



Marissa Fletcher, PhD, M.S., B.S.
Senior Director, Regulatory Strategy

Dr. Marissa Fletcher is a Senior Director of Regulatory Strategy at Advyzom. Marissa provides strategic regulatory guidance and serves as a US Agent to FDA for domestic and international biopharmaceutical companies. Marissa has a strong and comprehensive understanding of product development providing strategic direction for projects ranging from early to late stage development, and marketed product support. Her therapeutic product experience includes oncology, neurology, immunology, respiratory, nephrology, rare disease, vasomotor, pain, and GI; encompassing small molecules and various biologic modalities, including monoclonal antibodies, antibody-drug conjugates, bispecifics, and gene therapy.

Marissa has over 15 years of Regulatory Affairs experience working in big pharma, small biotech and OTC companies. Prior to Advyzom, Marissa has led the development and implementation of innovative regulatory strategies for early and late stage development programs. She prepared teams for FDA meetings and acted as primary interface to FDA. Marissa has acted as a US Lead and a Global Regulatory Lead focused on developing regulatory strategies to support successful filings to INDs, BLAs and NDAs. She also has recent experience in the successful filing and approval of an NDA. In her previous roles, she successfully led FDA milestone meetings, applications for Fast Track designation, Orphan Drug designation and Pediatric Study Plan, and worked with biomarker/companion diagnostic strategies. Marissa has also successfully led cross-functional teams in the preparation and conduct of global health authority meetings and post meeting activities, conducted international due diligence for pipeline products, and developed and implemented regulatory strategies for the roll-out of commercial launch plans in the EU, US and rest-of-world markets.

Marissa is the recipient of multiple awards including the Global Regulatory Affairs External Partner Award for Accountability from Sanofi, Impact Award from Novartis Consumer Health, Research and Technology Excellence Award and Distinguished Achievement Award from Block Drug Company, and Outstanding Student Award in Chemistry from the American Institute of Chemists Foundation and the NJ Institute of Chemists.



Marissa earned her Doctor of Philosophy in Biochemistry and Master of Science in Chemistry from Seton Hall University, and Bachelor of Science in Chemistry (magna cum laude) from New Jersey City University.