Michael J. Miller, Ph.D.

Experience

Microbiology Consultants, LLC, Lutz, Florida
President
February 2009 to present

Provide regulatory, quality and compliance solutions for the pharmaceutical, biotech, medical device 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, Pharmacopoeial 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 (e.g., FDA 483 and warning letters), 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. 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, contamination control, antimicrobial and preservative effectiveness, sterilization, pharmacopoeia interpretation and compliance, 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 is capable of supporting 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

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

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 (current)
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)
- Chair, Technical Report #33 Task Force
- Technical Book Advisory Board

International Society for Pharmaceutical Engineering (ISPE)
American Society for Microbiology (ASM)

Professional Memberships and Appointments (past)

PDA Strategic Planning Committee and Annual Meeting Program Committee
PDA Program Advisory Board
Co-chair, PDA 1st and 3rd Annual Global Conference on Pharmaceutical Microbiology
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

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) consolidated into Civil Action No.: 1:08-CV-1512.

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

2013 Miller, M.J. An Introduction to Rapid Microbiological Methods: Regulatory Acceptance, Validation and Implementation. *BioPharma Asia*. 2(3): ***in print***.

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): ***in print***.

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

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