Greenleaf Health

GREENLEAF HEALTH
ADVISORY 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.

ADVISORY SERVICES TEAM

Greenleaf's team of advisors offers a rare blend of perspectives developed as leaders in both the public and private sectors. This wealth of experience informs Greenleaf's understanding of the broad life sciences industry and enables us to deliver valuable insight throughout the product lifecycle.

BRIAN CORRIGAN

EVP, Regulatory Policy

More than a decade of experience in the biopharmaceutical industry provides in-depth understanding of U.S. health care system.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

Former Director of the Office of New Drugs within the FDA's Center for Drug Evaluation and Research (CDER).

BOB MEYER, M.D.

Principal, Drug & Biological Products

A leader in drug and biological product lifecycle management with over 25 years of regulatory and academic leadership.

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

25-year compliance career includes serving as Director of the FDA's drug compliance office.

MAURA NORDEN

EVP, Medical Device & Combination Products

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

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

Distinguished FDA career of 20+ years, serving in many high-profile positions, as well as in senior leadership roles within industry.

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combination Products

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

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

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.

MARK KRAMER

EVP, Medical Device & Combination Products

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

ADVISORY SERVICES

Greenleaf's in-depth knowledge and understanding of the FDA equips clients with a trusted partner when considering life sciences transactions. Greenleaf's advisory services are more than a compilation of public data. Greenleaf goes a step further by using the firm's vast institutional knowledge to provide in-depth analyses tailored to our clients' specific needs.

The firm's multidisciplinary team uses its extensive expertise to perform risk assessments that take into account business objectives, transaction timelines, and the industry landscape. The end result is an unbiased analysis identifying a target company's key regulatory risks, likelihood of the risks materializing, potential impact on the business, and opportunities to manage and mitigate risks in order to achieve desired regulatory outcomes. Greenleaf's comprehensive due diligence services evaluate a company's pipeline, or a specific asset, in the following areas:

PRODUCT DEVELOPMENT & REVIEW

Analysis of the target company's regulatory filings and product development plans, including approvals and clearances, special designations, advisory committee decisions, labeling review, and investigational products.

QUALITY MANUFACTURING

Assessment of the target company's manufacturing practices, compliance with quality system regulations (QSRs), good manufacturing practices (GMPs), and identification of inconsistencies that may affect the regulatory risk of a product or the company.

IDENTIFICATION OF REGULATORY RISK

Evaluation of the target company's compliance with FDA regulations and identification of issues that may require attention and resources for remediation.

STRATEGIC & TECHNICAL CAPABILITIES

Greenleaf's advisory services include research and analysis of the following potential data sources:

PRODUCT DEVELOPMENT

Evaluation of clinical development plans to assess alignment with FDA regulations and product-specific guidance through review of clinical and nonclinical data, FDA correspondence, safety reporting, and sponsor proposals for future clinical studies.

REGULATORY PATHWAYS

Determine opportunity for special designation(s) for early-stage assets, including requests for priority review, fast track, accelerated approval, breakthrough therapy designation (BTD), and regenerative medicine advanced therapy (RMAT) designation.

REPORTING REQUIREMENTS

Confirm that the target company has complied with all requirements for registration, authorization, filing, and listing associated with approved products, including user fee payments and fulfillment of postmarket obligations.

QUALITY MANUFACTURING

Evaluation of the target company's compliance with FDA quality and manufacturing regulations related to inspections, standard operating procedures, quality assurance activities, and relevant contract manufacturers.

SUBMISSIONS

Review of pending product submissions to assess completeness and approval prospects. Review includes interactions during the course of the FDA's review, such as information requests, mid- and late-cycle meetings, advisory committee outcomes, labeling negotiations, and inspectional results.

MARKETING & PROMOTION

Evaluation of promotional practices and marketing materials, including labeling claims, promotion of unapproved products or off-label uses, and related FDA correspondence or enforcement actions.

COMPLIANCE

Research and summarize the target company's FDA compliance and enforcement history, including a review of FDA correspondence relating to compliance matters and identification of outstanding or pending compliance and remediation actions.

ADVERSE EVENT REPORTING

Review of adverse event reports (AERs) and good manufacturing practice (GMP) complaints to ensure that the target company has taken appropriate measures for review and investigation.

DISTRIBUTION & SUPPLY CHAIN

Assessment of import-export practices, supply chain audit reports, outsourcing arrangements, and distribution procedures.

CLINICAL QUALITY SYSTEMS

Assessment of compliance with FDA current good laboratory practice (GLP) and good clinical practice (GCP) regulations.

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