Lieselotte L. Bloss, DVM

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EDUCATION

- **Bachelor of Science;** 1981 Tuskegee Institute
- **DVM, Veterinary School;** 1985 Tuskegee University, School of Veterinary Medicine
- **DVM, Internship;** 1986 University of Glessen

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, LLC**
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
- 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

PROFESSIONAL EXPERIENCE

- 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

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 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 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

1998 - 1991 **USDA, APHIS, VS(Veterinary Services), Mercerville, NJ.**
Veterinary Medical Officer

- Regulated all aspects of imports and exports of animals and animal products in 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