

Curriculum Vitae



Louise C. Johnson, M.S.
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Senior Consultant
Biologics Consulting Group, Inc.
San Mateo, CA

AREAS OF EXPERTISE

- Immediate- and controlled-release solid oral dosage forms, injectables, transdermal
- CBER Therapeutic Biologics, Neurology (previously Neuropharm), Oncology, Anesthesia, Analgesia, and Rheumatology (previously Anesthetic & Critical Care), Gastroenterology, Controlled Substance Staff, Reproductive, Cardio Renal, DDMAC
- Neurological Diseases (epilepsy, Parkinson's disease, pain, spasticity, Alzheimer's disease, multiple sclerosis), Oncology (cytotoxic agents for metastatic breast and prostate cancers), Cardiovascular (hypertension), Hormone and Nicotine Replace Therapies, irritable bowel syndrome
- Creation, implementation, and review of regulatory strategies to support business goals
- Smooth negotiation of regulatory approvals and effective interpretation of FDA requests
- Broad experience in regulatory filings including original INDs, IND maintenance, original NDA, and MAA filings, marketed product support (advertising and promotion, labeling, supplements, adverse experience reports), FDA, MHRA, and TPD meetings (Pre-IND, End of Phase 2, negotiation of marketing approval, responses to agency questions), and presentations to an FDA Advisory Committee
- Establishment of Regulatory Affairs' goals, procedures, and policies
- Assurance of compliance with regulatory requirements for submissions
- Creation and maintenance of regulatory intelligence activities to keep abreast of change at regulatory agencies and regulatory developments with competitors' products

EDUCATION

M.S. *Applied Statistics*, Villanova University (1992)

B.A. *Psychology*, University of California, Santa Barbara (1978)



EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant
San Mateo, CA (Feb. 2007 - present)

Renovis, Inc., Senior Director, Regulatory Affairs
(April 2004 – Jan. 2007)

- Provided regulatory and development assessment to business development and executive management to evaluate opportunities for in-licensing, acquisition, and merger.
- Led and conducted regulatory and development review in due diligence.
- Assessed regulatory strategy of each opportunity and provide recommendations for likelihood of success and alternative approaches.
- Identified development and approval risks for investigational products.
- Defined and evaluated competitive landscape for business development opportunities and internal research programs.
- Directed Regulatory Affairs and Quality Assurance staff of three to support four investigational products.
- Served as primary regulatory contact to CDER for all projects.
- Responsible for defining regulatory strategy for all products in development.
- Represented Regulatory Affairs on development teams and presented to corporate management and board of directors.
- Established and maintained regulatory and QA policies.
- Responsible for project management of one investigational product.
- Ensured corporate goals and timelines were met for all regulatory filings.

Pain Therapeutics, Inc., Senior Director
(Sep. 2002 – Apr 2004)

- Directed Regulatory Affairs and Quality Assurance staff of four to support seven INDs.
- Primary regulatory contact to CDER and international regulatory agencies (MHRA, Israeli MOH) as well as corporate partners.
- Responsible for defining regulatory strategy for all products in international development.
- Represented Regulatory Affairs on development teams and to corporate management.
- Established and maintained regulatory and QA policies to support Phase 3 development.
- Accomplishments included
 - Successful pre-IND and End of Phase 2 meetings
 - Initiation of three Phase 3 studies
 - Identification of an Israeli contact person to identify process for clinical study approval
 - Successful export of Schedule II clinical supplies by obtaining a DEA export permit within one week
 - Organization of controlled document files
 - Initiation of the company's first QA clinical audits
 - Restructuring of SOPs to support a broader range of company activities.



Elan Pharmaceuticals, Inc. (formerly Athena Neurosciences, Inc.) *Director*
(Feb. 1999 – May 2002), *Associate Director* (Apr. 1997 – Feb. 1999), *Manager* (Oct. 1995 – Mar. 1997)

- Responsible for defining regulatory strategy for biologic and drug products in international development and commercialization.
- Represented Regulatory Affairs on development and commercialization teams.
- Primary regulatory contact to FDA (CBER, CDER, and DDMAC) and TPD as well as international corporate partners (Canada, Germany, Japan, Switzerland, UK, and US).
- Supervised staff of six to support five marketed products, five US INDs for drug products, one US IND for a therapeutic vaccine, and five Canadian INDs.
- Represented Regulatory Affairs on the clearance committee to review and approve promotional materials.
- Established regulatory standards for promotional material, communicated them to marketing colleagues, and ensured compliance.
- Provided regulatory intelligence to colleagues and trained regulatory staff on regulatory intelligence activities.
- Participated in due diligence of two products that were successfully in-licensed (Mysoline[®] and Frova[®]).
- Collaborated with European colleagues on international product development, regulatory strategy, and regulatory submissions.
- Accomplishments included:
 - Filing 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).
 - Negotiated approval of an NDA and an NDS for an orphan drug product (Diastat[®]) and negotiated NDA approval of an anti-epilepsy drug (Zonegran[®]).

Cygnus, Inc., *Manager*
(Aug. 1994 – Oct. 1995)

- Responsible for all regulatory activity for five investigational transdermal products.
- Coordinated all planning for an NDA.
- Supported an on-site manufacturing facility by providing detailed review and approval of SOPs, analytical specifications, stability protocols, and master records.
- Supervised a staff of two.
- Collaborated with Analytical colleagues to define a comprehensive format for stability reports.
- Monitored Federal Register and FDA guidances, evaluated their impact on the company, and communicated assessment to colleagues.
- Represented Regulatory Affairs in re-engineering the drug development process at Cygnus.

The Du Pont Merck Pharmaceutical Co., *Manager* (1992 –1994), *Senior Regulatory Associate* (1991 – 1992)

- Responsible for all US regulatory activity for two experimental anti-cancer drugs, including all FDA negotiations.
- Coordinated all planning for the preparation and submission of marketing applications in Europe, Canada, and the US. Monitored Federal Register and FDA guidances, evaluated their impact on the company, and communicated assessment to colleagues.



- Worked at Merck Research Labs to help file a worldwide marketing application for a new antihypertensive (Cozaar[®]/Hyzaar[®]).
- Actively participated in standardizing documents, streamlining document creation, and developing new electronic submission processes.

E.I. du Pont de Nemours & Co., *Regulatory Affairs Associate*
(1989 -1990)

- Filed numerous INDs, IND amendments, and NDA supplements.
- Reviewed CMC submissions, annual reports (IND and NDA), periodic and expedited adverse experience reports, clinical study protocols and documentation, labeling, and advertising.
- Coordinated labeling changes.
- Monitored Federal Register and communicated relevant notices to colleagues.

E.I. du Pont de Nemours & Co., *Pharmacologist*
(1978 -1989)

- Performed discovery research in the Pharmaceuticals Division, specializing in CNS diseases including epilepsy, schizophrenia, depression, and Alzheimer's disease.
- Responsibilities grew from performing experiments to independently running a lab with eight technicians, including direct supervision and staff development.