiological Methods - Volume 1*, M. Miller (ed.) DHI Publications, Washington, DC. pp 123-156. 2005
31. [Microbial Identification Systems](#); with J. Moldenhauer. *IN Environmental Monitoring: A Comprehensive Handbook - Volume 2*, J. Moldenhauer (ed.) DHI Publications, Washington, DC. pp 281-296. 2006
32. [Preservative Efficacy Testing and Microbial Content Testing](#). *IN Cosmetic Microbiology 2nd Ed*, P. Geiss (ed.) Marcel Dekker, Inc., NY. pp. 111-145. 2006.
33. [Compendial Requirements for Automated Microbiological Method Validation: The Role of USP Chapter <16> “Automated Methods of Analysis” and the Proposed Chapter <1058> “Analytical Instrument Qualification”](#) with David Jones *PDA Newsletter* 42(6):23-26 2006.
34. [Microbial Surface Monitoring](#); *IN Environmental Monitoring* Anne Marie Dixon (ed) Informa Healthcare. 2006.
35. [The Harmonization of the Microbial Limits Tests](#); *Pharmaceutical Technology* 30(12):66-73 2006.
36. [Is Real-Time-Release Through PAT Compatible with the Ideal of “Science-Based Regulation?”](#) *Pharmaceutical Technology* 31 (2):97-98. 2007

37. [Articles of Interest to the Microbiologist](#); *PDA Letter* 18(2):7-10. 2007
38. [Compounding of Sterile Medications in the Pharmacy - USP Chapter <797> Provides Guidance](#) with David Porter *Controlled Environments* 10(6):11-13. 2007
39. [Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics](#) DHI Publishers, Inc. 2007
Awarded PDA's "Distinguished Author" for 2008
40. **Microbiology and the Internet** *IN Microbiology in Pharmaceutical Manufacturing 2nd Ed* Richard Prince (ed) DHI Publ 2008
41. **Global Harmonization of Microbiology-Related Compendial Chapters** *IN Microbiology in Pharmaceutical Manufacturing 2nd Ed* Richard Prince (ed) DHI Publ 2008
42. **Disinfectant Rotation**; *IN Disinfection and Decontamination: Principles, Applications and Related Issues* Gurusamy Manivannan (ed) Taylor and Francis **in press**

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Presentations - listing (over 200 total) truncated at 2005

- Invited SPEAKER to the Barnett Conference "Advances in Rapid Methods" held February 10-11, 2005 in Washington, DC. Presented WORKSHOP on "Rapid Microbiology and Contemporary Identification Systems in Support of Manufacturing."
- Invited SPEAKER to the Barnett Conference "Rapid Microbiological Methods" held March 23-26, 2005 in Brussels, Belgium
 - "Rapid Microbiology and Process Analytical Technology"
 - "Rapid Identification Methods in an Environmental Monitoring Program"
- Invited SPEAKER to the PDA Metro Chapter meeting held March 28, 2005 in Newark, NJ "Rapid Microbiology in Process Analytical Technology (PAT)"
- "Current Compliance Expectations in the QA/QC Microbiology Laboratory – USP Proposed Chapter <1117> Microbiological Best Laboratory Practices" presented at the 2005 PDA Annual Meeting held April 3 – 5, 2005 in Chicago, IL.
- Organizing Committee USP Workshop held May 2-4 by USP for FabraFarm in Sao Paulo, Brazil. Spoke on "Microbiological Validation", "Alternate Microbiological Methods" and "Best Microbiological Practices"
- Seminar Lecturer for High Peaks Associates 2005 Spring Course Series – Taught several day-long courses on:

- Microbiology and the USP
 - Validation of Microbiological Methods
 - Auditing the Pharmaceutical QC Microbiology Lab
- Invited in-house courses provided to pharmaceutical companies during 2005 on "Microbiology for the Non-microbiologist"
- "Alternative Microbiological Methods: Current Trends and Impact on the Industry" presented September 20, 2005 at the Parenteral Drug Association's (PDA) Rapid Microbiological Methods meeting in Milan, Italy
- "European Proposed Draft Chapter 5.1.6. Alternate Methods for Control of Microbiological Quality" presented at the 2005 RMUG Conference September 26-27, 2005 in Washington, DC.
- "Rapid Microbiology and Contemporary Identification Systems in Support of Manufacturing" presented September 28, 2005 at the PDA Capital Chapter meeting.
- "Microbiology for the Technical Professional" a two-day course taught for ISPE on October 12 and 13, 2005 in Brussels, Belgium
- Convenor of "Microbiology in Support of Manufacturing – The Role of the Compendia" held October 16-17 by PMF in Rochester, NY
 - "USP Activities"
 - "Best Microbiological Practices"
- Invited Speaker First Latin American Microbiology Conference, held November 7-12, 2005 in Buenos Aires, Argentina.
 - Two-day course on "Validation of Rapid and Compendial Microbiological Methods"
 - "Preservative Systems"
 - "Validation of Microbiological Methods"
 - "Microbial Limits Tests: 'Objectionable' vs 'Specified' Microorganisms"
- Invited Speaker to the A3P conference on "Equipment Decontamination and Applied Microbiology" held November 22 and 23 in Montreal, Canada. Spoke on "Rapid and Compendial Microbiological Methods"
- Invited Speaker to IVT's "Microbiology Event of the Year" held December 4-7, 2005 in Amsterdam, The Netherlands. Presented workshops:
 - "Validation of Microbial Methods"
 - "Auditing a Microbiology Laboratory"
 - "Current USP Activities"
- Invited Speaker to Biopharm Manufacturing and Distribution Summit held December 12-13, 2005 in Reston, VA. Spoke on "FDA's Guidance to Industry on Manufacture of Product by Aseptic Processes."
- Faculty of USP's Pharmacopeial Education Course "Fundamentals of Microbiological Testing" held January 11, 2006 in Berkeley, CA.
- Moderator and Speaker at IIR Aseptic Processing Conference held in London, UK February 27 and 28, 2006.
- Invited Speaker J&J CORD Meeting held March 2, 2006 in New Jersey on topic of "Environmental Isolates as Control Strains"
- Moderator and Conference Organizer to 2006 PMF Good Manufacturing Practice for Microbiology Conference held June 6-7, 2006 in Philadelphia, PA.

- GMP for Microbiology – The Impact of USP Chapter <1117> Best Microbiology Laboratory Practices
 - ISO 17025 in the Microbiology Lab
 - Microbial Identification
 - Course – “Validation of Microbiological Methods”
- Microbial Identification in Environmental Monitoring – Presented as part of the 2006 Japanese Pharmaceutical Forum June 14, 2006.
- Validation Issues with the Harmonized Microbial Limits Tests – a 90-minute webinar presented for PDA on August 10, 2006
- Instructor “Laboratory Controls” at PDA-TRI Aseptic Processing course August 23, 2006
- Invited Speaker at IVT’s Environmental Monitoring Conference August 25 – 26, 2006 in Washington, DC
 - Microbiology Methods Used for EM and the Impact of Method Variability
 - Bacterial Identification in Environmental Monitoring
- Microbiology Methods Used in the Pharmaceutical QC Laboratory” presented at the 2006 AOAC Annual Meeting held September 17-21, 2006 in Minneapolis, MN
- Faculty of USP’s Pharmacopeial Education Course “Fundamentals of Microbiological Testing - held September 25, 2006 held at the USP Annual Scientific Meeting in Denver, CO.
- Invited Speaker to EDQM Scientific Symposium “New Microbiology Chapters of the European Pharmacopoeia” meeting October 3-4, 2006 in Strasbourg, France
 - “USP Implementation of the New Chapters”
 - “USP Implementation of the Chapter on Rapid Microbiological Methods”
 - “Towards an Improved Sterility Test”
- Moderator of PMF 2006 Fall Forum held October 12-13, 2006 in Rochester, NY. Presented on “Harmonized Microbial Limits Tests in the USP, Pharm Eur and JP”
- “Rapid Microbiological Methods in Support of Manufacturing” presented as a webinar on October 19, 2006.
- “Preservative Neutralization a.k.a. Method Suitability Studies” presented October 25, 2006 at the CTFA Annual Meeting in Newark, NJ Invited Speaker
- “Validation of Alternative Microbiological Methods – USP <1223> presented October 31, 2006 at the PDA Microbiology Symposium in Bethesda, MD Invited Speaker
- “Validation Issues with the Harmonized Microbial Limits Tests” presented November 14, 2006 at the NJPQCA Meeting in Union, NJ Invited Speaker
- Invited Speaker to the 2006 Annual Pharmig meeting in Nottingham, UK November 29-30, 2006.
 - “The Harmonized Microbial Limits Tests”
 - “Towards an Improved Sterility Test”
- “Media Concerns with the Harmonized Microbial Limits Tests” presented to REMEL Sales meeting January 16, 2007 in Nashville, TN.
- “Validation Issues with the Harmonized Microbial Limits Tests” presented January 18, 2007 and January 19, 2007 to the Southern

- California Chapter of PDA in Los Angeles, CA.
- "A Comparison of the USP and Pharm Eur Chapters on Validation of Alternate Microbiological Assays" presented January 22, 2007 in Baltimore, MD at the 2007 RMUG Meeting.
- *Organizer and Chief Instructor* – Environmental Databases. 3 day course taught February 7-9, 2007 at PDA-TRI
- "Recent Advances in Environmental Monitoring" presented February 14, 2007 at the ISPE Winter Meeting in Tampa, FL
- *Organizer* of the 2007 PMF Open Conference on Compendial Issues held February 19-21, 2007 in Baltimore, MD.
- *Organizer and Moderator* of PMF 2007 Conference on Validation Issues in Microbiology held May 14-15, 2007 in Fort Worth, TX.
- Invited Speaker to the 2007 Annual Summer Pharmig meeting in Dublin, Ireland June 13-14, 2007.
 - "The Harmonized Microbial Limits Tests"
 - "Towards an Improved Sterility Test"
- *Organizer and Moderator* of PMF 2007 Cosmetic Microbiology Conference held September 17-18, 2007 in Newark, NJ.
- *Organizer and Moderator* of PMF 2007 Fall Forum held October 15-16, 2007 in Rochester, NY.
- *Organizer* of the 2008 PMF Open Conference on Compendial Issues held February 12-13, 2008 in Baltimore, MD. Presented "Microbial Limits Tests"
- "Audits of Microbiology Labs" presented to FDA/ORA February 28, 2008 as part of FDA Inspector Training at FDA Headquarters in Rockville, MD.
- "Focus on Air" presented at the 2008 PMF Conference on Environmental Monitoring held March 10-11, 2008 in Philadelphia, PA
- "Microbial Monitoring of Water" presented April 1-2 at the PDA Europe annual meeting in Frankfurt, Germany.
- *Organizer and Moderator* of PMF 2008 GMP in Microbiology Conference held April 7-8, 2008 in the DFW Metroplex, TX. Presented
 - "The CFR and a History of GMPs"
 - "USP <1117> and the FDA Guide to Inspections of Pharmaceutical QC Microbiology Labs"
- "PAT and Real-Time-Release – Does This Work for Microbiology?" presented at the PDA Annual Meeting April 14-18, 2008.
- "Rapid Methods and the Sterility Test" presented at the Applied Biosystems conference on methods development in Orange County, CA on May 7, 2008.
- "Finished Product Investigations" presented at the 2008 PMF Conference on Microbial Data Deviations in San Francisco, CA on May 20, 2008.
- "Proficiency Testing for the Pharmaceutical QC Microbiology Laboratory" Presented at the ASM workshop *Management of the QC Microbiology Laboratory* June 1, 2008 (at the AASM Annual Meeting)
- "Rapid Microbiology & Water" Presented at the ISPE Annual Meeting June 4, 2008 in Washington, DC
- *Organizer and Moderator* of PMF 2008 Validation Conference held May 28-29, 2008 in Philadelphia, PA. Presented "Validation Studies in Microbiology Testing"
- "The Emergence of Microbial Identification Systems to Meet Today's Needs in the cGMP Environment" presented at the Applied Biosystems SEQ™ Rapid Molecular Methods Workshop in Amsterdam, The Netherlands on

June 6, 2008.

- "Analytical Methods: Method Validation for Sterility and Microbial Limits" Presented to FDA Inspector Training Course *LB215 Introduction to Pharmaceutical Inspections for Analysts* on July 15, 2008.
- "Viewpoint: Pharmaceutical Perspective and Experience on Harmonization of Methods Validation" Presented at the IAFP (Int'l Assoc Food Protection) Annual Meeting on August 4, 2008 in Columbus, OH.
- "Why Does Bulk Soap Become Contaminated?" Presented to Industry group August 12, 2008.
- "Summary of the USP/ Pharm. Eur. Microbial Limits Chapters <61>/2.6.12, <62>/2.6.13 & <1111>/5.1.4" Presented at the 2008 PMF Conference on Cosmetic Microbiology in Newark, NJ September 15-16, 2008.
- "Validation of Microbiological Methods" Presented at the 2008 PMF Conference on Cosmetic Microbiology in Newark, NJ September 15-16, 2008.
- "Harmonized Microbial Limit Tests" Presented at the 2008 United States Pharmacopeia Annual Scientific Meeting in Kansas City, MO on September 24, 2008.
- *Organizer and Moderator* of 2008 PMF Fall Forum held October 13-14, 2008 in Rochester, NY. Presented "Recent Changes in USP <1116> Microbiological Control and Monitoring Environments Used for the Manufacture of Healthcare Products".
- "Validation Overview of Rapid Microbiological Methods" Presented at the Personal Care Products Council 2008 Meeting on *Rapid Microbiological Methods* on October 23, 2008 in Newark, NJ.

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In-house Training Courses

Courses Available

These courses are available in formats and content customized to meet your particular needs:

- **Microbiology for Non-microbiologists**; 2 day course on **basic pharmaceutical microbiology** for those needing background in the subject (formulators, RA, QC management)
- **Microbiology for Manufacturing Management**; 1 day course on pharmaceutical microbiology designed for **manufacturing managers**
- **Microbiology for Manufacturing Personnel**; 2 hour course on pharmaceutical microbiology designed for **manufacturing operators**
- **Rapid Microbiological Methods**; Overview of RMM specifically tailored to site needs. **Focus is on analysis of needs** and generation of User Requirements Document to drive selection and validation of appropriate technology.
- **Auditing the Microbiology Lab**; 1 day course. This is taught from a goal-oriented auditing philosophy. GMP issues are covered, but the **primary focus of the course is recognition of common problems in QC microbiology laboratory operation as well as the development of practical solutions** to difficulties in data generation, recording, analysis and effective reporting.
- **GMP for the Microbiology Lab**; GMP training tailored specifically to the needs of microbiology. Course covers basic GMP, guidance documents on microbiology lab operations, and recent FDA 483

activities in microbiology. This course is tailored to site needs and meets requirements for annual GMP training in a relevant fashion.

- **Microbial Identification in Environmental Monitoring** – 2 hour introductory overview of available technologies and applications for use in the microbiology function.
- **Understanding the Harmonized Microbial Limits Tests** - 3 hour lecture/discussion format stressing the new compendial chapters, validation, verification and new expectations in USP <1111>.
- **Compendial Chapters for the Microbiologist** - 3 hour review of USP chapters with relevance to the QC Microbiology Lab. Course focuses on practical methods to achieve compliance.
- **GMP for the Manufacturing Operator**; 3-day intensive course providing GMP training tailored specifically to the needs of manufacturing line operators. Course covers basic GMP (and the reasons behind the regulations). This course is not a listing of the CFR regs, but uses them to focus on current practice and the science behind contamination control. This course is tailored to site needs and meets requirements for annual GMP training in a relevant fashion.

Others as needed - contact scott.sutton@microbiol.org.

Courses taught in 2005

Microbiology for Non-microbiologists; 2 day course.

Courses taught in 2006

GMP for the Microbiology Lab; GMP training tailored specifically to the needs of the QC microbiology lab. Presented once.

Microbiology for Manufacturing Personnel; a 2 hour overview provided to manufacturing personnel (Aseptic as well as Non-sterile manufacturing) as part of GMP training. Focus on the role of cleanliness to successful product manufacture. Course tailored to site requirements. Presented 5 times.

Microbiology for Manufacturing Management; a day-long course provided to manufacturing management of a non-sterile facility.

Rapid Microbiological Methods; Overview of RMM specifically tailored to site needs. Presented twice.

Fundamentals of Microbiological Testing; Day-long introductory microbiology course provided as part of the USP's Pharmacopeial Education program. Presented 4 times.

Microbial Identification in Environmental Monitoring – introductory overview of available technologies and applications provided to Japanese companies. Presented twice.

Courses taught in 2007

Rapid Microbiological Methods – Overview of RMM specifically tailored to site needs.

Environmental Monitoring – 1 day overview of methods, regulatory expectations for aseptic and non-sterile manufacture of pharmaceuticals and medical devices. Presented twice.

GMP for the Microbiology Lab; GMP training tailored specifically to the needs of the QC microbiology lab.

Best Laboratory Practices; Current industry standards with an in-depth review of USP <1117> "Best Microbiology Laboratory Practices".

Courses taught in 2008 (to date)

Environmental Monitoring – 1 day overview of methods, regulatory expectations for aseptic and non-sterile manufacture of pharmaceuticals and medical devices. Taught three times.

Investigations of Microbial Data Deviations; A half-day course focusing on microbiology-related investigations and the role the microbiologist plays on investigation teams. Specific attention paid to investigations of environmental monitoring excursion, media fill issues and sterility failures. Presented four times.

GMP for the Microbiology Lab; GMP training tailored specifically to the needs of the QC microbiology lab.

- Half-day version of course taught twice
- Full-day version of course taught twice (once following full GMP audit of lab to assist in focusing course material to company's needs)

Best Laboratory Practices; Current industry standards with an in-depth review of USP <1117> "Best Microbiology Laboratory Practices". Taught twice.

Microbiology and Contamination Control for Manufacturing; Current industry standards with an in-depth review of USP <61>, <62> and <1111> (Microbial Limits) taught as a day-long course to non-sterile manufacturing supervisors

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