Greenleaf Health

# DRUG & BIOLOGICAL PRODUCTS

## GREENLEAF'S APPROACH

Greenleaf's Drug and Biological Products Team has a robust blend of regulatory and policy expertise and institutional knowledge of the U.S. Food and Drug Administration (FDA).

The team's approach, firmly grounded in established principles of public health, is guided by decades of regulatory experience in drug and biological product development, spanning all therapeutic areas.

## STRATEGIC & TECHNICAL CAPABILITIES

Greenleaf experts specialize in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements.

The team offers guidance on scientific and regulatory practices for clinical programs and regulatory submissions; identification of and eligibility for special designations, such as breakthrough therapy designation, RMAT, fast track, and accelerated approval; and preparation for FDA milestone meetings, such as EOP2, pre-filing meetings, mid-cycle review, and end-of-review meetings.

For sponsors developing cell and gene therapies, Greenleaf assists with FDA interactions and submissions - including early INTERACT and pre-IND meetings; requests for orphan drug, RMAT, and rare pediatric disease designations; and data comparability questions - and helps to clarify FDA requirements for specific types of cellular products. Greenleaf also helps maximize clinical trial design for rare and ultra-rare diseases.

The team's multidisciplinary expertise helps companies evaluating and prioritizing their drug development pipeline to understand and effectively manage regulatory risk.

***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 regulatory experience, Greenleaf's team of experts assists clients with all aspects of the regulatory review process for drug and biological products.***

## ABOUT GREENLEAF

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

Greenleaf is committed to serving our clients' needs with extensive expertise, unwavering integrity, and strategic insight in a manner that supports availability of safe, effective, and high-quality drugs, biologics, and devices.

## UNMATCHED EXPERTISE

Greenleaf's team is comprised of experts with a combined total of more than 300 years of FDA experience. The firm includes former leaders and regulatory professionals from the FDA, Capitol Hill, top global pharmaceutical and medical device companies, leading law firms, and the top U.S. biotechnology trade organization.

With decades of experience in senior positions at the FDA and throughout industry, Greenleaf's team of respected professionals brings unmatched expertise that companies need when working directly with the FDA and when navigating today's evolving regulatory environment.

*Greenleaf is a regulatory consulting firm and does not provide legal advice or legal services.*

# DRUG & BIOLOGICAL PRODUCT SERVICES

### Unmatched Regulatory Experience
*Strategic consultation on:*

- FDA's regulatory programs and procedures
- Product development
- Endpoint and biomarker selection, development, and regulatory review
- Premarket review
- Postmarket safety requirements
- Pipeline decisions and optimization
- Market analysis for potential competition

### Premarket Review Process
*Experienced guidance on:*

- Scientific and regulatory practices for clinical programs and regulatory submissions
- Identification of and eligibility for special designations, such as breakthrough therapy designation, RMAT, fast track, and accelerated approval
- Preparation for FDA milestone meetings, including EOP2, pre-filing, mid-cycle review, and end-of-review meetings
- Advisory committee meetings and decisions
- FDA communications, including formal, in-person, and regulatory correspondence

### Regulatory Policy Guidance
*Specialized insight on:*

- FDA policies and procedures
- User fee requirements
- Implementation of new FDA legislation, regulations, guidance documents, and FDA standard operating procedures

### Marketing & Promotional Practices
*Skilled support on:*

- Labeling requirements
- Promotional materials
- Direct-to-consumer advertising review processes
- Remediation of untitled and warning letters
- Use of social media

# TEAM

### JOHN JENKINS, M.D.
**Principal, Drug & Biological Products**
Former Director of the Office of New Drugs within the FDA's Center for Drug Evaluation and Research (CDER).

### BOB MEYER, M.D.
**Principal, Drug & Biological Products**
A leader in drug and biological product lifecycle management with 25+ years of regulatory and academic leadership.

### KAREN MIDTHUN, M.D.
**Principal, Drug & Biological Products**
28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

### KATE COOK
**Principal, Regulatory Policy**
20 years of FDA experience in policy development and as legal counsel on biological, medical device, and drug issues.

### JOSEPH GRIFFIN
**Executive Vice President, Drug & Biological Products**
20+ years of FDA service with a vast knowledge of the drug regulatory process, promotion, and labeling.

### BRIAN CORRIGAN
**Executive Vice President, Regulatory Policy**
10+ years of experience in the biopharmaceutical industry provides in-depth knowledge of the U.S. health care system.

### JULIA BARRETT, M.D.
**Executive Vice President, Drug & Biological Products**
23-year career in clinical regulatory consulting for biologics and drugs and 5 years with the FDA's CBER.

### STEPHEN MASON
**Senior Vice President, Regulatory Policy**
Accomplished and diverse career specializing in regulatory and legislative policy development and analysis.

### KATIE MCCARTHY
**Senior Vice President, Regulatory Policy**
10+ years of policy experience specializing in scientific and regulatory issues impacting biotechnology companies.

### CHRIS LEPTAK, M.D., Ph.D.
**Senior Vice President, Drug & Biological Products**
14-year FDA tenure, including service as Acting Office Director of CDER's Office of Drug Evaluation Science.

### SEAN HILSCHER
Associate Vice President, Regulatory Affairs

### RHONA BANIQUED
Director of Operations, Drug & Biological Products

## COMPREHENSIVE SERVICES

Members of the Greenleaf team work cross-functionally to provide a full-service engagement that ensures clients can count on expert direction as they encounter regulatory challenges. Greenleaf's collaborative services include:

### Cell & Gene Therapy
Greenleaf experts assist sponsors of cell and gene therapies by optimizing FDA interactions and submissions to support development and regulatory review of cellular and gene therapy products.

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

### Advisory Services
Greenleaf understands the complex environment within which life sciences transactions take place and advises investors on potential issues and regulatory risks that may be identified during such transactions.