Amy McCord, Ph.D.

Senior Regulatory Affairs Consultant

Core Competencies

- Agency Type A&B Meetings
- Oncology & Vaccine
- Project Management
- Small Molecule and Device
- Device/Drug Combo Products
- Biologics and Biosimilars
- Orphan Drug Submissions
- Liposomal Formulations
- Briefing Books

Professional Summary

Dr. McCord facilitates the movement of drug products from pre-clinical and clinical phases through and beyond commercialization by leveraging her diverse scientific background, regulatory experience and project management capabilities.

Over her 14-year career, Dr. McCord has managed multiple parallel projects and represented CMC regulatory on multi-disciplinary teams. Her expertise includes authoring Module 3 eCTD documents and white papers for various topics related to the regulation of biologics, device and small molecule products. She is experienced in reaching key objectives for the business related to biologics and biosimilars.

Education

Ph.D.	Biomedical Sciences	University of South Florida
B.S.	Microbiology and Cell Science	University of South Florida

Professional Experience

Design Space Inpharmatics, LLC **2016-Present**

Senior Regulatory Affairs Consultant

- Provides consulting for site changes, process development and validation, scale-up, container/closure changes, container size changes, analytical method changes, and process changes requiring comparability studies,
- Authors synopses and protocols for IND-opening study and subsequent clinical trials,
- Participates in meetings with regulatory authorities on behalf of clients, including Type A and Type B meetings with FDA,
- Manages the lifecycle of client submissions, including annual reports, amendments, and supplements for INDs, NDAs, and DMFs.

Cardinal Health Regulatory Sciences **2015 - 2016**

Principal Scientist and Consultant

- Provided consulting for site changes, process development and validation, scale-up, container/closure changes, container size changes, analytical method changes, and process changes requiring comparability studies,
- Participated in meetings with regulatory authorities on behalf of clients, including Type A and Type B meetings with FDA,
- Prepared IDE and PMA submission for devices and combination products,
- Managed multiple parallel projects and represented CMC on projects with multi-disciplinary teams,
- Authored white papers for various topics related to regulation of biologics,
- Actively participated in peer review for numerous projects,
- Managed the lifecycle of client submissions, including annual reports, amendments, and supplements for INDs, NDAs, and DMFs,
- Helped identify and realize key objectives for the business related to biologics and biosimilars.

Biovest International **2009 - 2015**

Sr. Vice President, Scientific and Regulatory Affairs (2013)

- Prepared or contributed to all written communications between company and international regulatory agencies, including Food and Drug Administration, European Medicines Agency, and Health Canada,
- Prepared and managed preparation of the Chemistry, Manufacturing, and Controls (Quality) section of the Biologics Licensing Application (BLA) and Marketing Authorization Application (MAA),
- Represented company at meetings with regulatory divisions at the EMA, FDA, and Health Canada,
- Organized and participated in submission of eCTD MAA to the EMA; Modules 1, 2 (QOS), and 3,
- Contributed to scientific papers and meeting abstracts pertaining to the vaccine product,
- Communicated about vaccine with broad audiences including potential investors, principal investigators, industry experts, and patient advocacy groups.

Director, CMC

- Prepared briefing packets and presentations for meetings between company and international regulatory authorities,
- Managed employees at manufacturing facility, including analytical method development, purification process development, and cell culture process development departments,
- Directed activities in support of process development and analytical method development/validation in accordance with relevant ICH guidelines, EU GMP, and FDA guidance,
- Directed activities in support of process validation and clean room preparation in accordance with EU GMP and 21 CFR Part 210 and 211,
- Participated in audit preparation activities and audits against EU GMP and scientific opinion leaders.

Accentia Biopharmaceuticals **2006 - 2009**

Senior Clinical Research Manager

- Responsible for regulatory submissions for Cyrevia (high dose cyclophosphamide) including IND preparation and pre-IND meetings with FDA,
- Participated in Phase 3 clinical trial design for multiple sclerosis and bone marrow transplant conditioning indications,
- Identified and communicated with clinical and scientific opinion leaders,
- Disseminated scientific results via papers and presentations concerning Cyrevia for the treatment of ultra-orphan, orphan, and common autoimmune diseases, including multiple sclerosis,
- Prepared three successful orphan drug designation requests and associated annual reports,
- Designed pre-clinical and Phase 1 program for a liposomal formulation of Aluminum Phthalocyanine for the treatment of wet age-related macular degeneration (Photo Target) using laser targeted photo-occlusion,
- Wrote and reviewed several patents for various methodologies and products.