Lisa D. Crockett, MS, RAC

PROFESSIONAL SUMMARY

Biotechnology professional with 19 years of regulatory experience. Career highlights include:

- Understanding regulatory requirements for medical products throughout the product life cycle, including: pre-clinical, product/ manufacturing design, clinical research, regulatory approval, and post-approval/business development activities.
- Successful, proficient worldwide submission coordination experience, including generation and maintenance of 510(k)s, INDs, IDEs, CTDs, BLAs and PMAs.
- Experience ensuring compliance to regulatory requirements and company policies and procedures with a high attention to detail.
- Motivated, results oriented individual with ability to manage multiple tasks while adjusting to unexpected shifts in priorities to meet tight deadlines for multiple projects.

CAREER HISTORY

InVivo Therapeutics Corporation, Cambridge, MA June 2013 – present

Vice President, Regulatory Affairs & Reimbursement Planning (Jun 2014 – present)

- Represent regulatory perspectives in strategic business planning with specific focus on medical device development, device/drug combination products, and business development and growth strategies.
- Develops reimbursement strategies for product platform

Vice President, Regulatory Affairs (Jan 2014 – Jun 2014)

- Holds leadership role in regulatory interactions within the Company and with Regulatory Agencies.
- Develops and manages the process of identifying key regulatory timelines and regulatory critical path activities.
- Develops and manages regulatory budgets and resources to actively support coordination of scientifically sound submissions and accountability against specified targets.

Director, Regulatory Affairs (Jun 2013 – Dec 2013)

- Develop regulatory strategies, systems, SOPs, and processes to ensure that product development, approval application, registration and commercialization plans meet US and foreign regulatory requirements and company goals.
- Member of Leadership Team – presents to the BOD, reviews SEC filing & PR documentation.

Northeastern University, Boston, MA Jan 2013 – present

Part-time Adjunct Lecturer (*Jan 2013 – present)*

- Develops, implements and performs evaluation of the course curriculum for the Master of Science Degree in Regulatory Affairs of Drugs, Biologics, and Medical Devices.
- Provides supervision, instruction and assists with the development of individualized learning objectives intended to facilitate each student's potential.

Genzyme, a Sanofi Company, Cambridge, MA May 2004 – May 2013

Associate Director, RA (*Jan 2012 – May 2013)*

- Responsible lead for the overall management of up to 4 direct reports: mentored, trained, performed performance reviews, coordinated projects, delegated tasks commensurate with skill level, and provided professional development.
- Coordinated, managed and directed all aspects of global regulatory projects from early stage development through post approval and life cycle management (Includes Request for Designations (RFD), pre-IND thru NDA, pre-IDE thru PMA).
- Acted as a liaison with FDA and other global regulatory agencies as needed for assigned programs.
- Coordinated and participated in preparation and revision of regulatory SOPs; presentations for meetings with FDA; and facilitates and prepares responses to queries from regulatory authorities.
- Performed due-diligence review of regulatory documents for potential acquisitions & partnerships.
- Collected regulatory intelligence to determine regulatory pathways, classifications, and testing for devices, including: standards, guidance documents, and research on competitor devices.
- Participated in ISO 14971 risk management and 820.30 design control required activities for aseptic and terminally sterilized products.

RA Product & CMC Manager (Mar 08 – Jan 2012)

- Generated timelines, organization charts, and identified staff responsibilities and authorities for development projects.
- Responsible lead for RA CMC assessments project to transition from manual to automated electronic system.
- Served as onsite Regulatory representative during audits and inspections (PMDA, FDA, EU Notified Body, Internal audits).
- Served as RA Management Representative during Sr. Management Reviews and presented RA Compliance updates to site.
- Responsible for oversight of CMC assessment process for sterile products at two manufacturing sites.
- Proactively identified, developed, and improved processes by initiating and editing SOPs and supportive documentation.

- Served as RA representative to AdvaMed for the PMA working group.

Principal Regulatory Associate (Mar 2006 – Mar 08)

- Responsible for the regulatory review and approval of promotional pieces in promotional review board (PRB) meetings.
- Represented Regulatory Affairs on global cross-functional project teams.
- Coordinated, participated in and responsible for writing and preparation, of investigational device exemption (IDE), premarket approval applications (PMA), PMA supplements (CMC & labeling), and EU Design Dossier submissions.

Senior Regulatory Associate (Sep 2004 – Mar 2006)

- Supported Class III medical device activities for US, EU, Japan and Canada.
- Thorough knowledge and experience with FDA Regulations, Medical Device Directives (MDD), Japanese Pharmaceutical Affairs Law (PAL), and Health Canada regulations.
- Filed a modular PMA, Design Dossier updates and supported filing of Japanese Gaiyo filing.

International Regulatory Associate Contractor (May 2004 – Sep 2004)

- Supported all International registration functions for new product and renewal certifications for multiple countries and several device/drug products.
- Facilitated compilation of PMA Annual Report including summarizing CMC changes as well as coordinating the relevant input from various departments.
- Updated Master File for a Device (MAF) by outlining relevant changes to process and controls used to produce several products.

V.I. Technologies, Inc. (Vitex), Watertown, MA Sept. 2000 – Nov. 2003

Sr. RA Specialist (Mar 2001- Nov 2003)

- Member of eBLA software evaluation team.
  - Conducted thorough product review and made recommendations to Senior Management.
  - Responsible for validation of CoreDossier™ software package into Vitex environment.
- Planned and submitted BLA supplements for significant CMC changes.
- Reviewed and approved clinical site documentation including informed consent forms in accordance with FDA and sponsor requirements.
- Randomization Coordinator: Responsible for assigning confidential treatment to enrolled patients on double-blinded clinical trials, review of all appropriate documentation and member of Blood Logistics team to coordinate the flow of documentation.

Regulatory Affairs Specialist II (Sep 2000 - Mar 2001)

- Generated and prepared IND and BLA regulatory submissions to CBER in accordance with FDA and department requirements.
- Utilized MS Access to develop databases for tracking submission filing, internal R&D reports and contract toxicology reports.

Biopure Corporation, Cambridge, MA Mar. 1998 – Sept. 2000

Regulatory Affairs Specialist I (May 1999 – Sep 2000)

- Responsible for submissions to CBER for Emergency Use INDs and CVM Adverse Events, Annual Reports, and Advertising & Promotional Materials.
- Coordinated release of Oxyglobin by Emergency Drug Release Authorization with the BVD in Canada.
- Maintained Central Files for ongoing Clinical Studies and performed audit of files.

Regulatory Affairs Administrative Assistant (Mar 1998 - May 1999)

- Managed daily activities of the Regulatory Affairs Department while providing support to Quality Assurance, Quality Control and Validation.
- Collated/Photocopied/Labeled and Mailed Submissions to FDA, EMEA, Canada and South Africa.

PROFESSIONAL ACHIEVEMENTS

Genzyme Corporation – received two Corporate SPOT awards and one Recognition Stock Option Award

Regulatory Affairs Professional Society - US Regulatory Affairs Certification (RAC)

EDUCATION

Northeastern University Boston, Massachusetts
M.S., Regulatory Affairs, April 2012

Johnson & Wales University Providence, RI
B.S., Equine Science/Business Management, May 1994

Additional Coursework: Mathematics & Stats (2010), Pharmaceutical Law (2011), Medicinal Chemistry and Therapeutics (2011), Pharmaceutical Formulation & Processing: Sterile Products (2012) University of Strathclyde, Glasgow, Scotland (via NSF-DBA QLP Cambridge, MA program) as part of the M.S., Pharmaceutical Quality and GMP program.