



**Rula Ibrahim-Saker, B.A., M.A., R.Ph., Pharm.D.
Senior Director, Regulatory Strategy**

Dr. Ibrahim-Saker is a Senior Director of Regulatory Strategy at Advyzom. She provides strategic and tactical regulatory services across all phases of drug development for Advyzom clients. Rula has led IND submissions, prepared Fast Track, Qualified Infectious Disease Product (QIDP) Designation requests, Orphan Drug Designation request, IND annual reports, developed briefing packages for key development milestone meetings, run meetings with health Authorities, labeling, regulatory strategic plans, regulatory risk assessments and worked with global and US development teams and personnel to assess regulatory plans. She understands the complex US regulatory environment and is skilled at providing research and regulatory precedent in different therapeutic areas to obtain the desired outcomes. Rula brings strong expertise to clients through her role as a US agent and as a liaison to the FDA.

Rula has over a decade of drug regulatory affairs experience. Prior to joining Advyzom, Rula joined Roche's Drug Regulatory Affairs Group wherein she worked within the Regulatory Strategy and FDA Program Management Group. She supported mature and marketed products including preparing for advisory committee meetings. Prior to Roche, Rula was in a Pharm.D. Post Doctoral fellowship program concentrating on clinical development and regulatory affairs for Phase I-III drug development. She prepared IND annual reports and updated investigator brochures, created briefing packages and developed competitive intelligence assessments for various diseases. Early in her career, Rula had worked as a Pharmacy Intern at Bristol Myers Squibb Company, as well as a Lab Director at St. Louis Hospital in Damascus, Syria.

Rula earned her Doctor of Pharmacy degree from Rutgers University. She received her Master's Degree with honors in Laboratory Diagnosis at The University Of Damascus School Of Pharmacy, and her Bachelor's Degree in Pharmacy & Pharmaceutical Chemistry at the University of Damascus, Syria. She is a Registered Pharmacist.