



Kristen Mayer, B.S., Ph.D.

Executive Director, Regulatory Strategy

Dr. Kristen Mayer is an Executive Director at Advyzom with experience working with FDA, EMA, and WHO on the development of innovative therapies. Her experience spans across the full product development pathway from pre-clinical through clinical, licensure, and post-marketing stages. In addition to her FDA and EMA expertise, Kristen has vast experience with global Health Authorities and provides strategic guidance on the nuanced considerations required for international clinical development and licensure.

Prior to joining Advyzom, Kristen was Head of Regulatory Strategy at Gates Medical Research Institute, providing regulatory expertise and oversight across the portfolio. She provided regulatory advice for a variety of therapeutic modalities (vaccines, mAbs, small molecules) to advance Gates MRI's programs. Kristen drove process improvement of regulatory practices across Gates MRI which ensured standardization, consistent messaging across the programs, and improved credibility. She also served as Global Regulatory Strategy Lead for a tuberculosis vaccine. Previous to her work at Gates MRI, Kristen worked for Sanofi Pasteur as a Director of Regulatory Affairs. She built and led a team responsible for all US FDA interactions, submissions and strategy for clinical, nonclinical, and labeling matters for the company's full portfolio of vaccine and mAb candidates. Kristen directed regulatory strategy and execution for 26 vaccine/mAb candidates, including the approval of Menquadfi® by FDA. Kristen planned, prepared for and led FDA meetings, including pre-IND, Type C, End-of-Phase 2 and pre-BLA, to obtain positive outcomes for the company.

Kristen earned her Ph.D. in Biochemistry from Penn State University and her Bachelor of Science in Chemistry from the University of Rhode Island.