

Cindy Dinella, R. Ph., Pharm.D.
Chief Executive Officer/President/Founder

Dr. Cindy Dinella is a founding partner and holds the position of President and Managing Partner of Advyzom. Advyzom is a leading boutique consulting company specializing in highly strategic regulatory and development advice and services for our partners in the pharmaceutical and healthcare industry. She is committed to providing experienced, scientific and proven successful leaders to advise and deliver on regulatory strategy, medical writing and regulatory intelligence.

Cindy specializes in leading, guiding, and assisting biopharmaceutical companies with global and US drug development programs to meet and influence health authority requirements. She has strong leadership, strategic thinking, influence management and cross-functional teamwork skills, gained over many years of experience working across therapeutic areas, throughout phases of development including commercialization, with Senior Corporate Management and Boards, and with the Food & Drug Administration (FDA). She has led numerous FDA meetings across divisions, centers and with FDA senior management. Cindy works with a diverse set of clients both locally and internationally ranging from start-ups, small to mid-sized and large Pharma/biotech companies. She provides guidance across therapeutic areas and phases of development for biologics, drugs, drug-device combinations, bioterrorism products, 505(b)(2)'s, accelerated approval and global regulatory pathways. She has led, presented and managed oversight for FDA Public Advisory Committees for NME approvals, safety issues and Risk Management. She is experienced with Breakthrough Designations, QIDP, Orphan Drug Designation, Fast Track Designation, Pediatric Investigation Plan and Pediatric Exclusivity. Cindy managed and mentored many employees over her tenure and believes in people with talent and core values as a critical asset to success. Based on her people experience, Cindy acts as a Global or US Head of Regulatory for clients to support building a Regulatory Affairs team internally to a number of variations, including providing a total outsourced team.

Prior to Advyzom, Cindy was Vice President of Drug Regulatory Affairs at Hoffman- La Roche wherein she managed strategic U.S. and global regulatory program management, FDA policy and regulatory intelligence, advertising/promotion, medical writing, labeling and CMC. She was Site Head for Global Development and

was a member of the CEO's North American Operating Committee responsible for meeting the North American business objectives.

Cindy received both the Upjohn Pharmacy Research Award for Excellence in Clinical Research and the Sandoz Pharmacy Award for Superior Academic Achievement and Contribution to Health Care. She graduated from the Leadership New Jersey program. She received the Tribute to Women in Industry (TWIN) Award in recognition of her significant contribution as a professional woman.

Cindy received her Doctor of Pharmacy from St. Johns University and earned her Bachelor of Science in Pharmacy from Rutgers University. She completed a post-doctoral fellowship in clinical research and drug regulatory affairs. Cindy lectured at Rutgers University College of Pharmacy and was a teaching assistant at St. Johns University.