

Angela Windt, Pharm.D.
Senior Director, Regulatory Strategy

Dr. Angela Windt is a Senior Director of Regulatory Strategy at Advydom. Angela provides strategic regulatory guidance and acts as a US Agent to FDA for domestic and international biopharmaceutical companies. Angela has diverse experience across therapeutic areas including oncology, metabolic/endocrine, cardiovascular, virology, gastrointestinal, liver disease, transplant, and rare diseases. Her oncology experience ranges across solid tumors, such as breast, ovarian, colon and lung, melanoma, multiple myeloma, soft tissue sarcoma, and gene therapies. Angela has strong leadership, influence management and strategic skills gained while working within global drug development across multiple therapeutic areas, phases of development and FDA divisions. She has acted as the US and/or Global Regulatory lead on drug development or marketed products team both remotely or on site. Angela can work with other client regulatory team members such as submissions, labeling, CMC and medical writing. Angela has led FDA meetings across various therapeutic areas. She has been successful in obtaining Fast-Track, Breakthrough and Orphan Drug Designations. Additionally, she has worked with teams to obtain Health Authority agreed upon Pediatric Plans (PIP/PSP's). She prepares teams for Health Authority meetings, supporting them and acting as the primary interface with FDA.

Angela has 15 years experience within the pharmaceutical industry. Prior to joining Advydom, Angela was a Regulatory Program Director at Hoffman-La-Roche wherein she gained expertise in early and late stage development across a broad range of therapeutic areas. At Hoffman-LaRoche, she served as US and Global Regulatory Leader for various development programs where she led team preparations for health authority meetings and FDA Advisory Committee meetings. Angela has worked on original NDA/BLAs as well as supplemental applications. Additionally, as the US regulatory lead for Tamiflu during the 2009 influenza pandemic, Angela developed strong experience in pandemic planning and Emergency Use Authorization (EUAs) where she received a Roche Pharma CEO Award for global pandemic team-leadership during a public health crisis.

Angela earned her Doctor of Pharmacy from Rutgers University. She received her Bachelor of Arts in Biology from Taylor University. Angela has completed the Rutgers mini-MBA in BioPharma Innovation. Angela did a post-doctoral pharmaceutical industry fellowship in partnership with Rutgers Institute for Pharmaceutical Industry Fellowships.