Manager of Engineering

AREAS OF EXPERTISE

- **Managed facility, and equipment projects with budgets of $2, $150, & $700 million**
- **Supply agreements**
- **Compliance**
- **Consent decree remediation**
- **Regulatory review**
- **Quality**
- **All aspects of validation**
- **Ran Engineering, Validation, and Production departments**
- **Coach, mentor, and teacher to entry level through CEOs**
- **Project management**
- **cGMPs**
- **Pharmaceuticals**
- **Vaccines**

INTRODUCTION

Consultant has over twenty-five years in the biotech & pharmaceutical industries in technical, R&D, quality, operations, production, validation, project management, senior management, process engineering, project management, finance, business development, with experience at companies under Consent Decree.

WORK EXPERIENCE

2000 – Present
Industry Consultant
Duties:

- Regulatory Compliance projects at top-tier bio and pharmaceutical companies (TTBAPCs) to bring facility/department into compliance with FDA, EMEA, WHO, and other regulations.
- Lead Reviewer & client contact for the Deviation Investigation Quality System
- Reviewer, coach, mentor for Change Control, Validation Quality Systems
- Audit, Gap Analysis, and Remediation of the Validation Departments at TTBAPCs designing/implementing new business processes.
- Mentoring of client personnel to teach them sustainable compliance.
- Audit of the validation status of various products.
- Writing SOPs to bring Validation and production departments into compliance with all current Good Manufacturing Practices, cGMPs, internal company policies and guidelines at TTBAPCs.
- Batch Record Review to assure compliance of batch records with all cGMPs.
- Installation of project and document tracking systems incl. Validation, Qualification, & Preventive Maintenance Systems.
- Verification of systems in-place and in-use for compliance for all Quality Systems.

1993 – 1996
Neose Technologies, Horsham, PA
Manager of Engineering
Manager of Validation
Manager of Manufacturing
Duties:

- Scaled-up, and installed the facility to make Neose's first product, under FDA regulations, cGMPs, in < 15% of the time and for < 25% of the cost.
- Discovered a new raw material source, and employed new technologies to reduce product cost of Neose's first product by two orders of magnitude; (US patents 5,575,916; 5,714,075; European Patent 95939486.7-2113).
- Trained subordinates in tracking and installing capital projects, reducing time and cost of installations using project management software.
- Introduced automation, saving $300,000/yr.
- Wrote much of the standard operating procedure (SOP) and manufacturing batch record (MBR) documentation to run the facility under cGMPs.
- Developed, oversaw and conducted the cleaning validation program.
- Developed cost models for all products that changed the focus of development efforts for the company to the areas that generated the greatest value.

1986 – 1993
Merck & Co., West Point, PA
Senior Project Process Engineer
Duties:

- Led review of all Merck processes for adherence to NIH biosafety guidelines.
- Upgraded a facility to produce PedvaxHIB®, on time and budget following all relevant cGMPs, FDA, OSHA, and DER governmental regulations.
- Renovated the Pneumovax® facility to meet safety standards in handling 5000 L of ethanol. Sold project to management. Completed on time and budget.
- Conducted Investigations to determine root cause for problems with current products.
- Initiated $150 million Biotechnology Manufacturing Complex facility.
- Acquired work experience in cGMPs, validation, bacterial vaccines, fermentation, purification, filtration, centrifugation, precipitation, derivatization, conjugation, clean-in-place (CIP), sterilize-in-place (SIP), installation qualification (IQ), operational qualification (OQ), performance qualification (PQ), EEC guide¬lines, and HAZOP.
- Advised on technology transfer of Recombivax hepatitis B vaccine to Shenzhen, China.

1977 – 1985
Air Products & Chemicals, Inc., Allentown, PA
Sr. Process Engineer
Duties:

- R&D, Fischer-Tropsh synthesis, bubble columns, (7 papers).
- Process development on air separation, LNG, liquid helium, sulfur recovery Claus cycles (US patent 4,888,162). Product development of novel heat exchangers.
- Safety design, plant site debottlenecking resulting in a 250% increase in capacity with less than 1% capital expenditure.
- Cost estimation of processes and equipment, business development.
- Equipment costing and design, product pricing, energy conservation.

EDUCATION

1986
Lehigh University
Ph.D.: Chemical Engineering

1977
Massachusetts Institute of Technology
Masters of Science: Chemical Engineering Practice

1977
Massachusetts Institute of Technology
Bachelor of Science: Chemistry

PROFESSIONAL AFFILIATIONS

- Member, American Society for Quality (ASQ)
- Member, American Institute of Chemical Engineers (AIChE)