Lieselotte L. Bloss

DVM

CONTACT

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LinkedIn Profile

www.theBrackenGroup.com

EDUCATION

Bachelor of Science 1981
Tuskegee Institute

DVM, Veterinary School 1985
Tuskegee University School of Veterinary Medicine

DVM, Internship 1986
University of Giessen

PROFESSIONAL MEMBERSHIPS

AVMA, American Veterinary Medical Association

DIA, Drug Information Association

RAPS, Regulatory Affairs Professional Society

Pennsylvania BioTech Center

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

April 2018 – Present

The Bracken Group

Senior Regulatory Consultant, Managing Partner

- Provides strategic input and regulatory guidance as part of development programs towards IND & NDA submissions in various therapeutic areas (i.e., Oncology, CNS)
- Leads and prepares clients for FDA meetings (i.e., pre-IND, EOP2, pre-NDA, sponsor labelling negotiations with FDA)
- Prepares regulatory submission gap analyses & review integrated gap analyses
- Prepares and reviews FDA written correspondence and IND/NDA components
- Provides US Agent role for ex US clients as needed
- Integrates 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
- Creates and leads NDA Core Submission and Rapid Response Teams to enhance efficiency of cross functional and global high-quality content submissions
- Prepares and submit Orphan Drug Application and Annual Reports

Apr 2018 – Present

Esperion Therapeutics, Ann Arbor, Michigan

Financial Advisor 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 labelling 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

Financial Advisor

- 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
- 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
- Led Medical Writing Group during transition phase of re-organization
- 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.

BRACKEN

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 labelling 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 and 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 2004 – 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

1998 – 1991

USDA, APHIS, Veterinary Services, Mercerville, NJ.

Veterinary Medical Officer

- Regulated all aspects of import and exports of animals and animal products in the US as they related to and affected southern New Jersey.

1986 – 1988

USDA, FSIS, MPIO, Souderton, PA

Veterinary Medical Officer