



Validation Engineer

AREAS OF EXPERTISE

- **New Fill/Finish Facility**
- **Facility Qualification Master Plan**
- **Qualification of Utilities**
- **Process Equipment**
- **Commissioning & Qualification**
- **Environmental Monitoring**
- **Media Simulations Support**
- **Facility Renovation Fill/Finish Facility**
- **Validation Master Plan (VMP)**
- **Installation/Operational/Performance Qualification (IO)**
- **Standard Operation Procedures (SOP)**
- **Gap analysis and media runs**
- **Quality Auditing**

INTRODUCTION

Diversified experience within the Pharmaceutical and Biotech industries. Senior leader dedicated to quality results in the areas of project management, engineering, validation, and quality assurance. Involved with the qualification of aseptic facilities, both isolator-based and open-environment, covering API manufacturing through fill/finish. Facilities handled single-product and multi-product, multi-format, including in-line, as well as remote freeze drying. Implemented a holistic approach to identify, quantify, and qualify process variables. This method considered the human factors that impact both the environment and the process at an early stage of the design and qualification activities.

WORK EXPERIENCE

2010 – Present

Industry Consultant

Example Engagements:

- Work closely with key stakeholders to achieve and maintain regulatory compliance for equipment, facilities, utilities, and processes by conducting GMP audits, investigating observations, determining root cause, and identifying corrective & preventative actions
- New Fill/Finish Facility – (Open-Environment Facility)
- Facility Qualification Master Plan
- Qualification of Utilities
- Process Equipment
- Commissioning & Qualification
- Environmental Monitoring
- Media Simulations Support
- Facility Renovation Fill/Finish Facility – (Open-Environment Facility)

2008 – 2016

Pfizer, Pearl River

Industry Consultant

Duties:

- Qualification of Vial Fill/Finish Line – (Open Environment Facility)
- Qualification of Isolator Based Vial Filling Operations – (Isolator-Based Filling Facility)
- Qualification Project Manager
- Environmental Monitoring
- Equipment Qualification – Syringe Line
- Qualification of the new QC Facility

2003 – 2008

Wyeth, Pearl River, NY

Industry Consultant

Duties:

- Managing cross-functional project team consisting of members of engineering, manufacturing, and quality control. Responsible for all aspects of validation projects, such as schedule and budget.
- Reviewed and approved various Operating Procedures
- Qualification and recertification program for Autoclaves, Washers, Ultrasonic Cleaners
- Qualification of Air samplers for viable and non-viable particulates
- Facility Qualification, including Class A, B, C & D Environmental Monitoring
- CIP/SIP System Qualification
- Freezer, Chill Room qualification, chart recorders and BMS system
- Emergency Power generator qualification, UPS qualification and BMS system
- Laboratory Instrument qualification, such as Scales, Bench top Bioreactors, Chromatography System
- HEPA re-certification procedure and schedule with third party contractor
- Qualification of the Sterility Testing Suite Environmental Monitoring
- Qualification of VHP generator
- Qualification of the Sterility Testing Lab Isolator System using Vaporized Hydrogen Peroxide (VHP)
- Barrier Isolator qualification for Fill-Finish line
- Assessment of computerized system and qualification
- Assessment of the 21 CFR Part 11 Compliance of computerized system

2002 – 2003

Wyeth Viral Vaccine Development, Pearl River, NY

Industry Consultant Validation Engineer

Duties:

- Overseeing, organizing, implementing and tracking Validation Programs for various functional groups. Qualification of Facilities, Utilities, and Process Equipment
- Development of Validation Mater Plan related to qualification activities/support for Cell Culture Pilot Plant

2000 – 2002

Schering-Plough Corporation, Kenilworth, NJ
Schering-Plough Research Institute, Kenilworth, NJ
Schering-Plough Products LLC, Las Piers, PR
Schering-Plough Products LLC, Manati, PR

Industry Consultant Engineer

Duties:

- Managed the Utilities Team for WFI, CS Systems in performing qualification and engineering gap analysis and remediations
- Managed Documentation Team in development of standardized protocols used for qualification activities
- Managed the Equipment Team of ten consultants in perform qualification and engineering gap analysis and remediations

1999 – 2000

Parke-Davis Pharmaceuticals (King Pharmaceuticals), Rochester, MI

Industry Regulatory Consultant Engineer

Duties:

- Qualification of the various software applications, including Batch Card Issuing System, Work Order System

1998 – 1999

Bayer Diagnostics, Middletown, VA

Regulatory Consultant Engineer

Duties:

- Design of test equipment and methods for various in line inspection systems to be used by Quality Control

1996 – 1998

Yellow Springs Instruments, Inc. (YSI), Yellow Springs, Ohio

Development Engineer

Duties:

- Member of the YSI Advanced Technology Group in charge with evaluation and development of new & under-utilized technologies
- Development of exclusive Opto-Chemical Technology for In Situ Measurement of Dissolved CO₂ Beta Test of YSI 8500 Dissolved CO₂ Monitor for pilot scale fermentation facilities at Bristol-Myers Squibb, PA & Abbott Laboratories, North Chicago IL
- Introduction of YSI 8500 Dissolved CO₂ Monitor
- Development and market introduction of the YSI 8500. On site installation, training, of the YSI 8500 Dissolved CO₂ Monitor for bioreactor application

1995 – 1996

General Motors MID-LUX, Flint, MI

Validation Engineer

Duties:

- Development of test scripts, review of test performance of various electronic components associated with the vehicle control systems
- Audit of vendor test facilities

EDUCATION

1992 – 1994

Wright State University, Dayton, OH

Biomedical Science Graduate Program: Computational Neuroscience

1992

Wright State University, Dayton, OH

Bachelor of Science: Biomedical Engineering

RESEARCH

- 1991 – 1995 – Department of Physiology & Biophysics, Wright State University, Dayton Ohio

PUBLICATIONS

- Poisson Process Electrical Stimulation: Circuit and Axonal Responses
- Computation of Long-Distance Propagation of Impulses Elicited by Poisson-Process Stimulation