Greenleaf Health

LITIGATION SUPPORT SERVICES

GREENLEAF'S APPROACH

Greenleaf and our network of experts work closely with litigators representing FDA-regulated clients in disputes related to medical devices, drug and biological products, and product quality, manufacturing, and compliance.

The Greenleaf team and network can offer litigators a high-level institutional knowledge of the FDA as well as more granular expertise regarding FDA regulation of a variety of product types across the product lifecycle. Greenleaf's well-regarded professionals have spent decades working at the FDA in senior positions, allowing them to render thoughtful advice and authoritative opinions.

Greenleaf and our network have extensive, in-depth experience regarding medical device and drug and biological product development, the premarket review process, as well as manufacturing, product quality and safety, compliance, and enforcement of all FDA-regulated products. Our experts have the knowledge, qualifications, and experience required to explain and clarify these and other issues to our clients, the courts, or juries and are credible, persuasive expert witnesses and litigation advisors.

Greenleaf and our network have experience advising litigators on the nuances of FDA regulation, preparing expert declarations or reports, and testifying during depositions and at trial. Greenleaf's team has worked with litigators engaged in a variety of disputes, including complex commercial litigation, unfair competition and false advertising cases, intellectual property litigation, product liability class actions, and securities class actions. We can also serve in a consulting capacity to identify key FDA regulatory issues that may impact litigation strategy.

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

In legal actions involving FDA-regulated entities, complex FDA regulatory issues are often critical components of disputes.

Greenleaf's deep bench and network of experienced and knowledgeable FDA experts can advise litigators grappling with FDA regulatory issues and provide authoritative, objective expert opinions that may make a difference in how disputes are resolved.

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.

LITIGATION SUPPORT SERVICES

Areas of Expertise

- Medical device product development
- Drug and biological product development
- Premarket review process
- Manufacturing
- Product quality and safety
- Compliance
- Enforcement

Services

- Sharing in-depth experience and knowledge of FDA regulation with litigators and their clients
- Identifying and consulting on FDA regulatory issues that may arise during the course of litigation and impact litigation strategy
- Preparing expert declarations and reports
- Providing deposition and trial testimony

Types of Litigation

- Complex commercial litigation
- Unfair competition / false advertising
- Intellectual property litigation
- Product liability class actions
- Securities class actions
- Other types of litigation such as tax matters and contract disputes

UNMATCHED EXPERTISE

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.

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.

Greenleaf's robust blend of technical skill and FDA institutional knowledge enables the firm's team to provide unmatched litigation support and expert witness services to FDA-regulated companies and their outside counsel in the midst of legal disputes.

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.