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 (RWE) 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.

REAL WORLD EVIDENCE

Trio Health

Real-world evidence (RWE) - the concept of using real-world data (RWD) to improve clinical evidence - has the potential to transform the drug development landscape.

The Food and Drug Administration (FDA) recognizes the opportunities presented by RWE and has taken steps to develop a new paradigm for its use in regulatory decision-making.

Companies prepared to employ the power of RWE will require more than just raw data -- that's why Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight.

GREENLEAF + TRIO

Greenleaf's exclusive agreement with Trio Health, a leading provider of real-time data on real-world patients, gives clients the advantage of Trio's groundbreaking Multi-Disease Platform (MDX) technology integrated with Greenleaf's unrivaled regulatory knowledge. The result is a comprehensive resource for enhancing and contextualizing evidence derived from RWD.

MDX PLATFORM

The first-of-its-kind MDX platform tracks patients throughout the course of their treatment by combining disparate information from the physician, pharmacy, and payer 'trio.' MDX offers life science customers best-in-class speed, data certainty, and unparalleled visibility across the clinical and commercial lifecycle.

Trio's comprehensive and high-quality databases are on caliber with FDA-level rigor, giving pharmaceutical and biotechnology companies, specialty pharmacies, and physicians access to information and opportunities that can be leveraged to support pre- and postmarketing activities.

UNRIVALED INSIGHT

When integrated with Greenleaf's regulatory expertise, Trio's advanced analytics MDX platform delivers unrivaled insights to the industry. In particular, clients gain the ability to transform real-world data into actionable intelligence to innovate and make better decisions, with greater confidence, throughout the product lifecycle. Greenleaf's team of regulatory experts provides end-to-end guidance to companies utilizing MDX data on how to optimize and validate the information to drive effective regulatory strategies.

Greenleaf Health

GREENLEAF'S RWE TEAM

Greenleaf's team of regulatory experts provides unmatched insight and consultation on all aspects of the FDA's regulatory application of RWE.

The combined achievements and substantial qualifications of the full Greenleaf team enable a cross-functional, full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges.

PATRICK RONAN

Chief Executive Officer

Greenleaf is led by regulatory veteran Patrick Ronan, whose 20+ years of experience include leadership positions on Capitol Hill, at a leading global pharmaceutical company, and at the FDA, where Ronan served as a principal advisor on all issues to a number of FDA commissioners.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

With a 25-year career at the FDA, including 15 years in senior leadership positions within the Center for Drugs, Dr. Jenkins is an expert in the statutes and regulations that guide drug development.

BOB MEYER, M.D.

Principal, Drug & Biological Products

Dr. Meyer brings more than 25 years of regulatory, industry, and academic leadership to Greenleaf, including prominent roles at the FDA, Merck, and the University of Virginia.

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

An infectious disease physician by training, Dr. Midthun's 28-year career in public service includes her role as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

DRUG & BIOLOGICAL PRODUCTS SERVICES

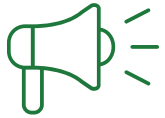
Greenleaf's Drug and Biological Products Team specializes in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements. Greenleaf assists clients with all aspects of the FDA regulatory process, including:

PRODUCT LIFECYCLE MANAGEMENT

Greenleaf serves as a trusted regulatory partner, 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, providing strategic and technical consultation on: scientific and regulatory practices for clinical programs and regulatory submissions; preparation for FDA meetings, including advisory committees; and FDA communications.



MARKETING & PROMOTIONAL PRACTICES

Greenleaf provides pharmaceutical and biotechnology firms with skilled support 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; advisory committee decisions and meeting preparation; 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 and policy expertise and FDA institutional knowledge. The team's approach is guided by decades of regulatory experience in drug and biological product development, spanning all therapeutic areas.

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.

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

An infectious disease physician by training, with a 28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

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 device, 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 biopharmaceutical industry provides in-depth understanding of the U.S. health care system.

KATIE MCCARTHY

Senior 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, Colleen Vivaldi, Sean Hilscher**

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