



Bobbi Drais, MS, RAC

President / Principal Consultant

Drais Regulatory Consulting, LLC

Results driven global leader with over 25 years in regulatory affairs specializing in regulatory strategic management in Biologics, Advanced Therapy Medicinal Products, Prescription and OTC Drugs, Medical Devices, Combination Products and Cosmetics. Former senior executive serving as member of multiple executive leadership teams with extensive experience in designing, developing and leading global regulatory teams.

Proven success in the development of regulatory strategy to support optimal progress of projects from product development through to initial approval as well as geographical roll-out and post-market compliance activities. Demonstrated success with therapies for orphan and rare diseases and expedited / accelerated programs. Led teams in defining strategy / plan of action in all interactions with Health Authorities.

Key partner to many business development opportunities resulting in multiple product and organization acquisitions and divestitures including the sale of Coria Laboratories to Valeant Pharmaceuticals, Healthpoint Biotherapeutics to Smith & Nephew, and Galderma Laboratories to EQT Partners.

Member of the Regulatory Affairs Professional Society, The Organization for Professionals in Regulatory Affairs, Canadian Association for Professionals in Regulatory Affairs, and the Drug Information Association. Holds Regulatory Affairs Certification (RAC).