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 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.

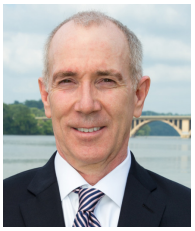
- Greenleaf's Advisory Services include evaluations of the following potential sources of risk: marketing authorization, manufacturing, product safety, labeling, promotion, research and development, and distribution and supply chain.

LEADERSHIP

John Jenkins, MD

Principal, Drug and Biological Products

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



Joseph Griffin

Executive Vice President, Drug and Biological Products

Joe Griffin brings more than 20 years of FDA service to Greenleaf. Clients benefit f rom J oe's extensive institutional knowledge of the drug application process, prescription drug promotion and labeling.

Kate Cook

Executive Vice President, Drug and Biological Products

Kate Cook is an FDA veteran with more than 20 years of experience in policy development. While at 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 comes to Greenleaf following an accomplished and diverse career that includes time in regulated industry, at 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 joined Greenleaf following more than a decade of professional experience in the biopharmaceutical industry. Brian uses his in-depth understanding of the U.S. health care system to provide strategic and technical guidance to Greenleaf clients.

Additional Team Members

Katie McCarthy | Christina Karas | Rhona Baniqued