Lisa D. Cooper

PhD, RAC

CONTACT

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LinkedIn Profile

www.thebrackengroup.com

EDUCATION

Bachelor of Science 2000
York College of PA,
Biology

Masters 2005
Farleigh Dickenson University,
Biology

Doctor of Philosophy 2015
Alvernia University,
Corporate Leadership

PROFESSIONAL CERTIFICATIONS

RAC, Regulatory Affairs Certified; 2005

CMWP, Certified Medical Writing Professional; 2010

PROFESSIONAL MEMBERSHIPS

RAPS, Regulatory Affairs Professional Society

DIA, Drug Information Association

ASCO, American Society of Clinical Oncology

PROFESSIONAL SUMMARY

Strategic Regulatory Affairs leader with extensive pre- and post-approval experience with drug and biologic products in the settings of oncology, pulmonary, auto immune, and infectious diseases. Adept at interpreting and applying regulations and guidelines to successfully drive programs through innovative pathways. Skilled writer, composing persuasive regulatory documents.

PROFESSIONAL EXPERIENCE

Feb 2019 – Present

The Bracken Group

Regulatory Consultant

- Perform gap analyses as part of strategic regulatory development plans for regulatory filings.
- Provide regulatory guidance and leadership to ensure IND and NDA communications relevant to the client company's products are following FDA's guidance.
- Lead and prepare clients for FDA meetings.
- Provide writing support for key regulatory documents including IND and BLA modules, labeling, IBs, DSURs, background documents, fast track, breakthrough, and orphan drug designation applications.
- Provide consulting role as integrated MLR team member for review of Advertising and Promotion material.
- Prepare, review, and develop regulatory processes (i.e., SOPs, policies, work instructions) for client quality management.

Apr 2018 – Present

Xennials Therapeutics, Inc.

VP Regulatory Affairs and Quality Assurance

- Provide guidance on strategic regulatory pathways for off-patent reformulation products intended for the 505(b)(2)/EU hybrid pathway and new nanotechnology platforms focused in oncology and autoimmune indications.
- Support corporate fundraising objectives including due diligence evaluations.
- Develop Regulatory and Quality project budgets.
- Engage Regulatory and Quality contract organizations to support project requirements for IND initiation.
- Lead global Health Authority interactions to gain alignment on development pathways leading to successful marketing registration.

Dec 2016 – Feb 2019

Immunocore, LLC

Director, Regulatory Affairs

- Developed strategic regulatory approaches for lead product candidate to maximize limited safety and efficacy data for global accelerated approval and support labeling goals.
- Authored and reviewed technical and clinical documentation. Specific documents included preliminary breakthrough designation application, EU and US pediatric waiver request, CAS, brand name and USAN applications, CTA applications, fast track designation, meeting background packages, and IND modules.
- Provided regulatory strategy for and development submission documents for companion diagnostic assays, including writing significant risk determination (SRD) requests and Q-Sub validation plan packages.
- Successfully led the preparation, submission, and approval of two INDs.
- Regulatory representative on two partnered programs, supporting due diligence and continued relationship interactions and obligations.
- Responsible for department budget, established an electronic submission partnership.
- Conducted regulatory intelligence and provided assessments cross-functionality.

The BRACKEN GROUP

PATENTS

Administration and Monitoring of Nitric Oxide in Ex Vivo Fluids
Filed December 3, 2013 (initial), Co-inventor, App. No. (2016): 15/066,672

ACADEMIC APPOINTMENT

Rutgers University, School of Health Professions: MS In Clinical Trials Management
Assistant Professor Aug 2020 – Present
Adjunct Professor May 2017 – Aug 2020

Aug 2014 – Dec 2016 **Taiho Oncology, Inc**
Associate Director, Regulatory Affairs

- Led the development and final FDA negotiation of the LONSURF label (USPI and Patient Information).
- Regulatory lead for LONSURF during NDA review including query responses.
- Established and chaired the Promotional Review Committee (PRC) for LONSURF promotional material pre-and post-launch. Responsible for the review of public facing materials, including corporate communication, call scripts, publications, press releases, websites, etc.
- Responsible for all life-cycle activities for LONSURF, including review of Investigator Initiated Trials (IITs), Medical Affairs materials, executing Health Authority applications for company sponsored worldwide clinical trials (Phase II – IV), Post-market requirements (PMRs), ex-US marketing application support, and maintenance requirements (PADER, DSUR, IB, NDA annual report, etc.).

Jan 2008 – Aug 2014 **Ikaria**
Associate Director, Global Medical Operations, Global Regulatory Affairs; Manager, Global Regulatory Affairs

- Primary Health Authority contact for three IND applications held in the Cardiopulmonary and Renal Drug Products and Pulmonary, Allergy, and Rheumatology Products Divisions, as well as multiple CTAs in various countries.
- Chairperson of the INOmax PRC and responsible for submission of promotional materials to OPDP.
- Led the successful End of Phase II (EOPII) face-to-face meeting for a drug/device combination product.
- Led the successful writing of drug device combination product Orphan Drug Designation (ODD) application for pulmonary arterial hypertension (PAH) and sickle cell disease.
- Led the writing of two Orphan Drug Grant (ODGs), target product profiles (TPPs), company core data sheet (CCDS).
- Participated in the successful dispute resolution of a pediatric written request, which resulted in a label change and additional 6-month exclusively for product.
- Regulatory lead at study and project team meetings, providing guidance on the strategy for moving products forward in life-cycle management including a supplemental NDA.
- Prepared and submitted a Certificate of Pharmaceutical Product request for Korea.
- Listed as co-inventor on patent for new potential use of company primary product.
- Wrote, reviewed, and approved departmental SOPs and co-developed department training program.

Aug 2002 – Jan 2008 **Medarex, Inc.**
Manager, Regulatory Affairs
Assistant Manager, Regulatory Affairs

Jun 2000 – Aug 2002 **INO Therapeutics, Inc.**
Regulatory Affairs Assistant
Document Coordinator, Regulatory Affairs