Liz Lucini, Pharm.D.
Vice President, Regulatory Strategy

Dr. Liz Lucini is a Vice President of Regulatory Strategy at Advyzom. Liz provides strategic regulatory guidance and acts as a US Agent to FDA for domestic and international biopharmaceutical companies. Liz's areas of expertise include infectious disease, virology, rare diseases, women's health, CNS and recently oncology. Liz has hands-on experience in obtaining breakthrough, QIDP, orphan, and rare pediatric disease designations from the FDA and has led NDAs to successful approval. Liz works within Global Research and Development and Commercial teams to lead and support a broad range of regulatory activities from early development to marketing support. Liz manages multiple complex projects simultaneously, including FDA meetings, IND submissions, amendments, responses to FDA requests, promotional materials review, advisory committee preparation and critical issue management. She brings strong expertise to clients through her role as US Agent and Global Regulatory Leader, providing strategic advice to small and large clients.

Liz has over ten years of experience in the pharmaceutical industry. Prior to joining Advyzom, She served as Executive Director and Head of Regulatory Affairs and Pharmacovigilance at Noven Pharmaceuticals. Under her leadership, Noven accomplished first-cycle approval of a new therapy. She served as the Development Team Leader for the company's Rx to OTC switch initiative. Prior to Noven, Liz was Associate Director, Global Regulatory Lead for Regulatory Affairs at Hoffmann-La Roche for a fast-track development program combining two NMEs developing US registration strategy and managing interactions with FDA. Earlier in her career, Liz was a Global Regulatory Leader and managed a regulatory sub-team of US/EU/ROW regulatory liaisons, medical writers, labeling managers, and submissions coordinators. Liz completed a post-doctoral fellowship at Schering-Plough Research Institute, in conjunction with Rutgers University. She worked in Global Regulatory Affairs, leading the development of global pediatric plans (US and EU) for an investigational product.

Liz won multiple awards including a STEP Ahead National Award for significant achievements in manufacturing, a Breakthrough Achievement Award in 2013 for her leadership in the FDA approval of Noven's non-hormonal therapy and Noven's Platinum Award.

Liz received her Doctor of Pharmacy and Bachelor of Science in Pharmacy Studies from the University of Connecticut and is a Pharmaceutical Industry Fellowship Mentor at Rutgers University.