Greenleaf Health

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ABOUT GREENLEAF HEALTH

Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical 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 provides unmatched expertise that companies need when navigating today's changing FDA regulatory environment.

UNMATCHED REGULATORY EXPERIENCE

Greenleaf's robust blend of regulatory expertise and FDA institutional knowledge allow the firm to provide unmatched guidance to companies developing medical products for the U.S. market.

Greenleaf experts draw on a combined total of more than 200 years of FDA experience to provide reliable, objective advice to FDA-regulated companies.

This wealth of experience allows Greenleaf to understand the broad health care industry and provide expert guidance throughout the product lifecycle.

GREENLEAF HEALTH LEADERSHIP

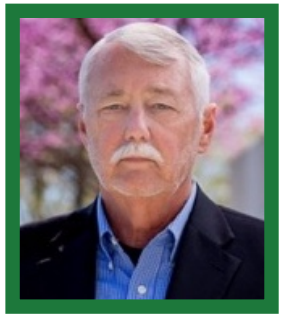
Founded in 2007, Greenleaf's team of experts includes former leaders and regulatory experts from the FDA, Capitol Hill, top global pharmaceutical companies, leading law firms, and the top U.S. biotechnology trade organization.

PATRICK RONAN
Chief Executive Officer

JOHN TAYLOR
President and Principal, Compliance & Regulatory Affairs

KATHLEEN SONNTAG
Chief Operating Officer

MAURA NORDEN
General Counsel

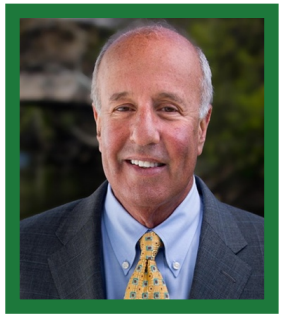


MICHAEL CHAPPELL
Principal, Regulatory Compliance

JOHN JENKINS, MD
Principal, Drug & Biological Products

KAREN MIDTHUN, MD
Principal, Drug & Biological Products

BOB MEYER, MD
Principal, Drug & Biological Products



DANIEL SCHULTZ, MD
Principal, Medical Devices & Combination Products

Greenleaf Health

GREENLEAF'S REGULATORY TEAMS

Greenleaf's experts lead teams specializing in product quality, manufacturing, and compliance; medical devices and combination products; and drug and biological products.

The firm's experts specialize in the following areas:

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 by advising companies on the complex process of bringing new therapeutics to market and guiding companies through product lifecycle management decisions.

MEDICAL DEVICES & COMBINATION PRODUCTS

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

PREMARKET SUBMISSION SUPPORT

Greenleaf offers strategic and technical guidance on all aspects of the medical device submissions process for 510(k) and PMA submissions, 513(g) requests, de novo petitions, HUD, HDE and IDE applications, pre-submissions, and requests for designation of a combination product.

ADVISORY SERVICES

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

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE SERVICES

In today's dynamic regulatory environment, keeping pace is not enough. Success is achieved by staying one step ahead of the pack. That's easier said than done, which is why successful companies recognize the need for a trusted regulatory partner to help navigate the challenging FDA landscape.

Greenleaf's Compliance Team has 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. Greenleaf's compliance experts combine their depth of knowledge and breadth of expertise to guide companies through the evolving quality, compliance, and regulatory environment. Team members include:

JOHN TAYLOR

President

Principal, Compliance & Regulatory Affairs

Former FDA senior official held many high-profile positions at the Agency, as well as a senior leadership roles within industry.

DAVID ELDER

Executive Vice President, Regulatory Compliance

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

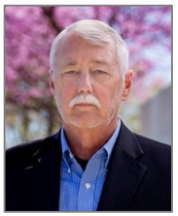
KRISTEN GRUMET

Senior VP, Regulatory Compliance

25-year compliance career, including role as an FDA field investigator specializing in medical devices.

ADDITIONAL TEAM MEMBERS

Samantha Eakes | Brittany Milby



MICHAEL CHAPPELL

Principal, Regulatory Compliance

Former FDA Acting Associate Commissioner for Regulatory Affairs, where he served as head of the FDA field force.

CYNTHIA SCHNEDAR

Executive Vice President, Regulatory Compliance

25-year compliance career, including role as Director of the FDA's drug compliance office.

KALAH AUCHINCLOSS

Senior VP, Regulatory Compliance & Deputy General Counsel

10+ years of experience on Capitol Hill, in the private sector and at the FDA, including Deputy Chief of Staff.

LIZ OESTREICH

VP, Regulatory Compliance

Diverse background of legal, public policy and non-profit sector knowledge.

EXPANDED QUALITY & COMPLIANCE SERVICES

The FDA's continued emphasis on proactive quality management and CGMP compliance presents new challenges and opportunities for the life science industry, making it essential for companies to build quality, safety, and integrity into their products.

Recognizing this, Greenleaf has expanded its portfolio of services to include comprehensive on-site compliance assessments, remediation, and inspection readiness. Greenleaf's expanded strategic capacity and capabilities include the following quality, compliance, and manufacturing services:

Compliance Assessments

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

Consultation, Training & Regulatory Guidance

Greenleaf partners with companies to deliver insight and guidance that helps companies achieve their business and regulatory objectives. The team also develops and delivers training in a variety of regulatory areas.

Inspection Readiness

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

FDA Communications

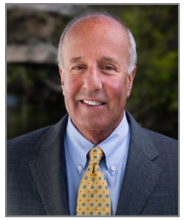
Greenleaf's best-in-class experts bring value to any communication with the FDA, including formal regulatory communication, in-person meetings and responses to compliance actions, and regulatory correspondence.

Compliance Remediation

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

MEDICAL DEVICES & COMBINATION PRODUCTS TEAM

Guided by decades of experience, Greenleaf's Medical Devices 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, MD

Principal,
Medical Devices & Combination Products

Former Director of 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).

MAURA NORDEN

Senior Vice President,
Medical Devices & Combination Products
General Counsel

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

HEATHER ROSECRANS

Executive Vice President,
Medical Devices & 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 FDA's 510(k) program.

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 Devices & Combination Products

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

MEDICAL DEVICES & COMBINATION PRODUCT SERVICES

Greenleaf's Medical Devices & Combination Products Team applies extensive FDA experience to determine the best regulatory approach for a product and provide a comprehensive strategy to achieve a successful result. Greenleaf's Medical Devices & Combination Product Services include:

Product Lifecycle Management

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

Premarket Review Process

Greenleaf partners with companies to provide scientific, medical, and regulatory guidance for clinical programs and regulatory filings. Experts also provide strategic guidance and preparation for FDA meetings, including advisory panels, and recommendation on FDA communications.

PREMARKET SUBMISSION SUPPORT

Greenleaf offers strategic and technical guidance on all aspects of the medical device submissions process for 510(k) and PMA submissions, 513(g) requests, de novo petitions, HUD, HDE and IDE applications, pre-submissions, and requests for designation of a combination product.

Marketing & Promotional Practices

Greenleaf works with medical device firms to provide strategic guidance 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 FDA enables the firm's experts to provide analysis of FDA policies and processes; user fee requirements; medical device advisory panel meeting analysis; and implementation of new FDA legislation, regulations, guidance documents and FDA standard operating procedures.

DRUG & BIOLOGICAL PRODUCTS TEAM

Greenleaf's Drug and Biological Products Team has a robust blend of regulatory expertise and FDA institutional knowledge, providing strategic and technical guidance in an array of areas, including clinical trial design, FDA filings and review process, and postmarket requirements such as safety monitoring.

JOHN JENKINS, MD

Principal, Drug and Biological Products

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

BOB MEYER, MD

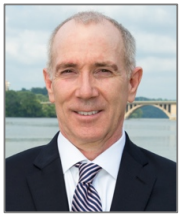
Principal, Drug and Biological Products

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

KATE COOK

Executive Vice President, Drug & Biological Products

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



JOSEPH GRIFFIN

Executive Vice President, Drug & Biological Products

20+ years of FDA service with a vast institutional knowledge of the drug regulatory process and prescription drug promotion and labeling.

KATE COOK

Executive Vice President, Drug & Biological Products

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

STEPHEN MASON

Senior Vice President, Regulatory Policy

Accomplished and diverse career specializing in regulatory and legislative policy development and analysis.

BRIAN CORRIGAN

Senior Vice President, Regulatory Policy

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

KATIE MCCARTHY

Vice President, Regulatory Policy

10+ years of policy experience specializing in scientific and regulatory issues impacting drug and biotechnology companies.

ADDITIONAL TEAM MEMBERS

Rhona Baniqued

Greenleaf Health

DRUG & BIOLOGICAL PRODUCT SERVICES

Greenleaf's in-depth knowledge and understanding of the FDA as a regulator provides clients with a trusted partner when navigating the complex process of bringing new therapeutics to market.

The Drug and Biological Products Team delivers a variety of services from the earliest stages of product development through post-approval commitments, including:

Product Lifecycle Management

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

Premarket Review Process

Greenleaf applies extensive regulatory expertise to guide companies through the premarket review process, including scientific, and regulatory guidance for clinical programs and regulatory filings; strategic guidance and preparation for FDA meetings and advisory committees; and analysis of, and recommendations on, FDA communications.

Marketing & Promotional Practices

Greenleaf works with pharmaceutical and biotechnology firms to provide strategic guidance 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 provide analysis of FDA policies and processes; user fee requirements; medical device advisory panel meeting analysis; and implementation of new FDA legislation, regulations, guidance documents and FDA standard operating procedures.

ADVISORY SERVICES

Greenleaf's in-depth knowledge and understanding of the FDA as a regulator provides clients with a trusted partner when considering life sciences transactions.

Greenleaf understands the complex environment within which life science transactions take place. This is why the firm considers multiple aspects of a business when performing advisory services, including product development, compliance, enforcement, and manufacturing.

By using cross-functional areas of expertise, the Greenleaf team is able to set appropriate expectations for investors and provide insights on the FDA's current thinking in key areas.

Greenleaf experts work together to provide guidance in the following arenas:

Drugs & Biological Products

Product Quality, Manufacturing & Compliance

Medical Devices & Combination Products


OUR EXPERIENCE. YOUR SUCCESS.

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