Greenleaf Health

DRUG & BIOLOGICAL PRODUCTS

To ensure success in today's rapidly evolving biopharmaceutical industry, companies must recognize and be prepared for a dynamic regulatory landscape. Guided by decades of experience, Greenleaf's team of experts provides unmatched knowledge of the life sciences regulatory process and serves as a trusted partner for companies navigating the complexities of product lifecycle management.

GREENLEAF'S APPROACH

- Greenleaf's in-depth knowledge and understanding of the U.S. Food and Drug Administration (FDA) as a regulator provides clients with a trusted partner when navigating the complex process of bringing new therapeutics to market. The team's approach, firmly grounded in established principles of public health practices, is guided by decades of regulatory experience in drug and biological products development, spanning all therapeutic areas.

- The Drug and Biological Products Team delivers a variety of services from the earliest stages of product development through postapproval commitments. Services include monitoring and assessing the regulatory environment for emerging trends, analyzing the impact of agency actions on current development programs, and reviewing the competitive landscape for specific therapeutic areas.

- Greenleaf experts specialize in clinical trial design, FDA submissions and the review process, as well as postmarket requirements, including safety monitoring.

- Experts from Greenleaf's Drug and Biological Products Team also provide advisory services that include extensive research and due diligence for firms engaged in potential mergers and acquisitions that require regulatory risk assessments before and after a life sciences transaction.

ABOUT GREENLEAF

Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical and medical device companies researching, developing and manufacturing innovative solutions to pressing global public health challenges.

COMPREHENSIVE SERVICES

Greenleaf's Drug and Biological Products Team has a robust blend of regulatory expertise and FDA institutional knowledge, providing strategic and technical guidance in an array of areas, including clinical trial design, FDA filings and review process, and postmarket requirements such as safety monitoring.

GREENLEAF'S DRUG & BIOLOGICAL PRODUCT SERVICES

Product Lifecycle Management

- Strategic guidance on the FDA's regulatory process
- All aspects of product development
- Premarket review
- Postmarket safety requirements
- Analysis of the market to identify potential competition

Premarket Review Process

- Scientific, medical and regulatory guidance for clinical programs and regulatory filings
- Strategic guidance and preparation for FDA meetings, including advisory committees
- Analysis of, and recommendations on, FDA communications

Marketing & Promotional Practices

- Strategic guidance on labeling requirements
- Promotional materials
- Direct-to-consumer advertising review processes
- Remediation of untitled and warning letters
- Use of social media

Regulatory Policy Guidance

- Analysis of FDA policies and processes
- User fee requirements
- Advisory committee analysis
- Implementation of new FDA legislation, regulations, guidance documents and FDA standard operating procedures

Compliance & Manufacturing Services

- The Drug and Biological Products Team works closely with Greenleaf's Product Quality, Manufacturing and Compliance Team to provide expertise in FDA's compliance, inspection and enforcement processes.

Advisory Services

- Greenleaf regularly partners with investors to evaluate potential issues and regulatory risks identified during life sciences transactions.

- Greenleaf's Advisory Services include evaluations of the following potential sources of risk: marketing authorization; manufacturing; product safety; labeling; promotion; research and development; and distribution and supply chain.

LEADERSHIP

John Jenkins, MD

Principal, Drug & Biological Products

With a 25-year career at the FDA, including 15-years in senior leadership positions within the Center for Drugs, Dr. Jenkins is an expert in the statues and regulations that guide drug development.

Bob Meyer, MD

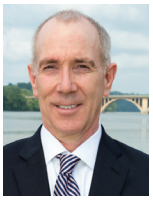
Principal, Drug & Biological Products

Dr. Meyer brings more than 25-years of regulatory, industry and academic leadership to Greenleaf, including prominent roles at the FDA, Merck and the University of Virginia.

Karen Midthun, MD

Principal, Drug and Biological Products

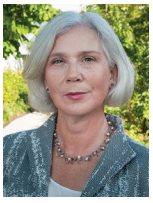
An infectious disease physician by training, Dr. Midthun's 28-year career in public services includes her service as Director of the FDA's Center for Biologics Evaluation and Research.



Joseph Griffin

Executive Vice President, Drug & Biological Products

Joe Griffin brings 20+ years of FDA service to Greenleaf. Clients benefit from Joe's extensive institutional knowledge of the drug application process, prescription drug promotion and labeling.



Kate Cook

Executive Vice President, Drug & Biological Products

Kate Cook is an FDA veteran with over 20-years of experience in policy development. While at the FDA, Kate served as legal counsel on critical agency issues related to biological products, medical devices and drug issues.

Stephen Mason

Senior Vice President, Regulatory Policy

Stephen Mason joins Greenleaf following an accomplished and diverse career that includes time in regulated industry, at the FDA, and on Capitol Hill. Stephen is a specialist in regulatory and legislative policy development and analysis.

Brian Corrigan

Senior Vice President, Regulatory Policy

Brian Corrigan utilizes more than a decade of professional experience in the biopharmaceutical industry to provide Greenleaf clients with strategic and technical regulatory guidance.

Additional Team Members

Katie McCarthy | Christina Karas | Rhona Baniqued