Bradley J. Glasscock, Pharm.D.

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PROFESSIONAL PROFILE

25 years of experience in drug development working in both industry and government positions. Highly visible leader respected by global peers and executive management. Capable of affecting significant change within and external to BioMarin, leading global initiatives, and influencing regulatory policies in rare disease drug development and emerging areas including gene therapy and regenerative medicine. Experienced in developing regulatory strategies across multiple therapeutic areas and treatment modalities and across all stages of the regulatory process. Established track record leading several successful global regulatory approvals, including 5 novel product approvals over the past 10 years leveraging expedited pathways and development incentives available to orphan products and breakthrough therapies. Served as the Global Regulatory Affairs Department Head overseeing approvals for Roctavian (2023), Voxzogo (2021), Palynziq (2018), and Brineura (2017); served as the Global Regulatory Leader overseeing global approvals for Vimizim (2014), Xgeva (2010), and Prolia (2010); and served as a member of the FDA review team responsible for approvals of Naglazyme (2005), Aldurazyme (2003), and Xigris (2001). Selected by the Biotechnology Innovation Organization (BIO) to serve as an Industry negotiator for PDUFA VII (2020-2021). Participated in FDA Advisory Committees across multiple therapeutic areas and technology platforms, including: Endocrinologic and Metabolic Drugs (Voxzogo 2018, Vimizim 2013, Aldurazyme/Fabrazyme/Replagal 2003); Peripheral and Central Nervous System Drugs (drisapersen 2015); Bone, Reproductive, and Urologic Drugs (Prolia 2009); Pediatrics (vosoritide 2018, denosumab 2010); Oncology Drugs (Xgeva 2012); and Anti-Infective Drugs (Xigris 2001). Served as a member of FDA's Gene Therapy Working Group (2001). Currently serving as Industry Representative for the Genetic Metabolic Diseases Advisory Committee.

CAREER HISTORY

March 2017 to Present — **Senior Vice President, Head of Global Regulatory Affairs**
BioMarin Pharmaceutical Inc.

- Lead all regulatory affairs functions on a global basis, reporting directly to the President of Worldwide Research and Development
- Develop and execute enterprise-level regulatory strategy and plans in support of corporate goals and objectives
- Develop and direct the execution of the company's ongoing regulatory strategy across a diverse therapeutic pipeline in support of both commercial and development products
- Review new product opportunities and provide regulatory guidance and opinion
- Direct the IND/CTA and marketing application processes and ensure high quality regulatory submissions are submitted to competent health authorities

- Foster strong relationships with global regulatory health authorities, corporate partners, company directors, consultants, and vendors and effectively influence and communicate development, regulatory, and registration strategies
- Negotiate highly sensitive issues with regulatory stakeholders
- Create a culture that promotes teamwork, collaboration, openness, and friendship
- Drive growth of the department and foster the development of its staff to meet the demands of a rapidly growing and constantly evolving pipeline

April 2014 to March 2017 **Vice President, Regulatory Affairs**
BioMarin Pharmaceutical Inc.

- Led the Global Regulatory Affairs team responsible for defining and executing the nonclinical and clinical regulatory strategy supporting drug development for early and late-stage drug and biologic candidates
- Led the Regulatory Affairs team responsible for Regulatory Project Management for the entire portfolio
- Oversaw planning, preparation, and submission of clinical trial applications and marketing applications in the US and internationally
- Oversaw maintenance of approved products and supported global expansion and commercialization of these products
- Led interactions with regulatory authorities, partners, and consultants
- Ensured appropriate communication within the department and with other functional areas

February 2012 to April 2014 **Senior Director, Regulatory Affairs**
BioMarin

December 2008 to February 2012 **Director, Regulatory Affairs**
Amgen

May 2005 to December 2008 **Senior Manager, Regulatory Affairs**
Amgen

December 2002 to May 2005 **Reviewer**
FDA, Office of the Commissioner, Office of Orphan Products Development (OOPD)

February 2000 to December 2002 **Regulatory Project Manager**
FDA, Center for Biologics Evaluation and Research (CBER), Office of Therapeutics Research and Review, Division of Application Review and Policy

EDUCATION

Education:	University of North Carolina at Chapel Hill	Doctor of Pharmacy	1999