Greenleaf Health

OUR EXPERIENCE.
YOUR SUCCESS.

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

ABOUT GREENLEAF HEALTH

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250+ 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.

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 navigating today's evolving FDA regulatory environment.

UNMATCHED REGULATORY EXPERIENCE

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.

Greenleaf experts draw on a combined total of more than 250 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.

GREENLEAF HEALTH LEADERSHIP

Greenleaf's team of experts 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.

PATRICK RONAN

Chief Executive Officer

JOHN TAYLOR

President
Principal, Compliance & Regulatory Affairs

KATHLEEN SONNTAG

Chief Operating Officer

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

BOB MEYER, M.D.

Principal, Drug & Biological Products

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combination Products

MAURA NORDEN

General Counsel
Senior Vice President, Medical Device & Combination Products

TARYN WALPOLE

Chief of Staff
Executive Vice President, Regulatory Affairs


Greenleaf Health
GREENLEAF TEAM

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.

DRUG & BIOLOGICAL PRODUCTS

Greenleaf serves as a trusted regulatory partner, advising companies on the complex process of bringing new therapeutics to market and guiding them through product lifecycle management decisions.

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.

REAL-WORLD EVIDENCE (RWE)

Greenleaf Health and Trio Health have united to provide a cutting-edge combination of technology and regulatory insight via Trio's groundbreaking real-world evidence technology platform.

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

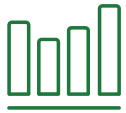
Greenleaf understands the complex environment within which life sciences transactions take place and frequently advises investors to evaluate potential issues and regulatory risks that may be identified during such transactions.

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. Services include:

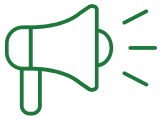
PRODUCT LIFECYCLE MANAGEMENT

Greenleaf guides clients through the complete product lifecycle, from the earliest stages of product development, through the FDA review process, to marketing authorization, 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.

REGULATORY POLICY GUIDANCE

Greenleaf's knowledge and understanding of the FDA enables the firm's experts to offer specialized insight on FDA policies and procedures; user fee requirements; medical device advisory panel decisions; and implementation of new FDA legislation, regulations, guidance documents, and FDA standard operating procedures.

MEDICAL DEVICE & COMBINATION PRODUCTS TEAM

Guided by decades of experience, Greenleaf's Medical Device and Combination Products Team provides unmatched knowledge of the life sciences regulatory process and serves as a trusted partner for companies navigating the complexities of product lifecycle management.

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combination Products

Former Director of the FDA's Center for Devices and Radiological Health (CDRH); distinguished 35-year career includes service as a physician, senior FDA official, and member of the U.S. Public Health Service (USPHS).

HEATHER ROSECRANS

Executive Vice President, Medical Device & Combination Products

One of the nation's leading 510(k) experts, with an FDA career that spanned more than 30 years and included a pivotal role in developing the FDA's 510(k) program.

MAURA NORDEN

Senior Vice President, Medical Device & Combination Products General Counsel

More than a decade of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

KATE COOK

Executive Vice President, Drug & Biological Products

Two decades of experience in policy development and as legal counsel on biological, medical device, and drug issues.

SAMANTHA EAKES

Senior Manager, Regulatory Affairs

Master's in Public Health from the Boston University School of Public Health provides critical public health, advocacy, and regulatory knowledge.

CATHERINE ROWE

Director of Operations, Medical Device & Combination Products

More than 20 years of professional experience in marketing, sales, and project management.

LITIGATION SUPPORT SERVICES

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.

Greenleaf works closely with litigators representing FDA-regulated clients in a wide array of disputes involving complex FDA issues throughout the lifecycle of their products.

EXTENSIVE KNOWLEDGE

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.

TARGETED EXPERTISE

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.

COMPREHENSIVE SERVICES

Greenleaf's experts have experience preparing expert declarations, drafting professional expert reports, being deposed, and testifying 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, tax litigation, intellectual property litigation, product liability class actions, and securities class actions.

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