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.

Greenleaf's Drug and Biological Products Team monitors and analyzes the regulatory environment for emerging trends, agency actions that could potentially impact current development programs, and changes to the competitive landscape for specific therapeutic areas. For sponsors developing cell and gene therapies, the Greenleaf team helps clarify and respond to FDA requirements for cellular products regulated as human tissues and for cellular products subject to additional regulation as biological products and/or medical devices. Greenleaf also assists with maximizing rare disease trial design and requests for regenerative medicine advanced therapy, orphan drug, and other FDA designations.

Additionally, Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight via Trio's groundbreaking real-world evidence (RWE) technology platform.

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 250 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'S DRUG & BIOLOGICAL PRODUCT SERVICES

Product Lifecycle Management

Strategic consultation on:

- FDA's regulatory programs and procedures
- Product development
- Premarket review
- Postmarket safety requirements
- Market analysis for potential competition

Premarket Review Process

Experienced guidance on:

- Scientific and regulatory practices for clinical programs and regulatory submissions
- Preparation for FDA meetings, including advisory committees
- FDA communications, including formal, in-person, and regulatory correspondence

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

Regulatory Policy Guidance

Specialized insight on:

- FDA policies and procedures
- User fee requirements
- Advisory committee decisions and meeting preparation
- Implementation of new FDA legislation, regulations, guidance documents, and FDA standard operating procedures

LEADERSHIP

JOHN JENKINS, M.D.

Principal, Drug and 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 and Biological Products
A leader in drug and biological product lifecycle management with over 25 years of regulatory and academic leadership.

KAREN MIDTHUN, M.D.

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

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.

KATE COOK

Executive Vice President, Drug & Biological Products
Two decades of experience in policy development and as legal counsel on biological, medical device, and drug issues.

STEPHEN MASON

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

BRIAN CORRIGAN

Senior Vice President, Regulatory Policy
More than a decade of experience in the biopharmaceutical industry provides in-depth understanding of the U.S. health care system.

KATIE MCCARTHY

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

ADDITIONAL TEAM MEMBERS

RHONA BANIQUED, COLLEEN VIVALDI, SEAN HILSCHER

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:

Real-World Evidence

Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight via Trio's groundbreaking real-world evidence (RWE) technology platform.

Compliance & Manufacturing 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 frequently advises investors to evaluate potential issues and regulatory risks that may be identified during such transactions.