Director, Regulatory Affairs

AREAS OF EXPERTISE

- **Strategic regulatory planning**
- **Label and SOP development**
- **Quality and regulatory auditing**
- **510(k)**
- **IDE**
- **PMA**
- **OTC**
- **CE Marking (MDD and AIMD)**
- **STED submission development**
- **Domestic and international compliance**
- **Quality management system initiation**
- **Preparation of initial clinical regulatory documentation**
- **IND**

INTRODUCTION

Consultant is an industry professional specializing in startups and research organizations with expertise in strategic regulatory planning; label and SOP development; 510(k), IDE, PMA, CE marking (MDD and AIMD) and STED submission development; domestic and international compliance activities; assistance with initiating quality management system; preparation of initial clinical and regulatory documentation; quality and regulatory auditing.

WORK EXPERIENCE

2008 – Present
Industry Consultant

2009 – 2015
Biomimetic Therapeutics, LLC, Franklin, TN
Director, Regulatory Affairs
Duties:

- Director of Regulatory Affairs with submission and compliance responsibilities for Investigational Device and New Drug Applications for Drug/Device combination products regulated as drugs and Class III medical devices. Other responsibilities include quality and regulatory auditing, developing and implementing Domestic and International regulatory strategies, preparing technical and design dossiers, STEDs and other international submissions and import/export documentation; quality and risk management; labeling; complaint handing and product reporting.
- Non - regulatory responsibilities: Tennessee State Board of Pharmacy contact, Designated Representative to the State of California Board of Pharmacy and manager of the Board of Pharmacy /Verified Accredited Wholesale Distributor program.

2005 – 2008
Alfred Mann Foundation, Santa Clarita, CA
Manager, Regulatory Affairs
Duties:

- Manger of Regulatory Affairs department of AMF, a research foundation which develops Class III medical devices intended use in muscle and neural stimulation. Responsible for managing, preparing

and maintaining investigational device submissions, domestic and international; medical device reporting (complaint handling) and vigilance reporting; device tracking; quality system, and risk management activities; facilities registrations, Good Laboratory Practices and internal quality system auditing; responsible for developing and maintaining clinical documentation for submission. Served as Home Medical Device Exemptee for sister company Bioness.

1996 – 2005
Medtronic Minimed, Northridge, CA
Manager, Regulatory Affairs
Duties:

- Manager of the Regulatory Affairs department of 12 individuals for Medtronic MiniMed, a company which manufactures and distributes Class II and Class III medical devices for use in the treatment of diabetes in the USA and in one-hundred and twenty-nine countries. Responsible for managing, preparing and maintaining investigational and remarket approval submissions for both drugs and devices, domestically and internationally; medical device (complaint handling) and vigilance reporting; device tracking; CE marking; facilities registration and drug and device listing; responsible for clinical drug product releases (Exempt Pharmacist) and implementation of the state of California regulations (home medical device retail and pharmacy requirements). Served as guest auditor for corporate regulatory (2001-2005). Served as RA liaison to Clinical Research and serve as "safety coordinator" for drug related studies.
- Simultaneously managed the Clinical Studies unit of 5 individuals in Hollywood Florida. Responsible for manufacture, distribution, and QC of the investigational drug; clinical subject support, licensing of the facility with FDA and the State of Florida, and import export of clinical product to Canada and Mexico.

1995 – 1996
Herbalife International, Inc., Los Angeles, CA
Regional Product Manager, Cosmetics, Europe and Africa
Duties:

- Manager of the International Cosmetics Projects; responsible of international regulatory and submissions activities in the EU, Baltic region and the Near East and Asia.

1991 – 1995
Allergan/AMO/Ioptex Research, Inc., Irwindale, CA/Irvine, CA
Senior Regulatory Analyst and Section Manager, International and Domestic Regulatory Affairs
Duties:

- Associate Manager of International Regulatory Affairs, managed a staff of three (IOPTEX, manufacturer of intra-ocular lenses - Class III medical devices formerly a Smith and Nephew Company). Responsible for all the international regulatory activities and CE marking and reported to the VP of Clinical and Regulatory Affairs.

1990 – 1991
Libby Laboratories, Berkeley, CA
Director of Scientific Affairs
Duties:

- Director of QA/QC and Regulatory Affairs for a small contract manufacturer of OTC drugs and cosmetics

1988 – 1990
Baxter Healthcare/Hyland Biotechnology Division, Glendale, CA
International Regulatory Administrator
Duties:

- Baxter/Hyland, manufacturer and distributor of Factor VIII, IX and Albumin products, Served as Senior Administrator in international regulatory affairs.

1986 – 1988
Redken Laboratories, Canoga Park, CA
R&D/Corporate Microbiologist
Duties:

- Corporate Microbiologist responsible for plant and water system hygiene and GMPs; preservative efficacy testing, systems formulation and QC microbiology of hair care and cosmetic products.

1983 – 1986
Swan Cumberland Mfg., Smyrna, TN
R&D/New Product Development Manager
Duties:

- New Product Development Manager for an OTC drug and cosmetic contract manufacturer, managed a staff of five, developed OTC analgesic and couch-cold preparations, hair care and personal hygiene products. Customers included Safe Way, Ralph's and Kroger's markets.

1978 – 1983
Vanderbilt University Medical School, Nashville, TN
Research Assistant III, Department of Biochemistry
Duties:

- Responsible for the preparation, purification and identification of the microbial toxin associated with Group B Streptococcal Neonatal Respiratory Syndrome. As the senior RA, worked with students and graduate student as Lab Proctor and advisor. Also served as an independent research associate to the Nashville, TN Public Health Department working with Gonorrhea strains.

Earlier experience includes:
Various technical and laboratory positions in chemistry and microbiology with cosmetology manufacturers. Formulating and QC chemist, microbiologist and laboratory supervisor for such companies and Revlon, Yardley of London and Lanvin-Charles of the Ritz/Squibb.

EDUCATION

1965 – 1969
Rutgers University
Major: European and Medieval History, Minor: Biological Sciences & Chemistry

Graduate courses in Industrial Microbiology

1971 – 1972
Columbia University School of Pharmacy
Cosmetic Formulation certification

1976 – 1978
University of Tennessee
Bachelor of Science: Biological Sciences/Microbiology, Chemistry

1979 – 1980
Vanderbilt University School of Allied Health
Registered Medical Technologist (ASCP)

1989 – 1991
University of California
Hazardous Waste Management and Industrial Hygiene

PROFESSIONAL CERTIFICATIONS, LICENCES, AND ASSOCIATIONS

- Designated Representative/Exempt Pharmacist: State of California: 2002 – 2005, 2010-2015
- Regulatory Affairs Professionals – 1988-Present
- Regulatory Affairs Certified -2000 – Present
- American Society for Quality and Biomedical Auditing, Quality Auditing ISO 9001: 2003-2012 (have not renewed)

PUBLICATIONS

- (1983) Abstract -Society of Pulmonary Medicine, New Orleans - Characteristics of Group B Strep. Toxin (Second Author).
- (1983) Abstract, ASM, Nashville TN - Characteristics of Group B Strep Toxin and worked with other authors.