OUR EXPERIENCE.
YOUR SUCCESS.

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

ABOUT GREENLEAF HEALTH

ABOUT GREENLEAF HEALTH

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.

DRUG & BIOLOGICAL PRODUCTS SERVICES

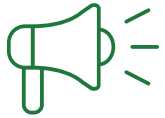
Greenleaf's Drug and Biological Products Team specializes in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements. Greenleaf assists clients with all aspects of the FDA regulatory process, including:

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 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**

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 services. Greenleaf's expanded quality, compliance, and manufacturing capabilities encompass the following:

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.

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

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.

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.

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE TEAM

Greenleaf's Product Quality, Manufacturing, and 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 experience to guide companies through the evolving quality, compliance, and regulatory environment.

JOHN TAYLOR

President
Principal, Compliance & Regulatory Affairs

Former FDA senior official held many high-profile positions at the Agency, as well as 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 Vice President, Regulatory Compliance

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

BRITTANY MILBY

Executive Director of Operations, Regulatory Compliance

Spearheads multiple operations, including the organization and management of the Greenleaf Independent Contractor Network.

CYNTHIA SCHNEDAR

Executive Vice President, Regulatory Compliance

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

KALAH AUCHINCLOSS

Senior Vice President, Regulatory Compliance
Deputy General Counsel

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

LIZ OESTREICH

Vice President, Regulatory Compliance

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

ADDITIONAL TEAM MEMBERS:

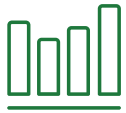
Madeleine Giaquinto, Laura Bartee

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:

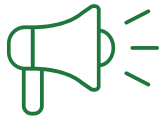
PRODUCT LIFECYCLE MANAGEMENT

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 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.

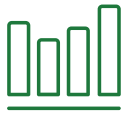
CATHERINE ROWE

Director of Operations, Medical Device & Combination Products

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

CELL & GENE THERAPY SERVICES

Greenleaf's cell and gene therapy services support companies striving to introduce new products to patients. The firm's team of experts has a robust blend of technical skill and FDA institutional knowledge that spans all therapeutic areas and quality, manufacturing, and compliance systems. By working cross-functionally, Greenleaf ensures that clients have the comprehensive, specialized guidance needed to understand and navigate the complex regulatory landscape for cell and gene therapies.



PRODUCT DEVELOPMENT & REVIEW

Greenleaf's team specializes in strategic communications with the FDA at every stage of product development – early INTERACT meetings, pre-IND and meetings throughout development, correspondence, clinical trial design, submissions, FDA review communications and labeling discussions, and postmarket requirements.

MANUFACTURING & QUALITY CONTROLS

Greenleaf experts provide strategic and technical support for establishing manufacturing and quality controls; pre- and postapproval inspection readiness; compliance assessments; evaluating and responding to FDA regulatory correspondence; and engaging with CBER's Advanced Technologies Team.

REGULATORY LANDSCAPE

Greenleaf experts monitor and analyze the regulatory environment for emerging trends in cell and gene therapy regulation – including orphan drug designation and exclusivity, long-term follow-up requirements, companion diagnostics, the development and use of real-world evidence, and other agency policies and actions that could potentially impact current development programs – as well as changes to the competitive landscape for cell and gene therapies.

CELL & GENE THERAPY TEAM

Experts from Greenleaf's Cell and Gene Therapy Team demonstrate unmatched levels of skill in their specialties of drug and biological products and product quality, manufacturing, and compliance. Led by Karen Midthun, M.D., and John Taylor, the team is guided by decades of regulatory experience in senior FDA positions, global public health organizations, academia, and industry.

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.

JOHN TAYLOR

President
Principal, Compliance & Regulatory Affairs

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

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

Former Director of the Office of New Drugs within the FDA's Center for Drugs.

CYNTHIA SCHNEDAR

Executive Vice President, Regulatory Compliance

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

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.

KALAH AUCHINCLOSS

Senior Vice President, Regulatory Compliance

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

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.

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.

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 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.

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.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

A 25-year career at the FDA, with 15 years in senior leadership positions within the Center for Drug Evaluation and Research, including as Director of the Office of New Drugs.

BOB MEYER, M.D.

Principal, Drug & Biological Products

More than 25 years of regulatory, industry, and academic leadership, 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, with a 28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research.

PATRICK RONAN

Chief Executive Officer

20+ years of leadership experience that includes positions on Capitol Hill, at a leading global pharmaceutical company, and at the FDA, serving as a principal advisor to a number of FDA commissioners.

SEAN HILSCHER

Associate Vice President, Regulatory Affairs

More than 10 years of experience as a consultant and product manager in the international and U.S. health care markets.

ADVISORY SERVICES

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

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

By working cross-functionally across our areas of expertise, the Greenleaf team is able to set appropriate expectations for investors and offer insights on the FDA's current thinking in multiple areas. Greenleaf experts work together to provide guidance in the following arenas:

- DRUG & BIOLOGICAL PRODUCTS
- PRODUCT QUALITY, MANUFACTURING & COMPLIANCE
- MEDICAL DEVICE & COMBINATION PRODUCTS
- CELL & GENE THERAPY
- FDA-REGULATED CONSUMER PRODUCTS

OUR EXPERIENCE.
YOUR SUCCESS.


Greenleaf Health