Cheryl Anderson, PharmD, MBA

Chief Executive and Founder

ACE Regulatory Affairs Consulting

Dr. Cheryl Beal Anderson stands at the forefront of regulatory expertise and experience to pave the way for patients to benefit from high-quality new drug products. In 2022, she took the helm as the visionary founder of Anderson Consulting Enterprises Regulatory Affairs Consulting, LLC, affectionately known as "ACE." With a focus on early- and clinical-stage biopharma ventures, ACE emerges as a guiding resource from pre-IND stages all the way to the commercial launch.

ACE is not just a consultancy; it is a compass navigating intricate and fast-changing regulatory demands. Anderson has a deep understanding of Target Product Profiles (being on the FDA-Industry team that resulted in publishing the first FDA TPP guidance) and a toolbox filled with workshops, know-how for relevant regulatory intelligence in areas such as digital health technology, decentralized clinical trials, novel biomarkers, and the prowess of artificial intelligence and machine learning in developing new biopharma therapeutics.

Dr. Anderson's expertise unlocks FDA regulatory pathways. With the wisdom of her seasoned 25-year career, which encompasses roles like Senior Vice President and Executive Team Member at Upsher-Smith Laboratories, she orchestrates FDA meetings, harmonious Sponsor-FDA interactions, moves obstacles for on-time regulatory submissions in eCTD, builds her team, and justifies investment in the regulatory affairs function to meet an organization present and future needs.