Greenleaf Health

REGULATORY POLICY SERVICES

Regulatory policy is an essential component of the Food and Drug Administration (FDA) regulatory landscape – it helps shape how regulators make decisions about the development, approval, and marketing of drugs, biological products, medical devices, and combination products. These policy decisions determine the feasibility of the development and use of new technologies and directly affect patient access to medical products.

Greenleaf's regulatory policy services are designed to support the needs of large and small clients as they navigate FDA regulations and regulatory policies. The firm's team of experts works cross-functionally to assist pharmaceutical and biotechnology companies, medical device manufacturers, patient groups, trade associations, and other stakeholders in communicating effectively about FDA regulatory policy issues and in understanding, implementing, and complying with the FDA's regulatory programs.

EXPERT INSIGHT

Greenleaf's well-regarded professionals have each spent decades working in leadership roles at regulatory agencies and within regulated industry. The Regulatory Policy Services Team provides advice and recommendations based on extensive institutional knowledge of the FDA's overarching regulatory approach, as well as deep and granular expertise regarding FDA regulation of medical product types across the product lifecycle.

TARGETED CAPABILITIES

Greenleaf offers unmatched insight on pre- and postmarket regulatory policy issues, product designations, expedited programs, regulatory intelligence, and scientific policy. Clients utilize our depth and breadth of knowledge to understand regulatory policy issues and build their capacity to implement, comply with, and communicate about FDA regulatory policy.

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.

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.

COMPREHENSIVE SERVICES

Greenleaf's robust blend of technical skill and FDA institutional knowledge enables the firm's team to provide unmatched guidance to companies developing medical products for the U.S. market.

This wealth of experience allows the Greenleaf team to work cross-functionally to provide a full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges.

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

COMPREHENSIVE SERVICES

Greenleaf's regulatory policy services address FDA regulations and regulatory policies to support clients' participation in FDA programs and regulatory compliance and to enhance patient access to innovative medical products. Comprehensive services include:

- Engage with stakeholders and leverage alliances to design and implement strategies that will advance regulatory policy in the public space.
- Support stakeholders in user fee negotiations and assess the impact of user fee agreements, statutory changes, regulatory initiatives, and other policy developments on clients, patients, and the broader regulatory landscape.
- Provide strategic regulatory guidance for sponsors seeking access to FDA programs and designations, including orphan drug, breakthrough therapy, RMAT, and other expedited pathways.
- Help clients navigate the emerging regulatory landscape and how novel tools and approaches can optimally be incorporated into development programs.
- Supply strategic regulatory guidance that enables sponsors to understand and respond to pediatric written requests, the scope of exclusive approval, and determinations related to priority review vouchers.
- Address policy issues related to development programs, combination products, submissions for marketing authorization, and the postapproval phase.
- Assist clients with structuring their regulatory policy capabilities to effectively advance their specific priorities.

EXPERT TEAM

Greenleaf's Regulatory Policy Services Team offers a rare blend of perspectives developed as leaders in both the public and private sectors. This wealth of experience equips clients with a trusted partner when seeking guidance on implementing, complying with, and communicating about FDA regulatory policy.

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

STEPHEN MASON
Exec. Vice President, Regulatory Policy
Accomplished and diverse 20+ year career specializing in regulatory and legislative policy development and analysis.

SEAN HILSCHER
Vice President, Regulatory Policy
10+ years of experience in the international and U.S. health care markets.

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

FULL-SERVICE SUPPORT

Greenleaf professionals work as teams specializing in product quality, manufacturing, and compliance; medical devices and combination products; and drug and biological products.

DRUGS & BIOLOGICAL PRODUCTS

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

QUALITY & COMPLIANCE

Greenleaf's Compliance Team provides services that are recognized as best in class by companies seeking to strengthen their quality management systems. Experts specialize in corporate quality and compliance systems; FDA inspections, communication, and enforcement processes; and the complete spectrum of compliance- and enforcement-related actions.

MEDICAL DEVICE & COMBO PRODUCTS

Greenleaf's Medical Device and Combination Products Team guides clients through the complete regulatory process, from the earliest stages of product development, through the FDA review process, to marketing authorization and compliance with postmarket requirements and quality systems.