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; endpoint and biomarker selection and development; identification of and eligibility for special designations, such as breakthrough therapy designation, RMAT, orphan drug, 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 of cell and gene therapies, Greenleaf helps to clarify FDA requirements and guidance applicable to these products and optimize FDA interactions and submissions at all stages of development. As development of cell and gene therapies often involves consideration of aspects of medical device and combination product regulation – another area of deep FDA expertise at Greenleaf – experts from the Drug and Biological Products Team collaborate regularly with the Medical Device and Combination Products Team. Greenleaf also provides guidance on clinical trial design for treatments for rare and ultra-rare diseases and conditions.

In addition, 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

EXPERT 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 30 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).

SANDRA KWEDER, M.D.
Principal, Drug & Biological Products
Former Deputy Director of the FDA's Office of New Drugs and Deputy Director of the FDA's Europe Office and EMA Liaison.

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
15+ years in the biopharmaceutical industry focused on regulatory policy development and strategic clinical development support.

WILSON BRYAN, M.D.
Executive Vice President, Drug & Biological Products
FDA career of 19 years, serving as Director of CBER's Office of Tissues and Advanced Therapies (OTAT) from 2016-2023.

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

CHRIS LEPTAK, M.D., Ph.D.
Executive 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
Vice President, Regulatory Policy
10+ years of experience as a consultant and product manager in the international and U.S. health care markets.

TANVI MEHTA
Manager, Regulatory Affairs & Policy
Brings analytical approach to regulatory policy from background in financial services and health care business.

RHONA BANIQUED
Executive Director of Operations, Drug & Biological Products
More than 18 years of private sector marketing and project management experience.

Becca Hunt, Associate Director, Drug & Biological Products
Stephen Power, Associate Director, 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:

Advisory Services | Greenleaf experts provide advisory services that include extensive research and due diligence for investors engaged in potential deals that require regulatory risk analyses before and after decisions and transactions.

Quality & Compliance Services | The Drug & 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.

Cell & Gene Therapy | Greenleaf experts assist sponsors of cell and gene therapies by optimizing FDA interactions and submissions to support product development, regulatory review, manufacturing technology, quality, and compliance.

Digital Health Services | Greenleaf Health serves as a trusted partner to both large and small clients developing and commercializing innovative digital health technologies as they navigate the complex landscape of FDA regulations and policies.