



Esha Gajjar, M.S. Associate, Regulatory Strategy

Esha Gajjar is an Associate of Regulatory Strategy at Advyzom. Esha acts as a regulatory primary US Agent for companies in various phases of development, including clinical, non-clinical and CMC. Esha has worked on small molecules and biologics across therapeutic areas of oncology [including hematology, cell-therapy, and immune-oncology], immunology, fibrosis, neurology, obesity, anti-infectives, gene editing, cardiovascular, etc. Esha has participated regulatory strategy development on INDs, CTAs, NDAs, BLAs, Fast Track Designation, and Orphan Designation applications in compliance with Health Authority regulatory requirements. To support these activities, Esha has prepared many regulatory submissions to the FDA. Esha has also contributed preparation and implementation of Health Authority meetings and interactions. Esha routinely performs regulatory landscape and precedent research in order to input into regulatory scenario analyses and regulatory strategic plans. Esha currently leads as well as is part of regulatory sub-teams, which include cross-functional members from within and external to Advyzom.

Previous to Advyzom, Esha worked as a Global Regulatory Strategy - Oncology Intern at Bristol Myers Squibb to support the lung global regulatory team in the US and EU. Esha also worked as a Regulatory Affairs Intern at MedPacto Therapeutics Inc. to support regulatory activities in early development. She also was a Research Assistant at the Children's Hospital of Philadelphia with the Division of Pediatric Neurosurgery at CHOP and a Clinical Associate at Princeton Brain, Spine & Sports Medicine.

Esha received her Master of Science, Regulatory Affairs from Northeastern University with a concentration in Biopharmaceuticals and received her Bachelor of Science in Biological Sciences from Drexel University.