Greenleaf Health

LITIGATION SUPPORT SERVICES

GREENLEAF'S APPROACH

Greenleaf works closely with litigators representing FDA-regulated clients in a wide array of disputes related to medical devices and product quality, manufacturing, and compliance.

Greenleaf's team of experts 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 has extensive, in-depth expertise regarding medical device product development and 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.

Greenleaf's experts have experience preparing expert declarations, drafting professional expert reports, being deposed, and testifying at trial. Greenleaf has worked with litigators engaged in a variety of disputes, including complex commercial litigation, unfair competition and false advertising cases, tax litigation, intellectual property litigation, product liability class actions, and securities class actions.

In legal actions involving FDA-regulated entities, complex FDA regulatory issues are often critical components of disputes. Greenleaf's deep bench 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.

SERVICES

Areas of Expertise

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

Services

Sharing in-depth experience and knowledge regarding the FDA and FDA regulation with litigators and their clients
Expert declarations
Expert reports
Deposition testimony
Trial testimony

Types of Litigation

Complex commercial litigation
Unfair competition / false advertising
Tax litigation
Intellectual property litigation
Product liability class actions
Securities class actions

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 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.

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.

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

Greenleaf's Product Quality, Manufacturing, and Compliance Team identifies and promotes practices that will align a client's approach with the FDA's quality, safety, and compliance expectations. Greenleaf's compliance experts have a proven track record of achieving success and providing services that are recognized as best in class by companies seeking to strengthen their quality management systems.

MEDICAL DEVICES & COMBINATION 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.