Louise C. Johnson, M.S. GOV. MSG. NO. 579

OVERVIEW

Over twenty-five years of experience in pharmaceuticals and biotech regulatory affairs including extensive liaison work with FDA, regulatory submissions and negotiations, advisory committee meetings, regulatory strategies, promotional material review, product lifecycle management, quality assurance, pharmacovigilance, due diligence, and liaison with corporate partners.

SIGNIFICANT ACHIEVEMENTS

- Successfully submitted over 2 dozen INDs for small molecules and biologics, 3 NDAs (including 1 application under 505(b)(2) and 1 NDS in Canada)
- Negotiated approval of 2 NDAs and the NDS
- Led and conducted numerous regulatory agency meetings with FDA, TPD, EMA, MHRA; planned and participated in one FDA advisory committee presentation
- Filed numerous IND and NDA amendments, orphan drug applications, fast track applications, annual reports, post-approval changes, and DDMAC submissions

EDUCATION

M.S Applied Statistics, Villanova University
emphasis in biostatistics and experimental design

B.A Psychology, University of California, Santa Barbara
emphasis in physiological psychology, neurology, and pharmacology

THERAPEUTIC EXPERIENCE

- Neurological Diseases (epilepsy, Parkinson's disease, pain, spasticity, Alzheimer's disease, multiple sclerosis)
- Oncology (cytotoxic agents for metastatic breast, ovarian, and prostate cancers and biologic agents)
- Cardiovascular (hypertension)
- Hormone and Nicotine Replace Therapies
- Irritable bowel syndrome
- Tropical diseases (diarrhea, malaria, soil-transmitted helminthiasis, visceral leishmaniasis)

FDA DIVISION EXPERIENCE

- Neurology (previously Neuropharm)
- CBER Therapeutic Biologics
- Oncology (Drug and Biologic)
- Anesthesia, Analgesia, and Rheumatology (previously Anesthetic & Critical Care)
- Gastroenterology
- Controlled Substance Staff
- Reproductive
- Cardio Renal
- DDMAC

INTERNATIONAL EXPERIENCE

- Canadian Therapeutic Products Directorate (CTA and NDS)
- India (clinical trials, product registration, pharmacovigilance)
- UK MHRA (Medicines and Healthcare Products Regulatory Agency)
- World Health Organization (Certificate of Pharmaceutical Product, Prequalification Program)
- European CTA submissions
- EMA Voluntary Harmonisation Procedure
- Israeli Ministry of Health

CAREER SUMMARY

Nektar Therapeutics
Executive Director, Regulatory Affairs *June 2011 – present*

Second most senior executive within Regulatory Affairs responsible for:

- Developing and implementing global strategies to expedite product development and approval
- Acting as primary senior regulatory representative in negotiations with US and international regulatory agencies
- Managing CRO to ensure all clinical trial applications for a multinational Phase 3 oncology trial were approved in time to meet program goals
- Ensuring all global regulatory submissions for oncology program are critically reviewed and submitted on time, including IMPD and CMC IND amendments
- Leading all NDA/MAA preparation activities for a planned 2015 filing
- Participating in developing and managing PAI inspection plan
- Working closely with project teams and other departments to agree on regulatory strategy and to ensure effective agency meetings and regulatory communications
- Participating in senior level interactions with external partner companies, Contract Research Organization (CRO) management, and external vendors
- Participating in due diligence activities for Nektar products
- Evaluating business impact of changes in government regulatory requirements and policies and developing responses
- Developing infrastructure and process improvements to enhance the efficiency of the Regulatory Affairs Department operations
- Standing in for VP of Regulatory Affairs as needed to manage the oversight of all key regulatory and departmental management activities to support corporate business goals
- Developing departmental budget, managing contracts
- Managing/mentoring regulatory affairs staff and providing interim management support for the Drug Safety group and the GCP Compliance group.

Neuraltus Pharmaceuticals
Senior Director, Regulatory and Quality Assurance *February 2011 – June 2011*

Senior regulatory executive responsible for:

- Developing regulatory strategy and providing regulatory guidance and expertise to project teams and senior management
- Preparing all regulatory submissions to FDA. Providing critically review of submissions to ensure appropriate scientific rationale and strategic impact
- Working closely with project teams and relevant colleagues to support development goals
- Supervising all regulatory and quality compliance activities for all development products
- Developing and maintaining a compliant quality system to support pharmaceutical development
- Managing/mentoring regulatory affairs staff

Biologics Consulting Group
Senior Consultant *March 2007 – February 2011*

As a regulatory affairs consultant, provided expert assistance in product development and marketing for small molecules and biologics. Consulting work included biologic INDs, a drug NDA, IND planning, clinical trials in India, manufacturing in China, and import/export guidance.

Renovis, Inc.
Senior Director, Regulatory Affairs *April 2004 – January 2007*

Senior regulatory executive responsible for:
- Supporting corporate planning and risk management by presenting regulatory strategy to corporate management and the Board of Directors
- Leading and managing a project team through company's first new chemical entity IND filing
- Ensuring all regulatory submissions are critically reviewed and submitted on time
- Creating the company's first QA group
- Leading the regulatory and QA functions, mentoring staff
- Providing regulatory analysis of potential in-licensing, acquisition, and merger activities
- Establishing and maintaining regulatory and QA policies
- Leading regulatory communications with development partner to transfer Phase 3 IND

Pain Therapeutics, Inc
Senior Director *September 2002 – April 2004*

Senior regulatory executive responsible for:
- Leading successful pre-IND and End-of-Phase 2 meetings for opiate analgesics
- Providing regulatory strategy and support to initiate the company's first Phase 3 studies
- Developing and implementing regulatory strategy for all developmental compounds
- Ensuring all regulatory submissions are critically reviewed and submitted on time
- Acting as primary regulatory contact to CDER and international regulatory agencies (UK MHRA, Israeli MOH) and corporate partners
- Leading the regulatory and QA functions, mentoring staff, upgrading controlled document files, improving SOP system

Elan Pharmaceuticals, Inc. (formerly Athena Neurosciences, Inc.)
Director *February 1999 – May 2002*
Associate Director *April 1997 – February 1999*
Manager *October 1995 – March 1997*

Responsible for:
- Providing regulatory strategy for development products and lifecycle management of marketed products
- Filing the NDA and the NDS (Canada) for an orphan drug product (Diastat®)
- Co-leading strategy creation, preparation for, and company presentations for Diastat Advisory Committee meeting
- Negotiating approval of the Diastat NDA and NDS, and negotiating NDA approval of an anti-epilepsy drug (Zonegran®)
- Supporting product launch activities for Diastat and Zonegran by working closely with marketing, sales training, the advertising agency, and participating in the launch meetings
- Filing successful INDs in the US and Canada for a therapeutic monoclonal antibody (Tysabri®) and a US IND for a therapeutic vaccine for Alzheimer's disease (AN-1792)
- Acted as primary regulatory contact to FDA (CBER, CDER, and DDMAC) and TPD as well as international corporate partners (in Canada, Germany, Japan, Switzerland, UK, and US)
- Managing/mentoring regulatory staff of six
- Representing Regulatory Affairs on the Clearance Committee to review and approve promotional materials
- Establishing regulatory standards for promotional material, communicating them to marketing colleagues, and ensuring compliance
- Participating in due diligence of two products that were successfully in-licensed (Mysoline® and Frova®)

Cygnus, Inc.
Manager *August 1994 – October 1995*

Responsible for:
- Acting as primary regulatory contact to FDA for five investigational transdermal hormone products
- Supporting an on-site commercial manufacturing facility by providing detailed review and approval of SOPs, analytical specifications, stability protocols, master records, and deviations
- Collaborating with Analytical colleagues to define and implement a comprehensive format for stability reports
- Managing/mentoring two regulatory associates

The Du Pont Merck Pharmaceutical Co.
Manager *1992 –1994*
Senior Regulatory Associate *1991 - 1992*
Regulatory Affairs Associate *1989 - 1990*

Responsible for:
- Acting as primary regulatory contact to FDA for two investigational oncologic drugs
- Participating in filing a worldwide marketing application for a new antihypertensive (Cozaar®/Hyzaar®) at Merck
- Filing numerous INDs, IND amendments, NDA supplements, and labeling changes.
- Monitoring Federal Register to identify changes in FDA regulatory requirements and policies and communicating relevant notices to colleagues.

Pharmacologist *1978 - 1989*

Responsible for:
- Performing discovery research in the Pharmaceuticals Division, specializing in CNS diseases including epilepsy, schizophrenia, depression, and Alzheimer's disease.
- Supervising staff of eight technicians

Proficiencies
- Microsoft Word, Excel, PowerPoint, Project
- EndNote