

Nicole Segalini, BS
Associate, Regulatory Strategy

Nicole Segalini is an Associate of Regulatory Strategy at Advyzom. Nicole provides regulatory US Agent support for companies in different phases of development and has worked on drugs and biologics across therapeutic areas of oncology, cardiovascular, neurology, nephrology, anti-infective, maternal health, primary care, obesity, and rare diseases. Nicole is a primary US regulatory lead on project teams (clinical, CMC, and non-clinical). Nicole has experience preparing and supporting NDA and IND filings, regulatory precedent research, Fast Track designation requests, orphan designation requests, pediatric study plans, and regulatory strategy plans. Nicole leads and liaises with both client and internal cross-functional teams in order to achieve development goals. Nicole has also been a part of various Health Authority interaction teams including those for End of Phase 1, Pediatric Advice, and BfArM Scientific Advice meetings.

Nicole is currently pursuing a Masters of Regulatory Affairs with a concentration in Biopharmaceutical Affairs at Northeastern University in Boston, Massachusetts. Prior to Advyzom, Nicole was a research assistant and surgical student at various medical institutions, responsible for writing, editing, and analyzing data for research publications, which has resulted in numerous publications and presentations in various professional conferences. She has also worked as an emergency medical technician (EMT) for eight years providing basic life support and treating injuries.

Nicole has a Bachelor of Science degree in Neuroscience from Lafayette College, Easton, Pennsylvania. She has received several service awards, including one sponsored by The White House.