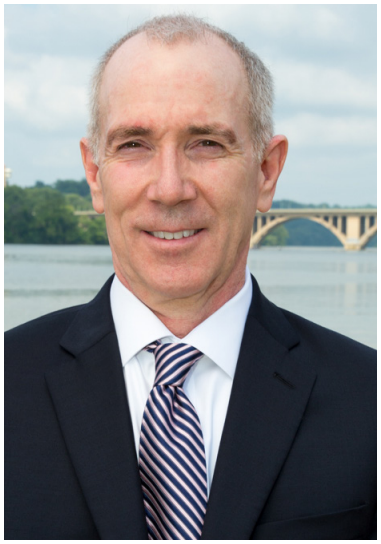
Greenleaf Health

Joseph Griffin

Executive Vice President, Drug and Biological Products



BACKGROUND	• 20 plus years with FDA
SPECIALTY	• Specialist in drug and biologics regulations and policy
EXPERIENCE	• Previous experience in expedited drug development mechanisms, biosimilars, investigational new drug applications, prescription drug promotion and labeling, good clinical practices, human subject protection, and expanded access to investigational drugs

Joe Griffin brings more than 20 years of service at the Food and Drug Administration (FDA) to his role at Greenleaf. Joe uses his extensive institutional knowledge to provide valuable insights and guidance to Greenleaf clients in his role as Executive Vice President of Drug and Biological Products.

Widely known for his extensive experience in policy development and comprehensive knowledge of the regulatory environment, Joe's career has given him particular expertise in expedited drug development mechanisms, biosimilars, investigational new drug applications, prescription drug promotion and labeling, good clinical practices, human subject protection, and expanded access to investigational drugs.

Joe's career includes several roles within FDA's Center for Drug Evaluation and Research (CDER). Most recently, he served as Associate Director for Policy Development in CDER's Office of Medical Policy. In this position, Joe focused on developing policy on a broad range of clinical and regulatory matters.

Joe began his FDA career in 1991 as a Regulatory Review Officer and went on to become Special Assistant to the Director/ Regulatory Counsel in the Division of Drug Marketing, Advertising, and Communication (now the Office of Prescription Drug Promotion). In 1995, Joe was promoted to Special Assistant to the Center Director, where he developed policy on complex clinical and regulatory issues, focusing on rulemaking and guidance to implement the FDA Modernization Act (FDAMA) of 1997 and improve prescription drug labeling. Joe continued in this role until moving to CDER's Office of Medical Policy in 1999.

Joe has received numerous FDA honors, including CDER's Center Director's Special Citation. He has also co-authored several publications on a number of drug regulatory matters, including observational research, development of combination therapies, biosimilars, and drug promotion.

Joe received his J.D. from Northeastern University Law School and holds a B.S. in Pharmacy from Northeastern University.