

## **EXPERIENCES**

### **Senior Consultant - Microbiology**

ValSource, Inc. | July 2023 – Present  
*Provide project management and leadership for pharmaceutical and biopharmaceutical projects, specializing in Contamination Controls Strategy, Microbiology, and Sterility Assurance. Lead client projects ensuring on-time delivery of defined Key Process Indicators (KPI), such as finances, report generation, process assessments, etc.*

### **Advisor – Sterility Assurance Technology**

Eli Lilly and Company | September 2019 – May 2022  
*Identify, lead, and deliver an overarching contamination control technical agenda. Lead implementation of process improvements to drive site performance and network harmonization. Provide technical support, including regulatory interaction, during inspections and internal audits.*

### **Consultant Scientist**

Eli Lilly and Company | October 2015 – September 2018  
*Sterility assurance lead to ensure delivery of new RABS filling capability. Responsible for leading implementation of electronic Intervention Logging System (ILS) across a global network. Provide technical support, including regulatory interaction, during 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.*

### **Advisor – Global Quality Compliance**

Eli Lilly and Company | May 2022 – July 2023  
*Identify and lead closure for global program gaps reducing regulatory risks 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.*

### **Research Scientist**

Eli Lilly and Company | October 2018 – September 2019  
*Deliver technical and strategic leadership including employee development, for aseptic manufacturing facility to improve overall contamination control. Provide technical support, including regulatory interaction, during inspections and internal audits.*

### **Associate Consultant Scientist**

Eli Lilly and Company | March 2011 – October 2015  
*Responsible for development and implementation for a new training program to align with new commercialization facility. Provide education to partners for Quality Risk Management needs. Provide technical support, including regulatory interaction, during inspections and internal audits.*

### **Microbiologist**

Eli Lilly and Company | October 2001 – March 2007  
*Responsible for relocation of multiple quality control laboratories. 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.*

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## **ADVISORY BOARDS**

### **NEVE Project, Inc.**

May 2024 – Present  
*Assist leadership in assessing data gathered to continue to develop the platform to provide the best customer experience.*

### **Parenteral Drug Association – Science 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. Selected as a Task Force member for multiple Technical Reports and Standards development.*

### **Ayuda Health**

July 2022 – Present  
*Assist leadership in analyzing customer feedback to continue development of a personal health app to increase patient adherence to medication treatments for chronic diseases.*

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## **VOLUNTEERING**

### **Parenteral Drug Association – ‘At-Large’ Member**

January 2022 – Present | January 2014 – December 2017  
*Responsible for organizing, hosting, and leading all-day event in Indianapolis. Worked with fellow Midwest 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 – President / President-Elect**

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 – Committee Member**

November 2021 – Present  
*Collaborate with other committee members to determine topics and selection of poster and podium presentations for the Pharmaceutical Microbiology Conference. Moderate sessions at conference including leading Q&A sessions with audience members.*

### **Parenteral Drug Association – Workshop Co-Chair**

January 2018 – November 2024  
*Develop agenda topics and identify volunteer speakers to provide presentations for PDA Workshops in Contamination Control Strategies and Annex 1 for the pharmaceutical and bio-pharmaceutical industry. Lead global events ensuring attendees obtain relevant knowledge and content from the workshops.*

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## **EDUCATION**

### **Franklin College of Indiana**

1999  
*Bachelor of Arts (BA) in Biology*  
Student-Athlete Letterman (1994-1998)  
Leadership Program (1997)  
Co-Captain & Most Valuable Player (1998)

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**Frederic (Fred) B. Ayers**  
**Contamination Control, Microbiology, and Sterility Assurance Expert**

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**PROFESSIONAL AFFILIATIONS / NETWORKS**

American Association of Pharmaceutical Scientists (AAPS)  
American Society of Microbiology (ASM)  
Indiana Biotechnology and Pharmaceutical Network  
International Society of Pharmaceutical Engineering (ISPE)

American Society for Testing and Materials (ASTM)  
Biophorum Operations Group  
International Organization of Standards (ISO)  
Parenteral Drug Association (PDA)

**PROFESSIONAL COMPENTENCIES**

Alternative Microbial Methods	Aseptic Manufacturing	Auditing	Barrier Systems
Contamination Control Strategy	Deviation Management	Inspection Readiness	Intervention Development
Process Development	Process Improvement	Project Management	Quality Risk Management
Regulatory Guidelines	Regulatory Inspections	Technical Writing	Training & Qualification

**LEADERSHIP COMPENTENCIES**

Employee Coaching	Employee Mentoring	Employee On-Boarding	Employee Recruiting
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**DEFINING MOMENTS**

**Courage:** *Speaking up with candor and transparency*

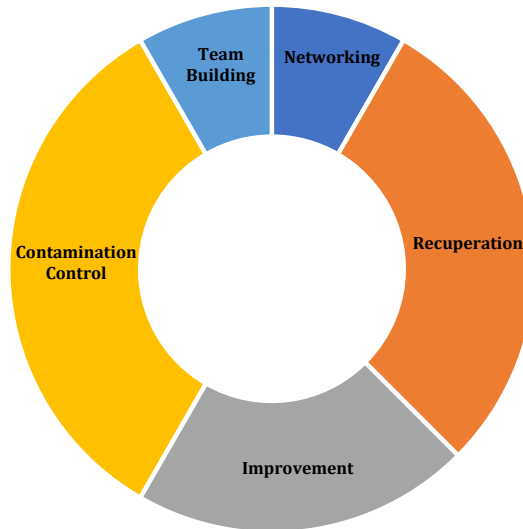
**Leadership:** *Building a Sterility Assurance organization through significant organizational changes.*

**Legacy:** *Collaborated to establish an attract and retain programs for microbiologists.*

**Growth:** *Elected as the PDA Midwest President and to the PDA Science Advisory Board by industry peers.*

**Perseverance:** *Leading the PDA Midwest chapter through the pandemic by transitioning to webinar events and ensuring the organization remained cashflow positive.*

**A DAY IN MY LIFE**



**Networking:** *Working with industry colleagues and clients to drive the biopharmaceutical industry to a future state to ensure a robust supply of high-quality medicine.*

**Improvement:** *Time for self-reflection on accomplishments, opportunities, learning, and family.*

**Team Building:** *Coaching, mentoring, and recruiting to build a strong and diverse organization.*

**Recuperation:** *Preparing the mind and body for another day.*

**Contamination Control:** *Evaluating, improving, and troubleshooting Contamination Control Strategies.*