Ketna Patel, Pharm.D.
Vice President, Regulatory Strategy

Dr. Ketna Patel is a Vice President of Regulatory Strategy at Advyzom. Ketna works within Global Research and Development and Commercial teams to provide strategic regulatory guidance for domestic and international biopharmaceutical companies. Ketna has recently filed and successfully obtained global approval for an anti-infective product for resistant pathogens and an opioid drug-device analgesic. She also has diverse experience across therapeutic areas including cardiovascular, oncology, virology, anti- infectives, gastrointestinal, dermatology, pain, anesthesiology and urology.

Ketna has strong leadership, influence management and strategic skills gained while working within global drug development across multiple therapeutic areas, phases of development from early development to post-approval. She has acted as the US and/or Global Regulatory lead on products in early development and marketed products on a range of regulatory activities including Pediatric Study Plans, Qualified Infectious Disease Designations, IND Submissions, NDA submissions including 505(b)2, amendments, and responses to FDA requests. Ketna can work both remotely or on site with the client's regulatory team members including team members in submissions, labeling, CMC and medical writing.

Ketna has 15 years experience within the pharmaceutical industry. Prior to joining Advyzom, Ketna was a Senior Director of Regulatory Affairs at The Medicines Company wherein she was a global regulatory lead on multiple complex projects across various therapeutic areas, oversaw all regulatory activities worldwide, lead multi-disciplinary teams on early development submissions, NDA and MAA submissions and approvals and related launch and post-approval activities. She served as US liaison with the FDA, and oversaw communications for global Health Authorities. She has prepared multi- disciplinary teams for Health Authority meetings, lead FDA and other national health authority meetings, promotional material review, gained QIDP designations, and oversaw REMS regulatory strategy.

Ketna earned her Doctor of Pharmacy from Philadelphia College of Pharmacy and graduated with honors. Ketna did her post-doctoral residency at AstraZeneca.