

Scott Van Wagenen Sutton

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Degrees:

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

B.S. (genetics) 1978

University of California at Davis

Experience:

The Microbiology Network (<http://www.microbiol.org>)

2/95 – Present: Owner and Principal

- Active Consultant and Trainer
 - GMP
 - Investigations
 - Contamination control
 - Aseptic Environments
 - Environmental Monitoring
 - Objectionable Organisms/Non-sterile production control
 - QC microbiology
- 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 (<http://www.microbiol.org/pmflist.htm>)
- Own and Moderate the PSDGList since 9/05 – an Email list devoted to pharmaceutical stability: study designs, regulatory and technical issues, etc. List has 15 year history in the stability community. (<http://www.microbiol.org/psdglis.htm>)

Vectech Pharmaceutical Consultants

3/04 – 11/09

Assignments have included manufacturing process redesign, aseptic manufacturing qualification, non-sterile manufacturing, laboratory design and development of quality systems for microbiology, in-house training on contamination control, QC testing and rapid microbiological methods.

The Pharmaceutical Microbiology Forum (<http://www.microbiologyforum.org>)

5/05 – Present: President; Editor - *PMF Newsletter*
(<http://www.microbiologyforum.org/news.htm>)

Rapid Micro BioSystems (formerly Genomic Profiling Systems)

4/02 – Present: Industrial Microbiology Advisory Board
Serve as advisor to management in the development of a novel rapid microbiological method for microbial enumeration.

Pharmaceutical Technology Magazine

6/10 - Present: Editorial Board

J Validation Technology & Journal of GxP

6/09 – Present: Columnist: Microbiology Topics

Controlled Environments Magazine

10/05 – Present: Editorial Board

PDA Newsletter Magazine

12/05 – 12/09: Editorial Board

MODA Technology Partners

12/06 – Present: Scientific Advisory Board

Serve as advisor to management on application of a wireless data collection system and dedicated database for Environmental Monitoring data in the pharmaceutical, medical device and personal products industries.

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.

University of Rochester, Rochester, NY.

Teaching assistant in introductory microbiology, 1981; in medical school microbiology, 1984; lectured in microbial physiology, 1986.

University of Rochester, Rochester, NY
Laboratory Technician III, 1978; Technical Associate I, 1980.

University of California at Davis, Davis, CA
Teaching assistant in introductory biology class 1976 and 1977.

Memberships:

United States Pharmacopeia (USP)

- Elected to serve on the Committee of Experts, Microbiology for the 1995-2000, 2000-2005, 2005-2010 and 2010-2015 revision cycles
- Elected Vice-chairman of the USP Committee of Experts, Analytical Microbiology, for the 2000-2005 and 2005 – 2010 revision cycles.
- Instructor in the USP Pharmacopeial Education group
- Member Project Team 18 (PAT); Working Group 6 (Rapid Microbiology Methods) from 2003 to present
- 1993 - Named to advisory panel (Preservation Efficacy and Aseptic Processing) to Microbiology Subcommittee of USP

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) (1991 – present)

- **Editorial Board** of PDA Newsletter 2007-2010
- **Faculty** for TRI (Training Research Institute) 2004 to present
- Member of several Task Forces
- Served on many conference planning boards

American Society for Microbiology (ASM)

- Board of Education and Training - Auditor/Reviewer for Workshops
- Faculty and convener in national workshops 1990, 1992, 1994, and 2004.
- Vice President of Central NY chapter 1991-1993
- President of Central New York Chapter 1993-1994
- Planning Committee, Texas Branch Fall Meeting, 1999

Publications

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.

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.

Membrane-associated and Solubilized ATPases of Streptococcus mutans and Streptococcus sanguis; with R.E. Marquis. *Journal of Dental Research* 66:1095-1098 1987.

- Fluoride Inhibition of Proton-Translocating ATPases of Oral Bacteria; with Gary R. Bender and Robert E. Marquis. *Infection and Immunity* 55:2597-2603 1987.
- A Spreadsheet for the Quantitative Validation of Direct Transfer Sterility Testing. *Binary: Computers in Microbiology*. 2:191-194. 1990.
- 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.
- 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.
- 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.
- A Universal Diluting Fluid for Use with Membrane Filtration Testing of Preservatives and Disinfecting Solutions; with David W. Proud. *Applied and Environmental Microbiology*. 58:1035-1038. 1992.
- 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.
- The Importance of Neutralizer Evaluations in the Microbicidal Testing of Preservatives and Disinfecting Solutions. *International Contact Lens Clinics*. 19:167-173. 1992.
- 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.
- 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.
- 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.
- USP Open Conference on Compendial Microbiology. *DIFCO Culture Club News* v6 Spring 1996 p.1.
- 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.
- In-use Shelf-Life Testing – What Data are Required and When?; with Brian Matthews and Danny Dunn. *Regulatory Affairs Journal* 9:728-733. 1998.

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

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 **Invited Paper**

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

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 **Invited Paper**

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

Development of the Antimicrobial Effectiveness Test as USP Chapter <51>; with David Porter. *PDA J of Science and Technology*. 56(6):300-311. 2002

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

Microbial Identification in the Pharmaceutical Industry; with Anthony Cundell. *Pharmacopeial Forum*. 30(5):1884-1894. 2004

Towards an Improved Sterility Test; with Jeanne Moldenhauer. *PDA J of Science and Technology* 58(6):284-286. 2004

Validation of Alternate Microbiology Methods for Product Testing - Quantitative and Qualitative Assays. *Pharmaceutical Technology*. 29(4):118-122. 2005

Activities of the USP Analytical Microbiology Committee of Experts During the 2000 - 2005 Revision Cycle; with Joseph E. Knapp and David Porter *PDA J Pharm Sci Tech*. 59(3):157-176 2005.

Disinfectant Rotation – A Microbiologist's View; *Controlled Environments*. 8(7):9-14. 2005

Cleanroom Microbiology; *IN Environmental Monitoring in the Pharmaceutical Industry Volume 1*, J. Moldenhauer (ed.) DHI Publications, Washington, DC. pp 97-118. 2005.

Opportunities for the Pharmaceutical Industry; *IN Encyclopedia of Rapid Microbiological Methods Volume 1*, M Miller (ed). DHI Publications, Washington, DC. pp. 123-156. 2005.

Microbial Identification Systems; with J. Moldenhauer. *IN Environmental Monitoring in the Pharmaceutical Industry*, J. Moldenhauer (ed.) DHI Publications, Washington, DC. 2006

Preservative Efficacy Testing; *IN Cosmetic Microbiology 2nd Ed*, P. Geiss (ed.) Marcel Dekker, Inc., NY. 2006

Automated Microbiological Method Validation and the Role of USP Chapter <16> Automated Methods of Analysis and the Proposed Chapter <1058> Analytical Instrument Qualification; with David Jones. *PDA Newsletter* June, 2006.

Microbial Surface Monitoring; *IN Environmental Monitoring for Cleanrooms and Other Controlled Environments*, Anne Marie Dixon (ed), Informa Healthcare. 2006

The Harmonization of the Microbial Limits Tests; *Pharmaceutical Technology* 30(12):66-73. 2006

Is Real-Time-Release Through PAT Compatible with the Ideal of "Science-Based Regulation?" *Pharmaceutical Technology* 31(2):97-98. 2007

Compounding of Sterile Medications in the Pharmacy - USP Chapter <797> Provides Guidance with David Porter *Controlled Environments* 10(6):11-13. 2007

Is Real-Time-Release Through PAT Compatible with the Ideal of "Science-Based Regulation?" *Pharmaceutical Technology* 31(2):97-98. 2007

Articles of Interest to the Microbiologist; *PDA Letter* 18(2):7-10. 2007

Disinfectant Rotation in a Cleaning/Disinfection Program for Clean Rooms and Controlled Environments; *IN Disinfection and Decontamination: Principles, Applications and Related Issues* Gurusamy Manivannan (ed). Taylor and Francis. 2007.

Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics DHI Publishers, Inc. 2007 **Awarded PDA's "Distinguished Author" for 2008**

Microbiology and the Internet *IN Microbiology in Pharmaceutical Manufacturing 2nd Ed* Richard Prince (ed) DHI Publ 2008

Global Harmonization of Microbiology-Related Compendial Chapters *IN Microbiology in Pharmaceutical Manufacturing 2nd Ed* Richard Prince (ed) DHI Publ 2008

Trending in the Environmental Monitoring Program: The Role of a Good Database Program; *IN Environmental Monitoring* Jeanne Moldenhauer (ed) DHI Publ 2009

USP <1211>: The Compendial Informational Chapter on Sterility Assurance - Origins and Future Direction *Pharm Technol Sterile Manufact 2009 Suppl*:s16-s21 2009

Does the International Harmonization of the USP Microbial Limits Tests Require Revalidation of Finished Product Tests? *J Val Technol* 15(3):10-16. 2009

Hand Washing—A Critical Aspect of Personal Hygiene in Pharma *J Val Technol* 15(4):50-55. 2009.

The International Harmonization of the Compendial Microbial Limits Tests - A Cautionary Tale of Compendial Participation. *J GxP* 13(4):8-15. 2009.

Handwashing, Hygiene, CGMP and Science. *J GxP* 14(1):62-69 2010.

Limiting Avoidable Microbiological Variability. *J Val Technol* 16(1):50-56 2010.

The Importance of a Strong SOP System in the QC Microbiology Lab. *J GxP* 14(2):44-52 2010.

Qualification of an Environmental Monitoring Program. *J Val Technol.* 16(2):78-82. 2010.

The Environmental Monitoring Program in a GMP Environment *J GxP* 14(3):22-30 2010.

Microbiology Laboratory Design: Quality and Facility Considerations (editor) for DHI Publ. 2010.

The Most Probable Number Method and Its Uses in Enumeration, Qualification and Validation *J Val Technol* 16(3):35-38. 2010.

Sterility Testing; *IN* Pharmaceutical Dosage Forms: Parenteral Medications, Third Edition Sandeep Nema and John D. Ludwig, (ed) **in press**

Abstracts and Oral Presentations

Hundreds of presentations and webinars have been made at international conferences, courses workshops and webinars. Recent invited presentations dealt with topics in Quality Control Microbiology, GMP, Aseptic Processing, Investigations of MDD (OOS), Environmental Monitoring, Manufacturing Contamination Control, Compendial Topics, Objectionable Organisms and alternate microbiological methods.

In-House Training Courses

Dozens of in-house courses presented since 2005 dealing with microbiological topics in pharmaceutical, medical device and personal product manufacture and testing. More than 1,000 students have attended these in-house courses.