Greenleaf Health

Julia Barrett, M.D., M.P.H.

Executive VP, Drug and Biological Products

BACKGROUND	• 28-year career in the clinical development of biologics and drugs
SPECIALTY	• Cell and gene therapy, vaccines, allergy immunotherapy, toxins, live biotherapeutics, small molecules, combination products
EXPERIENCE	• 5 years at the FDA and 23 years of clinical regulatory consulting

Dr. Julia Barrett joined Greenleaf Health with 23 years of biopharma consulting experience. An internist with a Master of Public Health (M.P.H.) and FDA expertise, Dr. Barrett has assisted clients worldwide with regulatory strategy and clinical development for a wide variety of biological products, drugs, and combination products across many indications. At Greenleaf, she applies the knowledge and unique perspective gained through this experience to her work as Executive VP, Drug and Biological Products.

Dr. Julia Barrett is a strong clinical research professional who received her bachelor's degree in biology from Smith College, an M.D. from Northwestern University, and an M.P.H. from George Washington University. She trained as a resident in internal medicine at the University of Minnesota and completed a fellowship in general internal medicine at George Washington University.

Julia began her 28-year career in biologics and drug development as a clinical reviewer in the Office of Vaccine Research and Review (OVRR) at the Center for Biologics Evaluation and Research (CBER). From 2004-2021 she was a Senior Clinical Consultant at Biologics Consulting Group, with a focus on clinical product development for U.S. licensure. Julia's expertise spans a broad range of product classes, with particular expertise in biological products, including cell and gene therapy/regenerative medicine, protein therapeutics, allergy immunotherapy, vaccines, toxins, and microbiome-based products. Julia has extensive experience in the review and oversight of regulatory submissions, including the clinical sections of pre-INDs, INDs, BLAs/NDAs, FDA meeting packages, FT/BT/RMAT designation requests, orphan drug designation requests, clinical protocols, and statistical analysis plans. She provides in-depth clinical development plans and strategy, clinical/regulatory gap analyses, clinical protocol development, "FDA-style" clinical data review, and assistance with regulatory meetings.

Julia's product development experiences cover a wide range of clinical indications including infectious disease, neurology, gastroenterology, allergy, genitourinary, gynecology, orthopedics, rheumatology, dermatology, cardiopulmonary, ophthalmology, metabolic, and orphan diseases.

Julia is a member of the Grants Working Group (GWG) of the California Institute for Regenerative Medicine (CIRM). The mission of CIRM is to accelerate stem cell and gene therapy treatments to patients with unmet medical needs. The GWG reviews the scientific merit of grant applications and is composed of subject matter experts from outside California and patient advocates.