Vice President of Product Development

AREAS OF EXPERTISE

- **Quality Assurance**
- **Quality Systems**
- **Develop & Monitor Clinical Research Operations**
- **GxP (GLP/GCP/GMP) Audits**
- **ISO-9000**
- **Regulatory Affairs**
- **Product Development**
- **Laboratory Operations Management**
- **Develop & Review Quality Systems**
- **QSR Audits**
- **QA/RA/Clinical Research**

INTRODUCTION

Consultant supplies leadership in Quality Assurance, Clinical Research and Regulatory Affairs to assist in quality systems improvements, product development, and marketing approval of medical products. Experienced in all aspects of quality management for pharmaceuticals, medical devices and biologicals. Expertise focuses on GLP, cGMP, GCP, ISO-9000 and ISO-13485 regulations as they apply to Quality Systems.

WORK EXPERIENCE

2001 – Present
Industry Consultant
Duties:

- Assist pharmaceutical, medical device and biological manufacturers as well as contract laboratories to develop and improve their quality systems.
- Assisted a major pharmaceutical company identify problems in their clinical development program that resulted in approval of a multi-billion-dollar product.
- Gained approval for a device manufacturer to resume production and sales following regulatory closure.
- Assisted numerous companies and laboratories overcome Consent Decrees and Warning Letters following FDA inspections.
- Has conducted numerous audits to identify differences in Quality Systems between current practices and regulatory requirements and guidelines.

1998 – 2001
Novadel (formally Flemington Pharmaceutical Corporation), Flemington, NJ
Vice President of Product Development
Duties:

- Responsible for Product Development and Quality Assurance, with emphasis on formulations which were designed to deliver rapid blood absorption.
- This encompassed analytical methods development, contract testing and manufacturing, clinical trials and development of regulatory documentation for licensing and product submissions.
- One sublingual product, developed during this time, has been approved by FDA.

1992 – 1998
Medical Development Quality Associates, Lenexa, KS
President
Duties:

- Supplied consulting expertise in Quality Assurance, Clinical Research and Regulatory Affairs to assist clients in development, marketing approval and maintenance of medical products.
- Conducted audits to assure compliance with regulations and standards.
- Major clients included Warner-Lambert Co., Hoechst-Marion-Roussel, Inc., Procter & Gamble, Battelle Laboratories, Novartis Pharmaceuticals, Cyberonics, Government of Pakistan, and Centeon Pharmaceutical Products.
- Assisted in the reversal of three Federal Court Consent Decrees.

1991 – 1992
Oread Laboratories, Inc., Lawrence, KS
Manager of Regulatory Affairs
Duties:

- Supervised Quality Assurance of contract laboratory services, including GLP and GMP compliance.
- Supervised the IND development, analytical testing, contract manufacturing, clinical trials and licensing of an approved orphan drug for premature infants.
- Developed client confidence, resulting in 30% growth in staff and new contracts.

1989 – 1990
Pharmaceutical Consultants, Inc., Leawood, KS
Director of Corporate Development
Duties:

- Directed all daily activities of Clinical Research and Regulatory Affairs staff of Contract Clinical Research Organization.
- This included numerous projects for domestic and international pharmaceutical and biological products clients.
- Additional responsibilities encompassed identification of new business opportunities, bids for contract, budget negotiations and technical/regulatory consulting.
- Staff increased by over 200% in eighteen months.

1988 – 1989
Martec Pharmaceutical, Kansas City, MO
Director of Clinical Research
Duties:

- Directed all aspects of clinical development of ethical and generic drugs.
- This included protocol design, investigator selection, budget preparation, data review, contract analytical testing, selection of Contract Research Organizations, and study monitoring.
- Interacted with all other departments to assure integrity of products and quality of regulatory submissions.
- Clinical research therapies included cardiology, rheumatology, gastroenterology and psychiatry.

1987 – 1988
Independent Consultant to the Medical Product Industry
Duties:

- Provided Clinical Research and Regulatory Affairs service to numerous pharmaceutical and medical device companies.

1984 – 1987
Seton Company, Malvern, PA
Director of Regulatory Affairs & Quality Assurance
Duties:

- Directed all Regulatory and Quality Assurance activities for five company divisions.
- Oversaw pre-clinical and clinical trials for new medical device components.
- Supervised manufacturing of all biologically-based products.
- Monitored bio-products research to ensure validity of procedures and equipment.
- Prevented the loss of a major customer by developing analytical support, manufacturing capabilities, and credibility to produce acceptable components for wound dressings.

1976 – 1984
Janssen Pharmaceutical, Inc., Piscataway, NJ
Director of Clinical Quality Assurance, (1982 – 1984)
Director of Clinical Research, (1979 – 1982)
Senior Clinical Research Associate, (1976 – 1979)
Duties:

- Identified an invalidating flaw in an NDA submission, which prevented the rejection of the application.
- Directed the activities of four Clinical Research groups for domestic and international drug development.
- This encompassed 12 new chemical entities, seven of which have been approved in the U.S. Clinical Research therapies included immunology, rheumatology, oncology, cardiology, mycology, anesthesiology, gastroenterology, and allergy.

1970 – 1976
Harleco, Division of American Hospital Supply Corporation, Gibbstown, NJ & Philadelphia, PA
Compliance Coordinator, R&D, (1973 – 1976)
Senior Research Chemist, (1970 – 1973)
Duties:

- Managed all documentation for a line of 400 *in-vitro* diagnostic products.
- Established expiration dates for all company products.
- Developed and patented an *in-vitro* test reagent in various packaged forms.

EDUCATION

1984
Temple University, Philadelphia, PA
Ph.D.: Pharmaceutics

1975
Temple University, Philadelphia, PA
Masters: Organic Chemistry

1968
Albright College, Reading, PA
Bachelor of Science: Chemistry

TEACHING AFFILIATIONS

2014 – Present
University of Maryland College of Pharmacy, Baltimore, MD
Adjunct Faculty

2012 – Present
Center for Professional Innovation and Education, Malvern, PA
Course Director – Good Laboratory Practices

2001 – Present
Center for Professional Advancement, New Brunswick, NJ
Focus of Instruction – GXP Compliance for Medical Product Development

1991 – 1997
The Business and Industry Institute, Johnson County Community College, Overland Park, KS
Part-Time Lecturer

1989 – 1997
University of Missouri College of Pharmacy, Kansas City, MO
Adjunct Faculty

BOARD OF DIRECTORS

- 2004 – 2014 SynVax Pharmaceuticals, Inc., North Logan Utah

EXPERT WITNESS SERVICES

- Fourteen cases, resulting in ten Opinions, one Deposition and one court testimony

PROFESSIONAL SOCIETY MEMBERSHIPS

- American Society for Quality