

Michael J. Miller, Ph.D.

Experience

Microbiology Consultants, LLC, Lutz, Florida

President

February 2009 to present

Provide technical, regulatory, quality and compliance support for the pharmaceutical, biotech, gene and cell therapy, medical device, personal care and other regulated industries. Develop microbiological monitoring, control and continuous improvement strategies for API and fill-finish manufacturing, fermentation, recovery and purification, and aseptic processing and non-sterile manufacturing. Design and administer microbiological programs including environmental monitoring, investigations of laboratory and manufacturing microbial excursions and out-of-specification findings, laboratory audits, optimization and management, laboratory and facility design and qualification, cGMP compliance, Pharmacopoeia compliance, barrier isolator design and microbiological validation, microbiology method and protocol development, validation and technology transfer, contact lens care formulation development, manufacturing, stability testing and product release, disinfection, sterilization and the use of biological indicators, cleaning validation, process development, regulatory audit response and management (e.g., FDA 483, Warning Letter, Consent Decree, product recalls), regulatory dossier development support, and Process Analytical Technology (PAT). Support microbiology and rapid microbiological method suppliers and industry end-users in developing next generation technology platforms, validation and testing plans, financial and return on investment (ROI) strategies, commercialization approaches, and global regulatory and pharmacopoeia compliance. Provide guidance on investigations, remediation and risk assessments for microorganism recovery in nonsterile finished product, including those involving *Burkholderia cepacia* complex (BCC) and other objectionable organisms. Act as subject matter expert for microbiology technology companies during due diligence, partnership, collaboration, merger, and acquisition activities. Expert witness for matters related to pharmaceutical microbiology, ophthalmic formulations, contamination control, antimicrobial and preservative effectiveness, sterilization, pharmacopoeia interpretation and compliance, USP microbiology test methods, laboratory, and manufacturing GMPs, formulation development and stability, sterile and nonsterile manufacturing, research and development, and product quality.

Eli Lilly and Company, Indianapolis, Indiana

Director, Microbiology Leader and Senior Research Fellow

Manufacturing Science and Technology

October 2003 to February 2009

Provide technical and strategic leadership for microbiology and across all Manufacturing networks (Parenteral, Drug Product, Small and Large Molecule Bulk API) and in Product Research & Development. Support the development and technology transfer of new molecules and processes while aligning these activities with Lilly's Single Process Map, Quality by Design (QbD) and World Class Commercialization programs. Partner with Quality, Engineering, Operations and Development to ensure that the company meets or exceeds industry standards and regulatory expectations from a microbiological and sterility assurance perspective. Focus on the interface between Manufacturing and Development as microbiological control strategies are defined for new products, production facilities and contract manufacturers. Champion efforts to assess and implement new technologies and corporate manufacturing strategies that are aligned with GMPs for the 21st Century and Quality by Design (QbD) initiatives, including PAT applications, rapid microbiological methods, and barrier isolator manufacturing platforms. Partner with Global Quality Control Laboratory Microbiology Validation function to develop and implement next generation QC microbiology in-process bioburden, raw material, finished product and environmental monitoring platforms. Develop and maintain highly capable and dedicated PAT staff comprised of Ph.D. Research Scientists, Analytical Chemists and Technical Associates, maintain function's annual budget, and conduct performance appraisals. Guide subordinates in carrying out responsibilities and provide adequate resources to ensure that the PAT function can support the network's goals and objectives. Influence changes to microbiology, sterility assurance and PAT industry best practices through external interactions with professional and international compendial organizations. Interface with the FDA PAT team, CDER compliance and review microbiology staff and international regulatory authorities to influence change to future dossier/submission expectations and a reduction of regulatory review requirements that are aligned with Lilly's long-term product development and manufacturing strategies.

***Pharmaceutical Systems, Inc., Mundelein, Illinois
Vice President, Consulting
February 2002 to September 2003***

Responsible for consulting, developing, and implementing pharmaceutical manufacturing, QA/QC and regulatory solutions in all areas of medical device and pharmaceutical operations including sterilization, aseptic and non-sterile compounding and filling, Research & Development, microbiology, environmental monitoring, isolator/barrier systems, GMP/QSR compliance, QA/QC, regulatory submissions, manufacturing and laboratory start-up operations and regulatory compliance. Directly manage the activities for more than 20 consultants at a major pharmaceutical manufacturing facility under consent decree.

***Bausch & Lomb, Rochester, New York
Director, External Technology
Global Vision Care
October 2000 to January 2002***

Identify external commercialization, new product development, joint-ventures, licensing, and acquisition opportunities that are consistent with the strategic direction within Bausch & Lomb's Vision Care, Pharmaceutical, Surgical, General Eye Care and Vision Accessories business units. Interact directly with the company's Global Category Leaders, Corporate Business Development and Legal, and the commercial functions within each business unit. Represent the Company in negotiations and leverage its position with external clients and other companies via business initiatives and acquisitions and alliances. Coordinate technical due diligence activities within the Research & Development, Engineering and Commercialization/Marketing organizations. Act as United States Delegate on ISO Technical Committee 172; Optics and Ophthalmics.

***Bausch & Lomb, Rochester, New York
Director, Biological and Sterilization Sciences
Global Vision Care
January 1997 to September 2000***

Lead Global Microbiology, Toxicology and Sterilization Core Competencies supporting Bausch & Lomb's Vision Care, Pharmaceutical and Surgical Divisions worldwide. Support R&D new product development management process (contact lens, lens care, general eye care, ophthalmic pharmaceuticals, surgical devices), new product strategic direction, global product stability, and on-site product performance (e.g., with LASIK surgeons). Direct all microbiological and toxicological pre-clinical testing for Vision Care Division. Support global Operations (product release, process improvements, validation, training, laboratory start-up, troubleshooting), New Product Business Development (technical due diligence), Marketing (product claims, publications, professional meeting presentations) and Quality (internal and external lab and manufacturing audits/issues, ISO certification, domestic and International Quality Systems; ISO 9001, EN 46001, GMP). Support Regulatory Affairs (510k, PMA, CE submissions, product returns, field issues), and Legal (patent support, product litigation, competitive claims). Identify and evaluate external technologies, research collaborations, and products and processes that are consistent with the Corporation's long-term vision. Technical support during ISO and FDA audits. Maintain financial accountability for the function. Serve as Corporate liaison for ISO/AAMI Sterilization Standards Committees and a United States Delegate on ISO Technical Committee 172; Optics and Ophthalmics.

***Bausch & Lomb, Rochester, New York
Manager, Research Microbiology
Global Vision Care
March 1994 to December 1996***

Direct Senior Scientist staff in support of Global Research & Development for Contact Lens Care, General Eye Care, Device and Health Care sectors. Project Manager for Disinfection Research, High Throughput Screening Core Technologies, and other product development management teams. Provide support for domestic (510k, PMA) and international registration of Contact Lens and General Eye Care products. Start-up, audit (cGMP/ISO) and certify analytical laboratories and manufacturing sites worldwide. Primary Microbiology contact during FDA on-site, pre-

approval and GMP inspections. Direct terminal sterilization validation studies for medical device sector. Corporate consultant for on-site global Microbiology issues (manufacturing, aseptic processing, sterilization, process improvements, regulatory and GMP compliance, environmental monitoring, marketing). Microbiology Core Technology for container/closure and preservative-free multi-dose delivery systems. Corporate liaison for ISO/TC 198 (Sterilization of Health Care Products), U.S. delegate for ISO/TC 172 (Contact Lenses; U.S. Expert for Microbiology Committee), ANSI, and FDA standards development committees. Manage cost/budgets for laboratory and product development projects. Manage radioisotope testing facility. Certified ISO 9000 auditor for Division.

***Bausch & Lomb, Rochester, New York
Manager, Quality Assurance Microbiology
Personal Products Division
August 1991 to February 1994***

Direct exempt and non-exempt scientists and technicians. Support Corporate manufacturing and engineering units (contamination control, environmental monitoring, terminal sterilization validations). Direct release and stability testing of devices and aseptically filled products for Personal Products, Contact Lens and Pharmaceutical Divisions worldwide. Review laboratory compliance issues, modify existing and create new systems to comply with current GMPs and International compendial guidelines. Responsible for personnel training and start-up of Microbiology analytical laboratories and manufacturing sites. Audit and certify contract laboratories. Supervise barrier technology sterility test workstation and vaporized hydrogen peroxide bio-decontamination system. Coordinate consumer affairs microbiology testing. Act as consultant on quality issues, troubleshooting, and standards review and development. Primary Microbiology contact during FDA on-site, pre-approval inspections. Represent Corporation on AAMI - ISO Technical Committee 198 - Sterilization of Health Care Products.

***Johnson & Johnson Medical, Inc., Arlington, Texas
Manager, Senior Microbiologist
Research & Development
July 1988 to July 1991***

Direct personnel in support of new product development for emerging hospital sterilization technologies (STERRAD peroxide/plasma system). Develop process validations for medical device sterilization. Interact with hospital administration and central supply during clinical trials of new sterilization technologies. Provide documentation of analytical test procedures, corresponding data, and interpretations for FDA 510(k) submissions. Support the development of pre-clinical studies for advanced wound care products.

Education

Ph.D. Microbiology and Biochemistry. Georgia State University, Atlanta, Georgia, 1988
Doctoral Dissertation: Adherence of *Pseudomonas aeruginosa* to Contact Lenses.

B.A. Anthropology and Sociology (double major). Chemistry (minor). Hobart College, Geneva, New York, 1983

Awards and Honoraria

2018 Martin VanTrieste Pharmaceutical Science Award, Parenteral Drug Association (PDA)
2014 Distinguished Editor Award, Parenteral Drug Association (PDA)
2008 John Henry Hobart Fellow in Residence for Ethics and Social Change, Hobart and William Smith Colleges
2006 Distinguished Service Award, Parenteral Drug Association (PDA)
2006 Microbiologist of the Year, Institute for Validation Technology (IVT)

Academic Affiliations

Adjunct Professor, Department of Biology, Georgia State University, Atlanta GA (past)
Adjunct Professor, School of Optometry, University of Waterloo, Ontario, Canada (past)
Alumni Council, Hobart College, Geneva, NY (current)

Editorial Review and Advisory Boards (current)

American Pharmaceutical Review
European Pharmaceutical Review
PDA Journal of Science and Technology

Professional Memberships and Appointments (current)

Parenteral Drug Association (PDA)
Chairperson, PDA Technical Report No. 33 Task Force

Professional Memberships and Appointments (past)

Advisor to United States Pharmacopeia (USP); Modern Microbiological Methods Expert Panel
American Society for Microbiology (ASM)
PDA Strategic Planning Committee and Annual Meeting Program Committee
International Society for Pharmaceutical Engineering (ISPE)
Contact Lens Association of Ophthalmologists (CLAO)
Contact Lens Institute (CLI)
British Contact Lens Association (BCLA)
American Association of Optometry (AAO)
Association for Research in Vision and Ophthalmology (ARVO)
United States Delegate, ISO Technical Committee 172, Optics and Ophthalmics
Committee member, Association for the Advancement of Medical Instrumentation (AAMI)
Committee member, American National Standards Institute (ANSI), Z80 Ophthalmics
ISO Technical Committee 198, Sterilization of Health Care Products
Chairperson, USP Technical Committee 18, Working Group 6 (Rapid Microbiological Methods)

Expert Witness Deposition and Trial Testimony

2022. Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG, Novartis Technology LLC, Novartis Pharmaceuticals Corp. Case IPR2021-00816.

2020. Christina King and Klay King, individually and as Co-Personal Representatives of the Estate of Stephen King, deceased, v. Pharmatech, LLC; Raidel Figueroa; The Harvard Drug Group, LLC dba Rugby Laboratories; Bayshore Pharmaceuticals, LLC. Case No. CACE 17-017934.

2019. Frances Ruiz as Personal Representative of the Estate of Luis Ruiz, deceased, v. Teva Pharmaceuticals USA, Inc.; Teva Parenteral Medicines, Inc.; Teva Pharmaceutical Industries, Ltd.; AmerisourceBergen Drug Corporation; Blue Medical Supply, Inc.; Jay Harlan Epstein, M.D.; Anesthesia Associates of Pinellas County, P.A. Case No. 11-005957.

2016. Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated, and Bausch & Lomb Pharma Holdings Corp. v. Lupin, Ltd., and Lupin Pharmaceuticals, Inc. Civil Action File Nos. 1:14-cv-00667-JBS-KMW, 1:14-cv-04149-JBS-KMW, 1:14-cv-05144-JBS-KMW, 1:15-cv-00335-JBS-KMW; Innopharma Licensing, Inc., Innopharma Licensing, LLC, Innopharma, Inc., Innopharma, LLC, Mylan Pharmaceuticals, Inc., and Mylan Inc. Civil Action File Nos. 1:14-cv-06893-JBS-KMW, 1:15-cv-03240-JBS-KMW.

2013-2014. Astrazeneca LP and Astrazeneca AB v. Apotex, Inc. and Apotex Corp. Civil Action File No. 1:09-CV-1518 (RMB) (AMD). Appeal.

2014. Apotex Corp. v. Alcon Research, Ltd. Case IPR2013-00428, 00429 and 00430.

2014. United Therapeutics Corp. v. Sandoz Inc. et al. Civil Action File No. 12-1617 (PGS) (LHG) and 13-316 (PGS) (LHG).

2013. Alcon Canada Inc. and Alcon Research, Ltd. and Apotex Inc. and The Minister of Health. Court File No. T-1667-12.

2013. Peter Robertson and Kindra Robertson v. McNeil-PPC, Inc. and Johnson & Johnson, and DOES 1. Case No. 2:11-CV-09050-JAK-SS.

2009-2012. Astrazeneca LP and Astrazeneca AB v. Apotex, Inc. and Apotex Corp. Civil Action File No. 1:09-CV-1518 (RMB) (AMD).

2011. Alcon Research, Ltd. v. Barr Laboratories, Inc., Par Pharmaceutical, Inc. Civil Action No. 09-318-LDD (Consolidated).

2009-2010. Aletia Moon and James Zachary Carrier v. Advanced Medical Optics, Inc. Civil Action File No. 4:08-CV-021-HLM.

Publications, Books and Book Chapters

- 2020 Miller, M.J. Rapid Methods, in Cosmetic Microbiology, in *Cosmetic Microbiology, Third Edition*. Edited by Philip A. Geis. CRC Press, Taylor & Francis Group, LLC.
- 2019 Miller, M.J. Rapid Microbiological Methods, in *Pharmaceutical Microbiological Quality Assurance and Control: Practical Guide for Non-Sterile Manufacturing*. Edited by David Roesti and Marcel Goverde. John Wiley & Sons, Inc. (in press).
- 2017 Miller, M.J. A Comprehensive Review of the Revised European Pharmacopoeia Chapter 5.1.6. Part 1. *European Pharmaceutical Review*. 22(5): 20-24.
- 2017 Miller, M.J. A Comprehensive Review of the Revised European Pharmacopoeia Chapter 5.1.6. Part 2. *European Pharmaceutical Review*. 22(6): 27-30.
- 2017 Miller, M.J. The Regulatory Acceptance of Rapid Microbiological Methods. *European Pharmaceutical Review*. 22(3): 55-58.
- 2017 Miller, M.J. The Role of Rapid Microbiological Methods in Aseptic Processing, in *Aseptic and Sterile Processing, Control, Compliance and Future Trends*. Edited by Tim Sandle and Edward C. Tidswell. PDA and DHI Publishing, LLC.
- 2016 Miller, M.J., van den Heuvel, E.R., Roesti, D. The Role of Statistical Analysis in Validating Rapid Microbiological Methods. *European Pharmaceutical Review*. 21(6): 46-53
- 2015 Miller, M.J. Rapid Methods Update: Revisions to a United States Pharmacopeia Chapter. *European Pharmaceutical Review*. 20(4): 38-43.
- 2015 Miller, M.J. A Fresh Look at USP <1223> Validation of Alternative Microbiological Methods and How the Revised Chapter Compares with PDA TR33 and the Proposed Revision to Ph. Eur. 5.1.6. *American Pharmaceutical Review*. 18(5): 22-35.
- 2014 Miller, M.J. Rapid Microbiological Methods and the Regulatory Environment. *European Pharmaceutical Review*. 19(5): 24-27.
- 2013 Miller, M.J. Rapid Microbiology and the Newly Revised PDA Technical Report No. 33. *American Pharmaceutical Review*. 16(7): 34-38.
- 2013 Miller, M.J., Ragheb, S.M. Towards the Real Application of Rapid Microbiological Methods in Developing Countries. *European Pharmaceutical Review*. 18(5): 13-16.
- 2013 Miller, M.J. An Introduction to Rapid Microbiological Methods: Regulatory Acceptance, Validation and Implementation. *BioPharma Asia*. 2(3): 28-33.
- 2013 Miller, M.J. The Encyclopedia of Rapid Microbiological Methods: The New Fourth Volume Discusses

- Technologies, Regulatory Acceptance and Validation Case Studies. *European Pharmaceutical Review*. 18(3): 11-13.
- 2013 Miller, M.J. Framework for Fast Microbiological Assessment. *Pharmaceutical Manufacturing*. 12(3): 39-41.
- 2013 Miller, M.J. Looking to the Future: Rapid and Automated Microbial Identification Technologies, in *Encyclopedia of Rapid Microbiological Methods*, Volume 4. Edited by Michael J. Miller. PDA and Davis Healthcare International Publishing.
- 2013 Miller, M.J.; Walsh, M.R.; Shrake, J.L.; Dukes, R.E.; Hill, D.B. Evaluation of the BioVigilant IMD-A, a novel optical spectroscopy technology for the continuous and real-time environmental monitoring of viable and nonviable particles. Part II: Case studies in environmental monitoring during aseptic filling, intervention assessments and glove integrity testing in manufacturing isolators, in *Encyclopedia of Rapid Microbiological Methods*, Volume 4. Edited by Michael J. Miller. PDA and Davis Healthcare International Publishing.
- 2013 Miller, M.J.; Lindsay, H.; Valverde-Ventura, R.; O'Connor, M.J. Evaluation of the BioVigilant IMD-A, a novel optical spectroscopy technology for the continuous and real-time environmental monitoring of viable and nonviable particles. Part I: Review of the technology and comparative studies with conventional methods., in *Encyclopedia of Rapid Microbiological Methods*, Volume 4. Edited by Michael J. Miller. PDA and Davis Healthcare International Publishing.
- 2013 *Encyclopedia of Rapid Microbiological Methods*, Volume 4. Edited by Michael J. Miller. PDA and Davis Healthcare International Publishing.
- 2013 Miller, M.J., Fragoeiro, S., Ramachandran, A., van Empel, P. Improving the Quantitation of Live Antigens Used to Produce Rabbit Generated Serotype Specific Aniserum. *European Pharmaceutical Review*. 18(1): 55-57.
- 2012 Miller, M.J.: Hot Topics in Rapid Methods: Revisions to Validation Guidance and Real-Time Environmental Monitoring. *European Pharmaceutical Review*. 17(6): 58-61.
- 2012 Miller, M.J. Looking to the Future: Rapid and Automated Microbial Identification Technologies, in *Microbial Identification. The Keys to a Successful Program*. Edited by Mary Griffin and Dona Reber, PDA and Davis Healthcare International Publishing. Chapter 15: 1-29.
- 2012 Miller, M.J.; Miyashita, N. Rapid Micro Methods and the Next Generation in ATP Bioluminescence. *European Pharmaceutical Review*. 17(5): 14-16.
- 2012 Miller, M.J. Opportunities for Rapid Methods Discussions: Where the Experts are Meeting! *European Pharmaceutical Review*. 17(4): 11-13.
- 2012 Miller, M.J. Rapid Sterility Testing and the Impact of Recent Changes to the US Code of Federal Regulations. *European Pharmaceutical Review*. 17(3): 65-67.
- 2012 Miller, M.J. Rapid Micro Methods and EMA's Post Approval Change Management Protocol. *European Pharmaceutical Review*. 17(2): 65-67.
- 2012 Miller, M.J. Case Study of a New Growth-Based Rapid Microbiological Method (RMM) that Detects the Presence of Specific Organisms and Provides an Estimation of Viable Cell Count. *American Pharmaceutical Review*. 15(2): 18-25.
- 2012 Miller, M.J. Rapid Micro Methods: New Year, Old Challenges! *European Pharmaceutical Review*. 17(1): 8-11.
- 2011 Miller, M.J. Detection of Microorganisms Using Micro-Electro-Mechanical Systems (MEMS). *European Pharmaceutical Review*. 16(6): 7-10.

- 2011 Miller, M.J. Detection of Microorganisms Using Nucleic Acid and Gene Amplification-Based Rapid Method Technologies. *European Pharmaceutical Review*. 16(5): 62-65.
- 2011 Miller, M.J. Detection of Microorganisms Using Optical Spectroscopic-Based Rapid Method Technologies. *European Pharmaceutical Review*. 16(4): 40-42.
- 2011 Miller, M.J. Detection of Microorganisms Using Cellular Component-Based Rapid Method Technologies. *European Pharmaceutical Review*. 16(3): 8-10.
- 2011 Miller, M.J. QbD, PAT, and the Future of Microbiology. Environmental monitoring with RMM. *Contract Pharma*. 13(4): 70-73.
- 2011 Miller, M.J. Direct Detection of Microorganisms Using Viability-Based Technologies. *European Pharmaceutical Review*. 16(2): 14-15.
- 2011 Miller, M.J. Rapid Microbiological Methods 2011. A Review of Growth-Based Technologies. *European Pharmaceutical Review*. 16(1): 38-41.
- 2011 Miller, M.J. The Implementation of Rapid Microbiological Methods, in *Microbiology and Sterility Assurance in Pharmaceuticals and Medical Devices*. Edited by Madhu Raju Saghee, Tim Sandle and Edward C. Tidswell, Business Horizons.
- 2010 Miller, M.J. Microbiology Series. Article 6: The Implementation of Rapid Microbiological Methods. *European Pharmaceutical Review*. 15 (6), 27-31.
- 2010 Miller, M.J. Microbiology Series. Article 5: The Implementation of Rapid Microbiological Methods. *European Pharmaceutical Review*. 15 (5), 9-11.
- 2010 Miller, M.J. Microbiology Series. Article 4: The Implementation of Rapid Microbiological Methods. *European Pharmaceutical Review*. 15 (4), 17-19.
- 2010 Miller, M.J. Microbiology Series. Article 3: The Implementation of Rapid Microbiological Methods. *European Pharmaceutical Review*. 15 (3), 18-21.
- 2010 Miller, M.J. Developing a validation strategy for rapid microbiological methods. *American Pharmaceutical Review*. 13 (3), 28-33.
- 2010 Miller, M.J. Microbiology Series. Article 2: The Implementation of Rapid Microbiological Methods. *European Pharmaceutical Review*. 15 (2), 24-26.
- 2010 Miller, M.J. Microbiology Series. Article 1: The Implementation of Rapid Microbiological Methods. *European Pharmaceutical Review*. 15 (1), 39-41.
- 2010 Miller, M.J.; Moldenhauer, J. Revision of PDA Technical Report Number 33. *American Pharmaceutical Review*. 13 (1), 86-91.
- 2009 Miller, M.J. Breaking the Rapid Microbiological Method Financial Barrier: A Case Study in RMM Return on Investment and Economic Justification. *BioPharm International*. 22 (9), 44-53.
- 2009 Miller, M.J. Evaluation of the BioVigilant IMD-A, a Novel Optical Spectroscopy Technology for the Continuous and Real-Time Environmental Monitoring of Viable and Nonviable Particles, in *Environmental Monitoring*, Volume 3. Edited by Jeanne Moldenhauer, PDA and Davis Healthcare International Publishing. 269-288.
- 2009 Miller, M.J. Rapid microbiological methods and demonstrating a return on investment: It's Easier than you think! *American Pharmaceutical Review*. 12 (5), 42-47.

- 2009 Miller, M.J. Real-time environmental monitoring: PAT solutions using rapid microbiological methods. *European Pharmaceutical Review*. 14 (4), 40-46.
- 2009 Miller, M.J. Ensuring ROI from your RMM. *Pharmaceutical Manufacturing*. 8 (6), 32-35.
- 2009 Miller, M.J.; Lindsay, H.; Valverde-Ventura, R.; O'Connor, M.J. Evaluation of the BioVigilant IMD-A, a novel optical spectroscopy technology for the continuous and real-time environmental monitoring of viable and nonviable particles. Part I: Review of the technology and comparative studies with conventional methods. *PDA J. Pharm. Sci. Technol.* 63 (3), 244 –257.
- 2009 Miller, M.J.; Walsh, M.R.; Shrake, J.L.; Dukes, R.E.; Hill, D.B. Evaluation of the BioVigilant IMD-A, a novel optical spectroscopy technology for the continuous and real-time environmental monitoring of viable and nonviable particles. Part II: Case studies in environmental monitoring during aseptic filling, intervention assessments and glove integrity testing in manufacturing isolators. *PDA J. Pharm. Sci. Technol.* 63 (3), 258 –282.
- 2009 Miller, M.J. Quality risk management and the economics of implementing rapid microbiological methods. *European Pharmaceutical Review*. 14 (2), 66-73.
- 2009 Miller, M.J. It's Time to Get Rapid! *PDA Letter*. April; 45 (4): 1-21.
- 2009 Miller, M.J. Rapid Microbiological Methods in Support of Aseptic Processing, in *Practical Aseptic Processing: Fill and Finish Volume 2*. Edited by Jack Lysfjord, PDA and Davis Healthcare International Publishing. 169-219.
- 2008 Miller, M.J. Rapid Microbiological Methods, in *Microbiology in Pharmaceutical Manufacturing Volume 2*, 2nd Edition. Edited by Richard Prince, PDA and Davis Healthcare International Publishing. 171-221.
- 2008 Miller, M.J.; Claerbout, M.E.; DeMaio, R.A.; et al. Microbiological Control Strategies during the Development of Pharmaceutical Products and Processes, in *Microbiology in Pharmaceutical Manufacturing Volume 1*, 2nd Edition. Edited by Richard Prince, PDA and Davis Healthcare International Publishing. 237-280.
- 2006 Miller, M.J. Rapid Microbiological Methods for a New Generation. *Pharmaceutical Manufacturing*. February; 5(2): 14-23.
- 2005 Foreword, *Encyclopedia of Rapid Microbiological Methods*, Volumes 1-3. Edited by Michael J. Miller, PDA and Davis Healthcare International Publishing.
- 2005 Miller, M.J. The Impact of Process Analytical Technology (PAT), cGMPs for the 21st Century and Other Regulatory and Compendial Initiatives on the Implementation of Rapid Microbiological Methods, in *Encyclopedia of Rapid Microbiological Methods*, Volume 1. Edited by Michael J. Miller, PDA and Davis Healthcare International Publishing.
- 2005 Miller, M.J. Rapid Microbiological Methods and FDA's Initiatives for Process Analytical Technology and Pharmaceutical cGMPs for the 21st Century: A Risk Based-Approach. *American Pharmaceutical Review*. January/February; 8(1): 104-107.
- 2003 Reich, R.; Miller, M.; Patterson, H. Developing a viable environmental monitoring program for nonsterile pharmaceutical operations. *Pharmaceutical Technology*. March 2003.
- 2002 Tchao, R.; McCanna, D.; Miller, M.J. Comparison of contact lens multi-purpose solutions by an *in vitro* sodium fluorescein permeability assay. *CLAO J.* 28: 151-156.
- 2001 Miller, M.J.; Emerson, R. Auditing the Pharmaceutical Microbiology Laboratory, in *Microbiology in Pharmaceutical Manufacturing*. Edited by Richard Prince, Davis Horwood International Publishing, Limited. Pages 647-686.

- 2001 Miller, M.J.; Callahan, D.E.; McGrath, D.; et al. Disinfection Efficacy of Contact Lens Care Solutions against Ocular Pathogens. *CLAO J.* 27: 16-22.
- 2000 Miller, M.J.; Manchester, R.J.; Callahan, D. Antimicrobial activity of ReNu MultiPlus against *Pseudomonas*. *Contact Lens Spectrum.* 15: 23-30.
- 2000 Miller, M.J.; Manchester, R.J.; Callahan, D. Setting the record straight on ReNu MultiPlus solution. *Optician.* 219: 40-42.
- 1999 Lever, A.M.; Miller, M.J. Comparative antimicrobial efficacy of multi-purpose lens care solutions using the FDA's revised guidance document for industry. *CLAO J.* 25: 52-56.
- 1995 Miller, M.J. Contact lens disinfectants. In *Handbook of Disinfectants and Antiseptics*, edited by J. Ascenzi. Marcel Dekker, Inc., New York, pp. 83-110.
- 1991 Miller, M.J.; Wilson, L.A.; Ahearn, D.G. Adherence of *Pseudomonas aeruginosa* to rigid gas-permeable contact lenses. *Arch. Ophthalmol.* 109: 1447-1448.
- 1990 Meridith, T.A.; Aguilar, H.E.; Miller, M.J.; et al. Comparative treatment of experimental *Staphylococcus epidermidis* endophthalmitis. *Arch. Ophthalmol.* 108: 857-860.
- 1990 Meridith, T.A.; Trabelsi, A.; Miller, M.J.; et al. Spontaneous sterilization in experimental *Staphylococcus epidermidis* endophthalmitis. *Invest. Ophthalmol. Vis. Sci.* 31: 181-186.
- 1988 Ward, M.A.; Miller; M.J. The microbiology of contact lens wear. *Contact Lens Forum.* 13(2): 25-29.
- 1988 Miller, M.J.; Wilson, L.A.; Ahearn, D.G. Effects of protein, mucin, and human tears on adherence of *Pseudomonas aeruginosa* to hydrophilic contact lenses. *J. Clin. Microbiol.* 26: 513-517.
- 1987 Miller, M.J.; Ahearn, D.G. Adherence of *Pseudomonas aeruginosa* to hydrophilic contact lenses and other substrata. *J. Clin. Microbiol.* 25: 1392-1397.

Invited Oral Presentations

- 2024 A New Guidance on the Validation of Rapid and Alternative Microbiological Methods. PDA Annual Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC.
- 2024 Current Industry and Regulatory Drivers for Alternative and Rapid Microbiological Methods. PDA Alternative Microbiological Methods Workshop. PDA, Washington, DC.
- 2024 Contamination Control Strategies for Pharmaceutical Grade Water Systems: Keeping it Clean and Preventing Biofilms. European Microbiology Conference. ECA, Munich, Germany.
- 2024 Revision of PDA Technical Report 33. Evaluation, Validation and Implementation of Alternative Microbiological Methods. European Microbiology Conference. ECA, Munich, Germany.
- 2023 Congress Keynote Speaker. The Impact on the Revised Annex 1 for Rapid Microbiological Methods Implementation. Pharmalab Congress and Exhibition. ECA, Düsseldorf, Germany.
- 2023 A Review of the Next Revision to PDA Technical Report #33. Pharmalab Congress and Exhibition. ECA, Düsseldorf, Germany.
- 2023 Case Studies on Contamination Control Strategies for Non-Sterile Manufacturing Facilities. European Microbiology Conference. ECA, Heidelberg, Germany.
- 2023 FDA's Current Regulatory Expectations for Rapid Microbiological Method Validations. European Microbiology Conference. ECA, Heidelberg, Germany.

- 2023 Case Studies on Contamination Control Strategies for Non-Sterile Manufacturing Facilities. QC Micro Summit. Charles River Laboratories Conference, Charleston, SC.
- 2023 Don't Be Afraid of Statistics: A Case Study on How to Demonstrate Rapid Method Equivalency. QC Micro Summit. Charles River Laboratories Conference, Charleston, SC.
- 2022 Case Studies on *Burkholderia cepacia* complex (BCC) Investigations and Remediation. Pharmalab Congress and Exhibition. ECA, Düsseldorf, Germany.
- 2022 Regulatory Expectations for Rapid Sterility Testing of ATMPs. Pharmalab Congress and Exhibition. ECA, Düsseldorf, Germany.
- 2022 Show Me the Data! An Interactive Case Study on Statistical Analyses for Rapid Methods. PDA Rapid Microbiological Methods Workshop. PDA, Washington, DC.
- 2022 Case Studies on *Burkholderia cepacia* complex (BCC) Investigations and Remediation. PDA Annual Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC.
- 2022 Regulatory Perspectives on Rapid Microbiological Methods. Rapid Micro Biosystems. Web seminar.
- 2022 Rapid Microbiological Methods: A Roadmap for Implementation. QC Micro Summit. Charles River Laboratories Conference, Charleston, SC.
- 2022 Regulatory Strategies For Rapid Sterility Testing of Gene and Cell Therapy Products. Biopharma Asia. Web seminar.
- 2022 We Are Going Back to the Future with Rapid Methods. Biopharma Asia. Web seminar.
- 2021 Back to the Future: Where are the Rapid Methods? PDA Annual Microbiology Conference. Web seminar.
- 2021 Regulatory Updates and Current Perspectives for the Validation and Implementation of Rapid Methods. Pharma Microbiology Congress. Pharma Education Center (PEC) Italy. Web seminar.
- 2021 Case Study on Rapid Sterility Testing for ATMP Products. Pharma Microbiology Congress. Pharma Education Center (PEC) Italy. Web seminar.
- 2021 Rapid Sterility Testing of ATMPs. PDA Singapore. Web seminar.
- 2021 Sterility Testing of ATMPs. PDA Brazil. Web seminar.
- 2021 Sterility Testing of ATMPs. PDA New England Chapter. Web seminar.
- 2020 Rapid Microbiology Applications in the COVID-19 Era. PDA Metro Chapter. Web seminar.
- 2020 Rapid Microbiology Applications in the COVID-19 Era. BioPharma Asia. Web seminar.
- 2020 The New Annex 1 Revision and the Impact on Using Rapid Methods for Environmental Monitoring. PDA Brazil. Web seminar.
- 2020 Rapid Microbiological Release. PDA Annual Meeting. Web seminar.
- 2020 Rapid Microbiological Methods. ISPE India. Web seminar.
- 2020 Rapid Microbiology Applications in the COVID-19 Era. PDA Metro Chapter. Web seminar.
- 2020 The New Annex 1 Revision and the Impact on Using Rapid Methods for Environmental Monitoring. Pharmaceutical Microbiology Forum Environmental Monitoring Summit. Web seminar.

- 2019 Obtaining Global Regulatory Approval for Rapid Microbiological Methods in Pharma QC. vertX Bioprocess Conference, Scripps Seaside Forum, La Jolla, CA
- 2019 Rapid Microbiological Methods Training Course. Accepted. Validated. Approved. Implemented. Pharmig, Dublin, Ireland
- 2019 Rapid Microbiological Methods Training Course. Rapid Microbiological Methods Training Course. Accepted. Validated. Approved. Implemented. Pharmig, Birmingham, UK
- 2019 Rapid Microbiological Methods Workshop. PDA, São Paulo, Brazil
- 2019 Selection, Validation and Implementation of Alternative and Rapid Microbiological Methods for ATMPs Training Course. Centre for Cell Manufacturing Ireland. Galway, Ireland
- 2019 Perspectives and Challenges for the Validation of New Environmental Monitoring Methods in Aseptic Processing Areas. 10th International Workshop Aseptic Processing in the Biopharmaceutical Industry. National Center for Biopreparations (BioCen). Varadero, Cuba
- 2019 Current View of EU Concerning Validation of Alternative Microbiological Analytical Methods and Perspective of Harmonization with US. 10th International Workshop Aseptic Processing in the Biopharmaceutical Industry. National Center for Biopreparations (BioCen). Varadero, Cuba
- 2019 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. PDA, Bethesda, MD
- 2018 Strategies for Rapid Sterility Testing of Gene and Cell Therapy Products. Pharmalab Congress and Exhibition. ECA, Düsseldorf, Germany
- 2018 Understanding the Revised Ph. Eur. Chapter 5.1.6 and How it Compares with USP <1223>, PDA Technical Report 33 and Industry Best Practices. Pharmalab Congress and Exhibition. ECA, Düsseldorf, Germany
- 2018 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. Annual Pharmaceutical Microbiology Conference. PDA Europe. Berlin, Germany
- 2018 Regulatory Strategies and Case Studies for Rapid Sterility Testing of Gene and Cell Therapy Products. Annual Pharmaceutical Microbiology Conference. PDA Europe. Berlin, Germany
- 2017 Case Studies on Selecting Statistical Approaches for the Validation of Alternative and Rapid Microbiological Methods (RMM). PDA 12th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, MD
- 2017 Rapid Microbiological Methods for Aseptic Processing. 9th International Workshop Aseptic Processing in the Biopharmaceutical Industry. National Center for Biopreparations (BioCen). Havana, Cuba
- 2017 Case Study. Equivalence Studies & the Use of Statistics. 8th Annual Pharmaceutical Microbiology Conference. PDA Europe. Porto, Portugal
- 2017 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. 8th Annual Pharmaceutical Microbiology Conference. PDA Europe. Porto, Portugal
- 2016 Navigating the New USP 1223 and How It Compares with PDA TR33 and Ph. Eur. 5.1.6. Pharmalab Congress. Rapid Microbiological Methods. ECA, Düsseldorf, Germany
- 2016 The Role of Rapid Microbiological Methods in the Future of Aseptic Processing. PDA 11th Annual Global Conference on Pharmaceutical Microbiology. PDA, Arlington, VA

- 2016 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. 7th Annual Pharmaceutical Microbiology Conference. PDA Europe. Berlin, Germany
- 2015 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. PDA 10th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, MD
- 2015 Where TR33 Has brought Us – From Past to the Present. PDA 10th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, MD
- 2015 Introduction to Rapid Microbiological Methods Applications, Implementation Strategies and Return on Investment. Tungsten Shield Group. Web Seminar.
- 2015 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. 6th Annual Pharmaceutical Microbiology Conference. PDA Europe. Berlin, Germany
- 2014 Revision of PDA Technical Report No. 33. Annual Irish Conference. Pharmig. Cork, Ireland.
- 2014 Overcoming Rapid Microbiological Methods Myths and Misconceptions. Annual Irish Conference. Pharmig. Cork, Ireland.
- 2014 Case Studies on Real-Time Environmental Monitoring. Annual Irish Conference. Pharmig. Cork, Ireland.
- 2014 Overcoming Rapid Microbiological Methods Myths and Misconceptions. Dinner Discussion Panel. New Jersey Pharmaceutical Quality Control Association. Newark, NJ
- 2014 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. 5th Annual Pharmaceutical Microbiology Conference. PDA Europe. Berlin, Germany
- 2013 Revision of Technical Report No. 33. PDA 8th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, MD
- 2013 Rapid Microbiological Methods Training Course: Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods. PDA 8th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, MD
- 2013 A Comprehensive Review of the New PDA TR33 - Validation and Implementation of Alternative and Rapid Microbiological Methods. Rapid Microbiological Methods Conference. European Compliance Academy (ECA). Barcelona, Spain
- 2013 Overcoming Rapid Microbiological Myths and Misconceptions. 21st Annual Pharmig Conference. Oxford, United Kingdom
- 2013 About RMM Validation: Technical Report No. 33. 4th Annual Pharmaceutical Microbiology Conference. PDA Europe. Berlin, Germany
- 2013 Rapid Microbiological Methods Training Course. 4th Annual Pharmaceutical Microbiology Conference. PDA Europe. Berlin, Germany
- 2012 Real-Time Environmental Monitoring Using Optical Spectroscopy Rapid Methods. Rapid Microbiological Methods Conference. European Compliance Academy (ECA). Munich, Germany

- 2012 Rapid Microbiological Methods Training Course: Overview of Technologies, Validation Strategies, Regulatory Opportunities and Return on Investment. PDA 7th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, MD
- 2012 Real Time Environmental Monitoring and the Quest for Parametric Release of Aseptically Filled Product. PDA 7th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, MD
- 2012 Rapid Microbiological Methods. Technopath Symposium. Dublin, Ireland
- 2012 Rapid Microbiological Methods: The Detection, Enumeration and Identification of Microorganisms Using Genetic-based Technologies. Tungsten Shield Group. Web Seminar.
- 2012 Rapid Microbiological Methods: The Detection, Enumeration and Identification of Microorganisms Using Cellular Component-based Technologies. Tungsten Shield Group. Web Seminar
- 2012 Rapid Microbiological Methods Training Course. BioForum Applied Knowledge Center. Tel Aviv, Israel
- 2012 Rapid Microbiological Methods. Recognizing the Perceived Issues Associated with Regulatory Expectations, Validation and ROI. PMF Conference on Alternate and Rapid Microbiological Methods. Pharmaceutical Microbiology Forum. Las Vegas, NV
- 2012 Rapid Microbiological Methods: The Detection, Enumeration and Identification of Microorganisms Using Viability and Spectroscopic-based Technologies. Tungsten Shield Group. Web Seminar.
- 2012 Case Studies in the Use of Continuous Air Monitoring During Manufacturing Interventions Within an Isolator Environment. Microbiology, Endotoxins and RMM Conference. PDA Europe. Berlin, Germany
- 2012 Industry: Tear Down this Wall! Removing the Barriers for RMM Implementation. Microbiology, Endotoxins and RMM Conference. PDA Europe. Berlin, Germany
- 2012 Quality Systems for Sterile Products. Microbiology, Endotoxins and RMM Conference. PDA Europe. Berlin, Germany
- 2012 Rapid Microbiological Methods Training Course. Microbiology, Endotoxins and RMM Conference. PDA Europe. Berlin, Germany
- 2012 The Future of Rapid Molecular and Microbiological Methods: A Review of Technologies, Validation Strategies and Regulatory Expectations. Validation of Molecular Biological Methods Conference. European Compliance Academy (ECA). Prague, Czech Republic
- 2012 Quality Systems for Sterile Products. Advances in Sterile Products Technologies, Future University International Conference on Pharmaceutical Technologies. Cairo, Egypt.
- 2012 Environmental Monitoring. Advances in Sterile Products Technologies, Future University International Conference on Pharmaceutical Technologies. Cairo, Egypt.
- 2012 Rapid Microbiological Methods: PAT and Microbiology for Sterile Products Testing and Release. Advances in Sterile Products Technologies, Future University International Conference on Pharmaceutical Technologies. Cairo, Egypt.
- 2012 Rapid Microbiological Methods: The Detection, Enumeration and Identification of Microorganisms Using Growth-based Technologies. Tungsten Shield Group. Web Seminar.
- 2011 Rapid Microbiological Methods Training Course: Overview of Technologies, Validation Strategies, Regulatory Opportunities and Return on Investment. PDA 6th Annual Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC

- 2011 Debunking the Myth's Surrounding Rapid Microbiological Methods and Their Impact on Pharmaceutical Manufacturing and the Quality of Medicinal Products. PDA 6th Annual Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC
- 2011 Developing a Return on Investment Strategy for Rapid Microbiological Methods. Tungsten Shield Group. Web Seminar.
- 2011 Validating Rapid Microbiological Methods Understanding USP 1223, Ph. Eur. 5.1.6 and PDA TR#33. Tungsten Shield Group. Web Seminar.
- 2011 Navigating the Regulatory Environment When Implementing Rapid Microbiological Methods. Tungsten Shield Group. Web Seminar.
- 2011 An Introduction to Rapid Microbiological Methods and the Link to Quality by Design. Tungsten Shield Group. Web Seminar.
- 2011 The Validation of Rapid Microbiological Methods. A Case Study on False Positive Testing Using Manufacturing Test Samples and an Environmental Monitoring Technology. PDA Annual Meeting. PDA, San Antonio, TX
- 2011 The Future of Microbiology – The Impact of Rapid Methods on Pharmaceutical Manufacturing and the Quality of Medicinal Products. Pharmaceutical Microbiology – Mycoplasma. Enhancing Quality in Process and Product. PDA Europe Conference. Berlin, Germany
- 2011 Validation Summit. Pharmaceutical Microbiology. Quality Academia. Istanbul, Turkey
- 2010 Pharmaceutical Microbiology for the 21st Century. GMPs, rapid method technologies, regulatory expectations and contamination control strategies. Quality Academia. Istanbul, Turkey
- 2010 Rapid Microbiological Methods Training Course. BioForum Applied Knowledge Center. Weizmann Science Park, Ness Ziona, Israel
- 2010 Rapid Microbiological Methods Training Course: Overview of Technologies, Validation Strategies, Regulatory Opportunities and Return on Investment. PDA 5th Annual Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC
- 2010 The Validation of Rapid Microbiological Methods. A Case Study on False Positive Testing Using Manufacturing Test Samples and an Environmental Monitoring Technology. PDA 5th Annual Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC
- 2010 Rapid Microbiological Methods; an Introductory Review of RMM Technologies, Validation Strategies, Applications, Regulatory Expectations, Financial Justification Models & Implementation Plans. Tungsten Shield Group. Web Seminar
- 2010 Rapid Molecular and Microbiological Methods: The Link Between Pharmaceutical Manufacturing and Quality by Design Principles. Applied Biosystems SEQ Seminar Series. Cambridge, Massachusetts
- 2010 Rapid Molecular and Microbiological Methods: The Link Between Pharmaceutical Manufacturing and Quality by Design Principles. Applied Biosystems SEQ Seminar Series. Princeton, New Jersey
- 2010 Case Study in the Return on Investment for Implementing Rapid Microbiological Methods. PDA Annual Meeting. Orlando, Florida
- 2010 Real Time Environmental Monitoring in Aseptic Processing Areas. ISPE Aseptic Processing of Sterile Products Conference, Tampa, Florida
- 2009 Update on Technical Report No. 33. PDA 4th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, Maryland

- 2009 Case Study in the Return on Investment for Implementing Rapid Microbiological Methods. PDA 4th Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, Maryland
- 2009 Breaking the Rapid Microbiological Method Financial Barrier: A Case Study in RMM Return on Investment and Economic Justification. Parenteral Drug Association (PDA) Southeast Chapter Meeting, Raleigh, North Carolina
- 2009 Rapid Microbiological Methods: Moving Microbiology Out of the Lab and into Manufacturing. Applied Biosystems SEQ Seminar Series. Boston, Massachusetts and Durham, North Carolina
- 2009 Breaking the Rapid Microbiological Method Financial Barrier: A Case Study in RMM Return on Investment and Economic Justification. Parenteral Drug Association (PDA) West Coast Chapter Meeting, San Francisco, California
- 2009 Breaking the Rapid Microbiological Method Financial Barrier: A Case Study in RMM Return on Investment and Economic Justification. Parenteral Drug Association (PDA) Delaware Valley Chapter Meeting, Malvern, Pennsylvania
- 2009 Update on Technical Report No. 33. PDA Annual Meeting. PDA, Las Vegas, Nevada
- 2009 Case Studies in the Use of the BioVigilant IMD-A for Real-Time Environmental Monitoring during Aseptic Filling and Intervention Assessments in a Manufacturing Isolator. PDA Annual Meeting. Las Vegas, Nevada
- 2008 Case Studies in the Use of the BioVigilant IMD-A for Real-Time Environmental Monitoring during Aseptic Filling and Intervention Assessments in a Manufacturing Isolator. PDA 3rd Annual Global Conference on Pharmaceutical Microbiology. Chicago, Illinois
- 2008 Continuous and Instantaneous Viable and Nonviable Air Monitoring Using Optical Spectroscopy. International Society for Pharmaceutical Engineering (ISPE) Annual Barrier Isolator Conference, Manchester, United Kingdom
- 2008 Microbiological Control Strategies During the Development of Pharmaceutical Products and Processes. Microbiology Interest Group, PDA Annual Meeting, Colorado Springs, Colorado
- 2008 Continuous and Instantaneous Viable and Nonviable Air Monitoring Using Optical Spectroscopy. ISPE Annual Barrier Isolator Conference, Washington, DC
- 2007 Evaluation of a Continuous and Instantaneous Viable and Nonviable Environmental Monitoring Technology Based on Optical Spectroscopy PDA 2nd Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, Maryland
- 2007 A Robust Strategy for the Use of Materials of Construction as Biological Indicators When Validating Manufacturing Isolators. ISPE Annual Barrier Isolator Conference, Berlin, Germany
- 2007 A Robust Strategy for the Use of Materials of Construction as Biological Indicators When Validating Manufacturing Isolators. ISPE Annual Barrier Isolator Conference, Washington, DC
- 2007 Microbiological Control Strategies During the Development of Pharmaceutical Products and Processes. Microbiology Interest Group, PDA Annual Meeting, Las Vegas, Nevada
- 2007 A Robust Strategy for the Use of Materials of Construction as Biological Indicators When Validating Manufacturing Isolators. General Session, PDA Annual Meeting, Las Vegas, Nevada
- 2007 A Review of USP <1223> and PDA Technical Report #33. PDA Meeting on Rapid Microbiological Methods, Verona, Italy

- 2007 The Next Generation of Microbial Identification Systems Invited Keynote Speaker. Rapid Microbiology Users Group (RMUG) Annual Meeting, Washington, DC
- 2006 The Next Generation of Microbial Identification Systems. PDA 1st Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, Maryland
- 2006 The Rapidly Changing Face of Rapid Microbiological Methods. PDA Annual Meeting, Anaheim, California
- 2005 Regulatory and Compendial Initiatives for Rapid Microbiological Methods. Global Compliance Strategies for Rapid Methods in Pharmaceutical and Biopharmaceutical Manufacturing, Barnett International, Brussels, Belgium
- 2005 Regulatory and Compendial Initiatives for Rapid Microbiological Methods. 7th Annual Advancing Technologies in Rapid Methods for Pharmaceutical and Biopharmaceutical Manufacturing, Barnett International, Washington, DC
- 2005 Opportunities and Applications for Rapid Microbiological Methods. PDA Annual Meeting, Chicago, Illinois
- 2004 Points To Consider When Evaluating the Return on Investment (ROI) For the Implementation of Rapid Microbiological Methods. Rapid Microbial Methods, IBC Life Sciences, San Diego, California
- 2004 Opportunities and Applications for Rapid Microbiological Methods. PDA Mid-West Chapter Meeting, Chicago, Illinois
- 2004 In-Depth Validation Strategies for Rapid Microbiological Methods. Rapid Microbial Methods, IBC Life Sciences, San Diego, California
- 2004 Opportunities and Applications for Rapid Microbiological Methods. Rapid Microbiological Methods, Institute for Validation Technology, Amsterdam, The Netherlands
- 2004 Rapid Methods in a Slow Pharmaceutical Environment: How PAT Can Help Industry in the Implementation of New Microbiological Technologies. Process Analytical Technologies for Biologics, IBC Life Sciences, Reston, Virginia
- 2004 Why Aren't We Further Along in Rapid Microbiology? Potential Regulatory Strategies. Invited Keynote Speaker, RMUG Conference, Chicago, Illinois
- 2004 In-Depth Validation Strategies for Rapid Microbiological Methods. Rapid Microbiological Methods, Institute for Validation Technology (IVT), Washington, DC
- 2004 Rapid Microbial Methods. Session on Process Analytical Technology, PDA SciTech Summit, Orlando, Florida
- 2004 The Successful Management of Validating Rapid Microbiological Methods. Addressing FDA's Full Support of Rapid Methods, Barnett International, Philadelphia, Pennsylvania
- 2003 The Successful Management of Validating Rapid Microbiological Methods. Rapid Microbiological Methods, IVT, Dublin, Ireland
- 2002 Can Existing Rapid Methods Detect Biological Warfare Agents? PDA Annual Meeting, New Orleans, Louisiana
- 2002 Can Rapid Methods Detect Microorganisms That Can Be Used In Bioterrorism? Rapid Microbiological Methods, IVT, Amsterdam, The Netherlands

- 2002 Strategies for Automation, Detection and Validation of Microbiology Test Methods, Barnett International, Philadelphia, Pennsylvania
- 2001 Understanding ISO 14729. Southeast Conference on Optometry (SECO), Atlanta, Georgia
- 2001 ISO 14729 and ReNu MultiPlus. Annual Meeting, Contact Lens Association of Ophthalmologists, Las Vegas, Nevada
- 2000 Understanding ISO Standards for Contact Lens Care Products. European Symposium on Contact Lenses, Berlin, Germany
- 2000 Disinfection of Clinical Strains of *Pseudomonas aeruginosa*. Kaiser Permanente OptiFest 2000, Portland, Oregon
- 2000 Use of the Chemunex Rapid Microbiological Detection System during Preservative and Disinfectant Efficacy Testing. Rapid Methods & Automation in Microbiology, Washington, DC
- 1999 Use of the Chemunex Rapid Microbiological Detection System during Preservative and Disinfectant Efficacy Testing. PDA Annual Meeting, Washington, DC
- 1999 New Approaches in Biological Indicator Technologies. Scientific Forum on Microbiology, PDA, Washington, DC
- 1999 Aerosol Challenge Testing for Container Closure Integrity. Scientific Forum on Microbiology, PDA, Washington, DC
- 1999 The Pharmaceutical Microbiology Laboratory of the Next Millennium. Annual Marketing/Sales Meeting, bioMérieux Inc., Phoenix, Arizona
- 1999 Contact Lens Disinfection. Annual Meeting, American Society for Microbiology, Chicago, Illinois
- 1998 GMPs and Laboratory Compliance. Georgia State University, Atlanta, Georgia
- 1997 Use of the bioMérieux Bactometer System for Screening New Disinfectant and Preserved Formulations. PDA Annual Meeting, Philadelphia, Pennsylvania
- 1994 The Epidemiology of Contact Lens-Related Infectious Keratitis. Latin American Symposium on Contact Lenses, Santiago, Chile
- 1993 ISO, Sterilization Standards and Validation. Bausch & Lomb Corporate Seminar on Validation, Rochester, New York
- 1992 Quality Analytical Services Consumer Returns Testing Program. AOCLE/National Research Symposium on Contact Lenses, Orlando, Florida
- 1990 Sterilization Technologies in the 1990's. Managing an O.R. In The 1990's Joint Meeting, Johnson & Johnson and Humana Hospitals, San Antonio, Texas
- 1990 Glow Discharge Plasma: An alternative technology for the sterilization of heat and moisture-sensitive instruments. Sixteenth Annual Symposium on Infection Control, Buffalo, New York
- 1989 Alternatives to ethylene oxide sterilization. Nosocomial Infectious Diseases and Hospital Epidemiology Conference, Harvard Medical School, Boston, Massachusetts
- 1988 Adherence of microorganisms to contact lenses. Annual Meeting, American Society for Microbiology, Miami, Florida

Poster Presentations

- 2022 Early adoption of RMM technologies to enable novel cell therapies for patient needs. PDA Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC
- 2011 Case Study of a New Growth-Based Rapid Microbiological Method (RMM) That Detects the Presence of Specific Organisms and Provides an Estimation of Viable Cell Count. PDA 6th Annual Global Conference on Pharmaceutical Microbiology. PDA, Washington, DC
- 2001 ISO 14729: Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses. Annual Meeting, Contact Lens Association of Ophthalmologists (CLAO), Las Vegas, Nevada
- 2001 Antimicrobial Activity of ReNu MultiPlus Multi-Purpose Solution against Human Clinical Isolates of *Pseudomonas aeruginosa*. Annual Meeting, CLAO, Las Vegas, Nevada
- 2000 Antimicrobial activity of ReNu MultiPlus Multi-Purpose Solution against human clinical strains of *Pseudomonas aeruginosa*. European Symposium on Contact Lenses, Berlin, Germany.
- 2000 Disinfection efficacy of contact lens care solutions against ocular pathogens. European Symposium on Contact Lenses, Berlin, Germany.
- 2000 ScanTox Assay Which Uses the Bovine Lens is Significantly More Sensitive than the BCOP for Measuring Ocular Irritancy. World Congress on In Vitro Biology, San Diego, California
- 2000 Evaluation of a Multi-Purpose Solution with Superior Biocidal Efficacy against Ocular Pathogens. British Contact Lens Association Annual Meeting, Birmingham, United Kingdom
- 2000 Reduction of Ocular Pathogens Using ReNu MultiPlus Multi-Purpose Solution. British Contact Lens Association Annual Meeting, Birmingham, United Kingdom
- 2000 Evaluation of a Multi-Purpose Solution with Superior Biocidal Efficacy against Ocular Pathogens. Annual Meeting, Contact Lens Association of Ophthalmologists, Las Vegas, Nevada
- 1999 A Comparison of the Antimicrobial Efficacy, Wetting and Lipid Cleaning of Boston Advance Comfort Formula to OPTI-SOAK Conditioning Solution with OPTI-SOAK Daily Cleaner. British Contact Lens Association Annual Meeting, Birmingham, United Kingdom
- 1999 An Antimicrobial Efficacy Regimen Evaluation Comparing ReNu Multi-Purpose Solution to Heat Disinfection Against Ocular Pathogens. British Contact Lens Association Annual Meeting, Birmingham, United Kingdom
- 1999 Toxicological Analysis of Several Contact Lens Cleansing and Disinfecting Solutions Using a Fluorescein Permeability Assay. British Contact Lens Association Annual Meeting, Birmingham, United Kingdom
- 1999 An Antimicrobial Efficacy Regimen Evaluation Comparing ReNu® Multi-Purpose Solution to Heat Disinfection Against Ocular Pathogens. Annual Meeting, CLAO, Las Vegas, Nevada
- 1999 A Comparison of the Antimicrobial Efficacy, Wetting and Lipid Cleaning of Boston Advance® Comfort Formula to OPTI-SOAK™ Conditioning Solution with OPTI-SOAK™ Daily Cleaner. Annual Meeting, CLAO, Las Vegas, Nevada
- 1999 Comparison of Several Contact Lens Cleansing and Disinfecting Solutions by an In Vitro Method Using the Fluorescein Permeability Method. Annual Meeting, CLAO, Las Vegas, Nevada
- 1998 Use of Impedance Microbiology for Screening New Disinfectant and Preserved Formulations. Annual Meeting, American Society for Microbiology (ASM), Atlanta, Georgia

- 1998 Comparative Antimicrobial Efficacy of Contact Lens Disinfecting Solutions. Annual Meeting, ASM, Atlanta, Georgia
- 1998 Use of Impedance Microbiology for Screening New Disinfectant and Preserved Formulations. Annual Meeting, ASM, Atlanta, Georgia
- 1998 A Comparison of the Antimicrobial Efficacy of ReNu MultiPlus Multi-Purpose Solution to Opti-Free Express with Opti-Free SupracLens. Annual Meeting, CLAO, Las Vegas, Nevada
- 1996 Comparison of Fluorescence and Impedance Assays to Determine the Antimicrobial Efficacy of Eye Care and Lens Care Products. Annual Meeting, ASM, New Orleans, Louisiana
- 1992 Continuous Antimicrobial Activity of Contact Lens Care Systems. European Research Symposium on Contact Lenses, Bordeaux, France

Chairperson Appointments

- 2022 PDA Workshop on Rapid Microbiological Methods. PDA, Washington, DC (scheduled).
- 2020 PDA Workshop on Rapid Microbiological Methods. PDA, virtual meeting.
- 2019 PDA Workshop on Rapid Microbiological Methods. PDA, Bethesda, Maryland
- 2018 PDA 9th Annual Europe Conference on Pharmaceutical Microbiology. PDA, Berlin, Germany
- 2017 PDA 8th Annual Europe Conference on Pharmaceutical Microbiology. PDA, Porto, Portugal
- 2015 PDA 6th Annual Europe Conference on PDA, Berlin, Germany
- 2014 PDA 5th Annual Europe Conference on PDA, Berlin, Germany
- 2013 PDA 4th Annual Europe Conference on PDA, Berlin, Germany
- 2012 PDA 3rd Annual Europe Conference on PDA, Berlin, Germany
- 2008 PDA 3rd Annual Global Conference on PDA, Chicago, Illinois
- 2007 PDA Global Conference on PAT. PDA, Bethesda, Maryland
- 2007 PDA Global Conference on Rapid Microbiological Methods. PDA, Verona, Italy
- 2006 PDA 1st Annual Global Conference on Pharmaceutical Microbiology. PDA, Bethesda, Maryland
- 2005 Global Compliance Strategies for Rapid Methods in Pharmaceutical and Biopharmaceutical Manufacturing, Barnett International, Brussels, Belgium
- 2005 7th Annual Advancing Technologies in Rapid Methods for Pharmaceutical and Biopharmaceutical Manufacturing, Barnett International, Washington, DC
- 2004 Rapid Microbial Methods, IBC Life Sciences, San Diego, California
- 2004 Rapid Microbiological Methods, Institute for Validation Technology (IVT), Amsterdam, The Netherlands
- 2004 Addressing FDA's Full Support of Rapid Methods, Barnett International, Philadelphia, Pennsylvania
- 2003 Rapid Microbiological Methods, IVT, Dublin, Ireland
- 2002 Rapid Microbiological Methods, IVT, Amsterdam, The Netherlands
- 2001 Strategies for Automation, Detection and Validation of Microbiology Test Methods, Barnett International, Philadelphia, Pennsylvania
- 2001 PDA Spring Meeting, PDA, Las Vegas, Nevada
- 2001 Rapid Methods & Automation in Microbiology, Barnett International, San Juan, Puerto Rico
- 2000 Rapid Methods & Automation in Microbiology, Barnett International, Brussels, Belgium
- 1999 Microbiology of the Eye Symposium, Annual Meeting, American Society for Microbiology (ASM), Chicago, Illinois

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