Director, PGM Quality Support for North America East Coast

AREAS OF EXPERTISE

- **Regulatory affairs and compliance with respect to product manufacturing, validation, product transfers, chemistry, fermentation, aseptic, and formulation**
- **Quality Assurance GMP and GCP auditing**
- **Pharmaceutical Manufacturing**
- **Formulation**
- **R & D**
- **International & Domestic auditing**
- **Project team management**

INTRODUCTION

Consultant has over 40 years' experience within Quality Assurance, Pharmaceutical and Biopharmaceutical Manufacturing, Formulation, Regulatory Affairs / Compliance, and R & D. Emphasis on quality assurance GMP and GCP auditing (international and domestic), regulatory affairs and compliance with respect to product manufacturing, validation, product transfers, chemistry, fermentation, aseptic, compounding, and formulation. Extensive experience in supervisory roles and project team management.

Responsibilities have included: Director, Quality Support North America East Coast; Director and Senior Corporate Quality Assurance Auditor, Manager / Associate Director of Regulatory Affairs and Compliance for U.S., Canada, and International; Manager of Chemical Development. Extensive experience dealing with both foreign and U.S. manufacturing facilities.

WORK EXPERIENCE

2009 – Present
Industry Consultant
Duties:

- Provides services to the pharmaceutical industry related to Quality Assurance and Quality Operations.
- Conducted quality audits of pharmaceutical manufacturing operations, quality systems and products.
- Have completed supplier qualification audits and data integrity audits.
- Consults on design and remediation of selected quality system areas.

Example Projects:

- Vendor qualification audit – 3 weeks - India
- Vendor qualification audit – 3 weeks – Italy
- Pharmacovigilance project – 5 months – Germany, Netherlands
- Vendor qualification audit – 2 weeks - Israel
- Quality systems (investigations, complaints, CAPA) remediation – 8 months – North Carolina
- Data integrity audit, quality systems audit – 10 months – India
- Quality systems (investigations, complaints, CAPA) remediation – 3 months – Nebraska
- Quality systems remediation- 9 months - Puerto Rico
- Quality systems audit, clinical and manufacturing data integrity audit – 15 months - Florida
- Interim Quality Operations Director – 8 months - South Carolina
- Quality systems remediation – 4 months – India

- Quality systems establishment & implementation – 9 months – Maine
- Quality systems remediation (CAPA, Field Alerts) – 6 months – Italy
- Quality systems remediation (medical device CAPA) – 5 months- Ohio
- DMF compilation / submission – 6 weeks- Illinois
- Interim Quality Operations Director Compounding Facility – 4 months - Illinois

1973 – 2007
Pfizer

Director, PGM Quality Support for North America East Coast, (2004 – 2007)
Duties:
- Director supporting quality initiatives for the 8 Pfizer East Coast U.S. and Canadian facilities.
- Project team leader resulting in numerous American Area guidances.

Director, Corporate Quality Assurance, (2003 – 2004)
Duties:
- Directed a group of Corporate QA Auditors responsible for Latin America / Canada and Puerto Rico regions.

Senior Corporate Quality Assurance Auditor, (1997 – 2003)
Duties:
- Performed Corporate Audits at Pfizer and contract vendor manufacturing & clinical facilities worldwide (42 countries).
- Special assignments include Pfizer Brooklyn support and a system-based audit team guidance.

Manager International Regulatory Affairs, Animal Health, (1996 – 1997)
Duties:
- Completed necessary registration dossiers for Latin America, Asia, South Africa and Canada Regulatory Authorities.
- Focused on the regulatory approval of the transfer of SmithKline Beecham Animal Health products to Pfizer facilities.

Associate Director, North America Regulatory Affairs Animal Health, (1994 – 1996)
Duties:
- Supervised Regulatory Affairs Group responsible for chemistry and manufacturing concerns for SmithKline Beecham Animal Health / Pfizer.
- Served a liaison between manufacturing plants and CVM / HPB.
- Worked on transfer project teams, devised regulatory strategy, complied dossiers, and negotiated approvals.
- Responsible for Regulatory Compliance at the Lincoln, NE facility.

Manager, Chemical Development and Regulatory Affairs Support, (1990 – 1994)
Duties:
- Supervised Animal Health formulation and chemical development group.
- Project team liaison between SBAH R & D and manufacturing.
- Responsible for CMC sections for Regulatory Affairs for CVM, HPB, and European dossiers.

Associate Senior and Senior Investigator, (1981 – 1990)
Duties:

- Identified development candidates, developed purification processes and radiolabeling techniques for fermentation products.
- Transferred projects to manufacturing.

Associate Medicinal, Medicinal, and Senior Medicinal Chemist, (1973 – 1981)
Duties:

- Synthesized and purified novel chemicals for SmithKline & French research and development projects.

EDUCATION

University of Rochester
Master of Science: Medicinal Chemistry

Duke University
Bachelor of Science: Chemistry