Randall Lis, Ph.D.

Senior Regulatory Affairs Consultant

Core Competencies

- Regulatory CMC Strategy
- Small Molecules
- Technical Writing
- Global Submissions
- eCTD Formatting
- Program Management
- Scientific Knowledge Depth
- Quality Risk Management
- Regulatory Starting Materials

Products

- Noctiva™
- Zosyn®
- Protonix®
- Enbrel®
- Mylotarg®

Professional Summary

Dr. Lis serves as our senior CMC consultant with 22 years of industry experience in the development of new drugs and therapeutic agents. He is responsible for setting the long-term strategy and vision for the regulatory function by providing global CMC regulatory management. He has filed over one hundred IND's, NDA's and other market product applications.

- Provides critical review of documentation supporting regulatory applications,
- Provides status of global regulatory affairs strategies and tactics, procedures, and practices,
- Articulates complex regulatory CMC issues supporting global development and commercialization of early and late state products.

Prior to joining DSI, Dr. Lis served as Senior Director, Global CMC Regulatory Affairs at Pfizer/Wyeth. He received a B.A. in Chemistry with High Distinction from Rutgers University in New Brunswick, NJ and a Ph.D. in Organic Chemistry from Indiana University in Bloomington, Indiana.

Education

Ph.D.	Organic Chemistry	Indiana University
B.A.	Chemistry (High Distinction)	Rutgers University

Professional Experience

Design Space Inpharmatics, LLC **2011 - Present**

Senior Regulatory Affairs Consultant

- Led cross-functional CMC initiatives, enabling successful product development, approvals and life-cycle management,
- Strong ability to establish and communicate clear team vision,
- Planned and executed US, EU and ROW marketing applications,
- Reviews CMC sections of IND/CTA, NDA/BLA/MAA, and other global submission documents.

Pfizer (Wyeth) R&D **1998 - 2011**

Senior Director, GCMC Regulatory Affairs (2006)

Led 15 staff at two sites (Collegeville, PA and Pearl River, NY) and provided all CMC regulatory submissions for new Market Product and global clinical Investigational New Drug applications. Served as liaison between several groups within the organization and 3rd Party manufacturers.

- Reviewed and approved new Market Product application dossiers in CTD format, clinical Investigational New Drug applications (INDs, CTAs and IMPDs) and global Board of Health CMC responses,
- Served as a liaison between several groups within the organization, such as, Regulatory Affairs, International and Domestic Quality Operations, Tech. Services and Tech. Operations & Product Supply,
- Interacted with 3rd Party Manufacturers in preparing Market Product applications,
- Responsible for the CMC sections of Package Inserts, Summary of Product Characteristics, Patient Information Leaflets and Investigator's Brochures,
- Group responsibilities were to provide all CMC documentation for all clinical trial material submissions globally and new Market Product applications,
- Wyeth Research – Team of the Year Award, 2006 (Twice, Relistor Development Team and Japan CMC Integration Team) and 2008 (Protonix Granules Pediatric).

Director, CMC Regulatory Submissions (2003)

Managed 8 staff at two sites (Collegeville, PA and Pearl River, NY). Group provided all CMC regulatory submissions for new Market Product and global clinical Investigational New Drug applications.

- Reviewed and approved new Market Product application dossiers, clinical Investigational New Drug applications and global Board of Health CMC responses,
- Contributed to global CMC regulatory strategy for Market Product Application,
- CMC regulatory representative to several project teams within the organization,
- Responsible for the CMC sections of Package Inserts, Summary of Product Characteristics, Patient Information Leaflets and Investigator's Brochures,
- Wyeth Research – Team of the Year Award, 2004 (Tygacil CMC Development) and 2005 (European Product Conformance).

Associate Director, CMC Regulatory Submissions (2000)

- Group responsibilities were to provide all CMC documentation for all clinical trial material submissions globally and new Market Product applications,
- Review, writing and compilation of documents for Drug Substances and Drug Products,
- Wyeth-Ayerst Team Accomplishment Award, 1999 (Twice, Rapamune Task Force and Minesse MRP Rapid Response Team).