GREENLEAF HEALTH
LITIGATION SUPPORT CAPABILITIES

OUR EXPERIENCE.
YOUR SUCCESS.

Greenleaf Health is a leading FDA regulatory consulting firm guiding companies through the changing FDA landscape.

ABOUT GREENLEAF HEALTH

300 YEARS
OF COMBINED FDA EXPERIENCE

WHY GREENLEAF

Founded in 2007, 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's robust blend of technical skill and FDA institutional knowledge enables the firm to provide reliable, objective guidance to companies developing medical products for the U.S. market.

UNMATCHED EXPERTISE

Greenleaf's team brings unmatched expertise that companies need when navigating today's evolving FDA regulatory environment. 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 U.S. biotechnology trade organization.

Greenleaf experts draw on a combined total of more than 300 years of FDA experience and a network of technical specialists. This wealth of experience informs Greenleaf's understanding of the broad life sciences industry and allows us to deliver valuable insight throughout the product lifecycle.

COMPREHENSIVE SERVICES

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

Greenleaf experts identify and promote practices and procedures that will align a client's approach with the FDA's quality, safety, and compliance expectations.

MEDICAL DEVICE & COMBINATION PRODUCTS

Greenleaf applies extensive regulatory expertise to guide medical device clients from early-stage development to marketing authorization and throughout the product lifecycle.

DRUG & BIOLOGICAL PRODUCTS

Greenleaf serves as a trusted regulatory partner, advising companies on the complex process of bringing new therapeutics to market in today's evolving FDA environment.

COMPLIANCE AUDIT, TRAINING & REMEDIATION

Greenleaf works with a network of independent technical experts who provide comprehensive on-site compliance assessments, remediation, and inspection readiness.

DIGITAL HEALTH SERVICES

Greenleaf experts provide guidance to clients developing, commercializing, utilizing, and investing in innovative digital health technologies as they navigate the evolving landscape of FDA digital health requirements.

CELL & GENE THERAPY

Greenleaf assists sponsors of cell and gene therapies by optimizing FDA interactions and submissions to support development, manufacturing, quality, and regulatory review.

ADVISORY SERVICES

Greenleaf understands the complex environment within which life sciences transactions take place and performs in-depth regulatory risk assessments tailored to investors' needs.

LITIGATION SUPPORT SERVICES

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.

REGULATORY POLICY SERVICES

Greenleaf supports the needs of small and large clients to understand, implement, and comply with the FDA's regulatory programs and policies and to enhance patient access to products.

LITIGATION SUPPORT 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.

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

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

EXTENSIVE KNOWLEDGE

Greenleaf and our network 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 medical 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.

TARGETED EXPERTISE

The Greenleaf team and network have extensive, in-depth expertise regarding medical 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.

COMPREHENSIVE SERVICES

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.

LITIGATION SUPPORT SERVICES NETWORK

The combined capabilities of Greenleaf professionals and our firm's network of FDA experts offer litigators enhanced guidance when grappling with FDA regulatory issues.

MAURA NORDEN

EVP, Medical Device & Combo. Products General Counsel

15 years of experience advising FDA-regulated entities, investors, and public health organizations on FDA regulatory matters.

KALAH AUCHINCLOSS

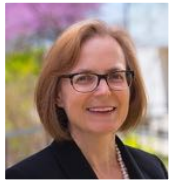
EVP, Regulatory Compliance Deputy General Counsel

15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combo. Products

35-year career includes service as Director of the FDA's Center for Devices and Radiological Health (CDRH).



CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

25-year compliance career includes serving as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER).

DAVID ELDER

Principal, Regulatory Compliance

23-year veteran of the FDA, with prominent roles in domestic and foreign inspections, recalls and emergencies, and compliance actions.

HEATHER ROSECRANS

EVP, Medical Device & Combo. Products

One of the nation's leading 510(k) experts, with an FDA career that spanned more than 30 years.

MARK KRAMER

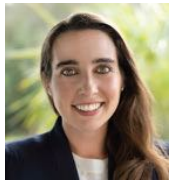
EVP, Medical Device & Combo. Products

17-year FDA career includes establishing and directing the Office of Combination Products and leading interdisciplinary review teams in CDRH.

KATHERINE MUELLER

Deputy General Counsel

10+ years of legal experience in the private sector, including national litigation management and guidance risk mitigation.



MARIA BONNER

VP, Regulatory Compliance

Policy and legal experience in both the public and private sectors provides deep understanding of regulatory policy.

MADELEINE GIAQUINTO

Manager, Regulatory Affairs

Legal and policy expertise and experience advising on compliance with federal health programs and regulations.

SAMANTHA EAKES

Director, Regulatory Affairs

Master's in Public Health provides critical public health, advocacy, and regulatory knowledge.

LITIGATION SUPPORT NETWORK

Greenleaf's litigation support capabilities include an outside network of experienced and knowledgeable FDA experts who were thoughtfully selected by Greenleaf and are adept at advising litigators representing FDA-regulated clients.

QUALITY & COMPLIANCE SERVICES

Greenleaf offers an enhanced portfolio of services that includes comprehensive on-site compliance assessments, remediation, and inspection readiness, in addition to the firm's core regulatory consulting capabilities.

COMPLIANCE ASSESSMENTS

Greenleaf works with life science entities to evaluate and strengthen compliance functions with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.

COMPLIANCE REMEDIATION

Greenleaf experts bring an unmatched level of credibility and trust when interacting with the FDA. The team has the experience and insight to successfully guide companies along the remediation pathway.

INSPECTION READINESS

Greenleaf experts strengthen clients' readiness for FDA preapproval and surveillance inspections through consulting, training, audits, and mock inspections.

SUPPLY CHAIN OPTIMIZATION

Greenleaf uses a systemic approach to help clients strengthen and safeguard the integrity of their supply chain management practices and comply with the regulatory requirements of the Drug Supply Chain Security Act.

FDA COMMUNICATIONS

Greenleaf's best-in-class experts bring value to any communication with the FDA, including formal regulatory communication, in-person meetings, and responses to compliance actions and regulatory correspondence.

CONSULTATION, TRAINING & REGULATORY GUIDANCE

Greenleaf delivers insight and guidance that help clients achieve business and regulatory objectives. The team also develops and delivers training on a variety of regulatory subjects.

GCP SERVICES

Greenleaf specialists use a risk-based methodology to develop and improve clinical quality systems. Because there is no one-size-fits-all approach to GCP compliance, each solution is built to fit the targeted needs of the client.

CELL & GENE THERAPY

Greenleaf helps sponsors establish manufacturing and quality controls and engage with the FDA to address potential technical and regulatory challenges related to emerging manufacturing technologies.

MEDICAL DEVICE & COMBINATION PRODUCTS SERVICES

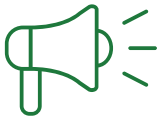
Greenleaf's Medical Device and Combination Products Team applies extensive FDA experience to determine the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

UNMATCHED REGULATORY EXPERIENCE

Greenleaf guides clients through the complex 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.

PREMARKET REVIEW PROCESS

Greenleaf provides expert direction on scientific and regulatory strategies for clinical programs and regulatory submissions. Experts also provide recommendations and preparation for FDA meetings, including medical device advisory panel meetings, and FDA communications.



MARKETING & PROMOTIONAL PRACTICES

Greenleaf provides strategic guidance to medical device firms on labeling requirements, promotional materials, direct-to-consumer advertising review processes, and use of social media. Experts also guide companies in remediation of untitled and warning letters.

LITIGATION SUPPORT SERVICES

Greenleaf's deep bench 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 professionals have experience preparing expert declarations, drafting professional expert reports and depositions, and testifying at trial, and have worked with litigators representing FDA-regulated clients in a wide array of disputes involving complex FDA issues.

DRUG & BIOLOGICAL PRODUCTS SERVICES

Greenleaf's Drug and Biological Products Team specializes in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements, working closely with clients to navigate today's evolving FDA regulatory environment.

UNMATCHED REGULATORY EXPERIENCE

Greenleaf serves as a trusted regulatory partner, advising clients on the complex process of bringing new therapies to market. The team's multidisciplinary expertise helps companies evaluating and prioritizing their drug development pipeline to understand and effectively manage regulatory risk.

PREMARKET REVIEW PROCESS

Greenleaf's team of experts provides strategic and technical consultation on: scientific and regulatory practices for clinical programs and regulatory submissions, including endpoint and biomarker selection and development; identification of and eligibility for special designations (e.g., breakthrough therapy designation, fast track, and accelerated approval); use of real-world evidence in regulatory submissions; and preparation for FDA milestone meetings (e.g., EOP2, pre-filing, mid-cycle, and end-of-review meetings).

REGULATORY POLICY SERVICES

Greenleaf offers strategic regulatory policy insight to support stakeholders' participation in and compliance with FDA programs and improve patient access to innovative medical products. Our team draws on deep expertise and institutional knowledge related to FDA regulatory policy, including novel programs; product designations and access to expedited programs; regulatory issues arising both pre and post market; regulatory intelligence and scientific policy; and building clients' capacity to effectively advance their regulatory policy priorities.

CELL & GENE THERAPY

The Drug and Biological Products Team assists sponsors of cell and gene therapies 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. The team also provides guidance on how to maximize clinical trial design for cell and gene therapies to treat rare and ultra-rare diseases.

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