

Frederic B. Ayers

Biopharmaceutical Microbiology & Sterility Assurance Expert

2412 Bristol Creek Drive, Morrisville, NC 27560

1.317.285.9876

fba_98@icloud.com



EXPERIENCE

Advisor

Eli Lilly and Company, May 2022 – Present

Serve as global sterility assurance lead for the Global Quality Systems and Global Parenteral Product Network. Identify and close global program gaps to reduce regulatory risks for the delivery of new facilities and technologies along with existing facilities within the enterprise. Lead global harmonization efforts across the enterprise for sterility assurance including disinfection, environmental monitoring, contamination control strategies, and personnel assessment, development, and retention.

Advisor

Eli Lilly and Company, September 2019 – May 2022

Lead implementation of New Technologies for Indianapolis Parenteral Manufacturing Sterility Assurance. Identify and deliver an overarching contamination control technical agenda. Ensure strategic leadership for current and new manufacturing facilities. Identify, develop and/or implement processes to drive Lilly Parenteral Manufacturing Network harmonization.

Research Scientist

Eli Lilly and Company, October 2018 – September 2019

Lead Sterility Assurance for Indianapolis Parenteral Manufacturing - Insulin Plant. Deliver technical and strategic leadership for insulin manufacturing facilities to improve overall contamination control. Lead, drive, and close identified deficiencies.

Consultant Scientist

Eli Lilly and Company, October 2015 – September 2018

Sterility assurance lead to ensure delivery of new cartridge RABS filling capability for Indianapolis Parenteral Manufacturing. Deliver technical and strategic leadership and guidance for multiple manufacturing areas. Responsible for leading implementation of electronic Intervention Logging System (ILS) across a Global Parenteral Network. Act as a technical lead during regulatory inspections and internal audits.

Associate Consultant Scientist

Eli Lilly and Company, March 2011 – October 2015

Responsible for development and implementation for new training program to align with new commercialization facility. Severed as external resource to provide education to ELANCO Animal Health and External Manufacturing for Sterility Assurance Risk Management. Act as a technical lead during regulatory inspections and internal audits.

Senior Scientist

Eli Lilly and Company, March 2007 – March 2011

Responsible for developing, executing and leading HACCP Risk Analysis for environmental monitoring performance qualification (EMPQ). Manage daily environmental monitoring investigations, CAPA development, implementation, and change agenda. Act as a technical resource for parenteral operations and provide daily floor support for multiple areas.

Microbiologist

Eli Lilly and Company, October 2001 – March 2007

Lead relocation of multiple quality control laboratories to new facilities. Perform quality control testing for raw materials and in-process samples including bioburden, microbial limits, growth promotion, antimicrobial effectiveness/preservation efficacy testing and biological indicator enumeration. Act as technical resource, trainer, lead investigator and second person verifier.

EDUCATION

Bachelor of Arts (BA), Biology, 1999 – Franklin College of Indiana Student-Athlete (1994-1998) | Letterman (1994-1998) | Leadership Program (1997) | Co-Captain (1998) | Most Valuable Player – Defense (1998)

PROFESSIONAL AFFILIATIONS / NETWORKS

American Association of Pharmaceutical Scientists
American Society of Microbiology
Biophorum Operations Group
Indiana Biotechnology and Pharmaceutical Network
International Society of Pharmaceutical Engineering (ISPE)
Parenteral Drug Association (PDA)

VOLUNTEERING

Parenteral Drug Association – Scientific Advisory Board

July 2022 – Present

Standing member of a diverse group of leading bio-pharmaceutical industry experts setting strategic direction for the PDA on technical topics associated with pharmaceutical manufacturing and quality.

Parenteral Drug Association – Midwest ‘At-Large’ Member

January 2014 – December 2017 | January 2022 – Present

Responsible for organizing, hosting, and leading all-day event in Indianapolis. Worked with fellow board members to identify topics and speakers for all scheduled events. Selected as a Committee Member for PDA National Meetings responsible for identifying speakers and developing content for the events.

Parenteral Drug Association – Midwest President

January 2020 – December 2021

Lead a diverse group of volunteers to drive solutions for the PDA Midwest Chapter and constituencies. Lead development of annual agenda and content development to ensure meetings provide networking and learning opportunities for members. Assist fellow Chapter Leaders in developing processes to improve chapter engagement and membership.

Parenteral Drug Association – Midwest President-Elect

January 2018 – December 2019

Assist volunteers to identify solutions for the PDA Midwest Chapter. Lead annual all-day event related to Sterility Assurance and Risk Management. Selected as a Committee Member for PDA National Meetings responsible for identifying speakers and developing content. Selected as a Task Force member for multiple Technical Reports and Standards development.

DEFINING MOMENTS

Courage	Speaking up with candor and transparency.
Growth	Developing scientists within the biopharmaceutical industry.
Leadership	Elected as the PDA Midwest President and to the PDA Science Advisory Board by industry peers.
Perseverance	Building a strong Sterility Assurance organization through organizational change.
Recruiting	Establishing a microbiologist attract and retain program.

CORE COMPETENCIES

Professional	
Auditing	Barrier Systems
Change Management	cGMP Knowledge
Deviation Management	Environmental Monitoring
Lean Six Sigma	Pharmacopeia
Process Control	Process Improvement
Regulatory Guidelines	Regulatory Inspections
Risk Management	Root Cause Analysis
Leadership	
Employee Coaching	Employee Mentoring
Employee On-Boarding	Employee Recruiting

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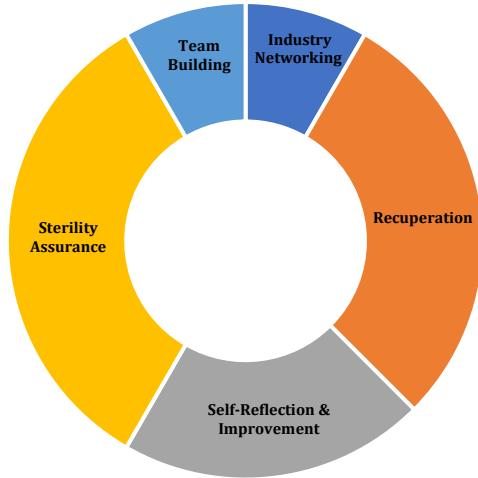
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A Day in My Life



<u>PURSUIT</u>	<u>DESCRIPTION</u>
<u>Industry Networking</u>	Working with industry colleagues to drive the biopharmaceutical industry to a future state to ensure a robust supply of high-quality medicine
<u>Recuperation</u>	Preparing the mind and body for another day
<u>Self-Reflection & Improvement</u>	Reflect on accomplishments, areas of improvement, learning, and family
<u>Sterility Assurance Program</u>	Evaluating, improving, and troubleshooting Indianapolis Parenteral Manufacturing's Sterility Assurance Programs
<u>Team Building</u>	Coaching, mentoring, recruiting, and networking to build a strong and diverse organization