



**Ama Berko, B.S., M.S., PharmD.**  
**Senior Director, Regulatory Strategy**

Dr. Ama Berko is a Senior Director at Advyzom with expertise spanning across the full drug development —from Pre-IND and clinical trials (Phases 1-3) to BLA submissions, post-marketing, and life cycle management activities. She drives complex initiatives that bring innovative and transformative therapies to market.

Ama has led multiple study initiation activities in the US and internationally for diverse therapeutic modalities, including small molecules, biologics, advanced therapy medicinal products (CAR-T), biosimilars, and drug-device combination products like autoinjectors and pre-filled syringes within key portfolios for rare and serious diseases such as hepatology, gastroenterology, immunology (cell and gene therapies), severe refractory autoimmune indications, dermatology, women’s health, neurology and anti-infectives portfolios.

Prior to joining Advyzom, Ama was a Director of Regulatory Affairs at Fresenius Kabi, USA, driving biosimilar programs in development, labeling, supplemental BLA approvals and launch activities. She also worked at Novartis Pharmaceuticals as Global Program Regulatory Manager (GPRM) and Senior GPRM after completion of her 2-year post-doctoral (PharmD) fellowship with Allergan in conjunction with St. Johns University in Clinical Development and Regulatory Affairs. Her US FDA experience includes leading pre-IND meetings, Type 2a/2b meetings, Type B/C meetings (including written requests), PIPs/PSPs, NDA, BLA submissions and critical designations including Fast track, Orphan drug, breakthrough/PRIME, RMAT designations and worked with the biomarker consortia within hepatology. Globally, Ama has navigated regulatory landscapes to lead MAA preparations as well as scientific advice meetings and interactions with key agencies like Sweden's MPA, Germany's PEI, the UK's MHRA, Health Canada, and authorities across the EU, AMEA, China, and Japan.

Ama earned her Doctor of Pharmacy and Masters in Clinical Research Administration at Fairleigh Dickinson University and a Bachelor of Science (Biology) from William Paterson University.