Lieselotte L. Bloss

DVM

The BRACKEN GROUP

CONTACT

PHONE
+1 908.612.5199

EMAIL
lbloss@thebrackengroup.com

WEBSITE
thebrackengroup.com

LINKEDIN
linkedin.com/in/lieselotte-liz-bloss-dvm-87a586b

EDUCATION

BACHELOR OF SCIENCE
Tuskegee Institute |1981

DVM, Veterinary School
Tuskegee University, School of Veterinary Medicine | 1985

DVM Internship
University of Giessen | 1986

PROFESSIONAL MEMBERSHIPS

AVMA, American Veterinary Medical Association

DIA, Drug Information Association

RAPS, Regulatory Affairs Professional Society

Life Sciences Pennsylvania

PROFESSIONAL SUMMARY

Seasoned regulatory leader with strong track record of delivering IND & NDA Submissions. Accomplished drug development strategist with hands on global experience. Exceptional cross-functional leader, bridging disciplinary and organizational boundaries to build committed teams that deliver innovative solutions.

PROFESSIONAL EXPERIENCE

Apr 2018 – Present

The Bracken Group
Senior Regulatory Consultant, Managing Partner

- *Provide strategic input and regulatory guidance as part of development programs towards IND & NDA submissions in various therapeutic areas (i.e. Oncology, CNS)*
- *Lead and prepare clients for FDA meetings (i.e. pre-IND, EOP2, pre-NDA; sponsor labeling negotiations with FDA)*
- *Prepare regulatory submission gap analyses & review integrated gap analyses*
- *Prepare and review FDA written correspondence and IND/NDA components*
- *Provide US Agent role for ex US clients as needed*
- *Integrate into sponsor regulatory affairs department as Interim Head of Regulatory and/or regulatory lead, cross functional development teams to bridge regulatory content strategies and submissions seamlessly*
- *Create and lead NDA Core Submission and Rapid Response Teams to enhance efficiency of cross functional and global high-quality content submissions*
- *Prepare and submitted Orphan Drug Application and Annual Reports*

Jan 2017 – Dec 2017

Esperion Therapeutics, Ann Arbor, Michigan (Remote)
Senior Director, Global Regulatory Affairs

- *Prepared NDA/MAA strategy and submissions in the cardiovascular therapeutic space: led the vendor selection team to identify vendors in support of the NDA/MAA preparations; directed global regulatory team to prepare content and publish ready documents*
- *Tracked and ensured all commitments were met with FDA and EMA for the NDA/MAAs across all disciplines*
- *Led the preparation and the internal approval process of draft labeling for all Marketing Applications and ensured content alignment with stakeholders*
- *Authored regulatory submissions to FDA and EMA*

Feb 2014 – Jan 2017

Taiho Oncology, Inc., Princeton, NJ
Global Senior Director, Regulatory Affairs

- *Achieved successful Oncology NDA approval in 9.5 months in September 2015; led cross-functional global core team to prepare and submit US NDA; created and led Rapid Response Team and responded to FDA Information Requests*

PROFESSIONAL EXPERIENCE

- *Submitted MAA; responded to Day 120 and Day 180 in support of the MAA, leading to CHMP positive opinion and MAA approval in February of 2016*
- *Developed regulatory strategies and led submission activities in the US and Europe for R&D for 8 oncology programs: led and prepared INDs and IMPDs*
- *Provided Breakthrough readiness regulatory insights to relevant project teams*
- *Prepared NDS submission in Canada*
- *Supported product pre-launch activities contributing to product launch within 1month from approval, Supporting Commercial with regulatory advice and document reviews*
- *Led Medical Writing Group during transition phase of re-organization*

Feb 2013 –Jan 2014 **GE Health Care, Life Sciences, Princeton, NJ**
Segment Lead, Regulatory Affairs
Development Strategy Lead, Regulatory Affairs

- *Led and participated in the preparation of INDs, CTAs, IMPDs and orphan drug applications*
- *Directed the coordination, compilation of responses to an NDA leading to an NDA approval; led the labeling negotiations*
- *Facilitated Competent Authority meetings in the US and EU, including pre-IND meeting, CHMP rapporteur meetings*
- *Interfaced with global project team members and senior leadership*

Aug 2004 –Jan 2013 **KYOWA HAKKO KIRIN PHARMA, Inc., Princeton, NJ**
Senior Director, Regulatory Affairs
Director, Regulatory Affairs

- *Developed regulatory strategic options for early and late stage projects*
- *Directed the coordination, compilation, submission and maintenance of INDs, BLA/NDA, Orphan Drug Applications, CTAs and DMFs in Oncology and Neurology to the FDA, Health Canada and EMA*
- *Led FDA interactions, including meeting preparation (i.e. pre-NDA, NDA)*
- *Led NDA Global Rapid Response Team that prepared responses to FDA NDA review questions*
- *Facilitated Advisory Committee preparations including interfacing with messaging consulting company*
- *Interfaced directly with Pre-clinical Development, CMC, Clinical Development, International Development Coordination, and Quality Assurance functions to assure integrity and quality of submissions*
- *Facilitated due diligence interactions as needed*

Nov 2000 –Jul 2004 **Bracco Diagnostics Inc., Princeton, NJ**
Director, Regulatory Affairs

Dec 1997 -Nov 2000 **Novo Nordisk Pharmaceuticals, Inc., Princeton, NJ**
Manager, Regulatory Affairs, Women's Healthcare
Asst. Director, Regulatory Affairs, Women's Healthcare

Feb 1995- Dec 1996 **Sanofi Winthrop, Inc., Malvern, PA**
Senior Regulatory Associate, US Regulatory Affairs

Feb 1995 –Dec 1996 **American Cyanamid, Princeton, NJ**
Senior Regulatory Associate, US Regulatory Affairs

1988- 1991 **USDA, APHIS, VS (Veterinary Services), Mercerville, NJ**
Veterinary Medical Officer

- *Regulated all aspects of imports and exports of animals and animal products for the United States as they related to and affected southern New Jersey*

1986 - 1988 **USDA, FSIS, MPIO, Souderton, PA**
Veterinarian in Charge at Moyer Packaging