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.

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

Unmatched Regulatory Experience

Strategic consultation on:

- FDA's regulatory programs and procedures
- Product development
- 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

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
- 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.

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.

SEAN HILSCHER

Associate Vice President, Regulatory Affairs

More than 10 years of experience as a consultant and product manager in the international and U.S. health care markets.

ADDITIONAL TEAM MEMBERS

RHONA BANIQUED, COLLEEN VIVALDI

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.