GREENLEAF HEALTH

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE CAPABILITIES

OUR EXPERIENCE.
YOUR SUCCESS.

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

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.

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 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.

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.

COMPLIANCE AUDIT, TRAINING & REMEDIATION

Greenleaf works with a network of independent technical experts who provide comprehensive on-site compliance assessments, remediation, and inspection readiness.

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.

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.

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.

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.

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

Greenleaf works closely with litigators representing FDA-regulated clients in a wide array of disputes related to medical devices and product quality, manufacturing, and compliance.

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.

To further enhance the firm's robust compliance services, Greenleaf has developed an Independent Contractor (IC) Network of additional technical experts who can be deployed to provide on-site services at entities that manufacture FDA-regulated products.

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

15 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.

MADELEINE GIAQUINTO

Manager, Regulatory Affairs

Legal and policy expertise and experience advising on compliance with federal health programs and regulations.

ADDITIONAL TEAM MEMBERS: **Laura Bartee, Maria Bonner**

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 capabilities.

COMPLIANCE ASSESSMENTS

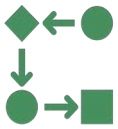
Greenleaf works with life science entities to evaluate and strengthen compliance functions with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.

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.



SUPPLY CHAIN OPTIMIZATION

Greenleaf uses a systemic approach to help clients strengthen and safeguard the integrity of their supply chain management practices and comply with the regulatory requirements of the Drug Supply Chain Security Act.

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 delivers insight and guidance that help clients achieve business and regulatory objectives. The team also develops and delivers training on a variety of regulatory subjects.

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.

CELL & GENE THERAPY

Greenleaf helps sponsors establish manufacturing and quality controls and engage with the FDA to address potential technical and regulatory challenges related to emerging manufacturing technologies.

REMOTE COMPLIANCE SERVICES

Entities regulated by the FDA encounter challenges on a regular basis. But no recent challenge has placed as great of a strain on the life sciences industry as COVID-19.

Greenleaf Health recognizes that quality and compliance activities cannot be stalled. Despite global disruptions in surveillance inspections and other regulatory operations, Greenleaf's work on behalf of our clients continues.

While companies face the complexities of navigating today's challenging public health landscape, Greenleaf and our network of independent compliance experts are prepared to assist clients with the following remote quality and compliance services:

PROCEDURAL & RECORD REVIEW

Comprehensive review of new or revised Standard Operating Procedures (SOPs) for acceptability and compliance with requirements and objective evaluation of selected records (e.g., deviations, nonconformance reports, OOS, complaints) for accuracy, completeness, and compliance with requirements.

CORRECTIVE ACTION ASSESSMENT

Evaluation of responses, corrective action records, and change control records related to issues identified by the client or identified during previous inspections by the FDA and other health authorities, and determination of whether the actions are appropriate, complete, and effective.

ISSUE-SPECIFIC INFORMATION

Review of information relating to a specific issue of interest identified by the client to provide an objective assessment and feedback to help with resolution, documentation, and communication.

DATA & TRENDING REVIEW

Examination of documents and objective feedback on key quality data and metrics, and trending reports prepared for quality or management reviews.

REGULATORY RESPONSE SUPPORT

Objective review and expert guidance on providing effective responses to FDA 483s, warning letters, requests for additional information, and other critical regulatory correspondence.

TRAINING

Live video training on specific topics such as inspection preparedness, design controls, CAPA, etc.

GOOD CLINICAL PRACTICE (GCP) SERVICES

Greenleaf's team of highly experienced specialists uses 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. The Product Quality, Manufacturing, and Compliance Team provides clinical quality and GCP services in the following areas:

COMPLIANCE ASSESSMENTS

Greenleaf works with life science entities to evaluate and strengthen clinical quality systems with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.

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.

CONSULTATION, TRAINING & REGULATORY GUIDANCE

Greenleaf delivers insight and guidance that help clients achieve business and regulatory objectives. The team also develops and delivers training on a variety of regulatory subjects.

FDA COMMUNICATIONS

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

AUDITING SERVICES

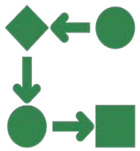
Greenleaf's skilled professionals provide auditing services that include the review and audit of GCP documents, sponsor and laboratory sites, and vendors for areas of nonconformance.

INSPECTION READINESS

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

SUPPLY CHAIN MANAGEMENT SERVICES

Guided by decades of regulatory experience, Greenleaf consultants use a systemic approach to help clients strengthen and safeguard the integrity of their supply chain management practices and comply with the regulatory requirements of the Drug Supply Chain Security Act.



GOOD SUPPLY PRACTICES

Greenleaf works with life science entities to evaluate and strengthen good supply practices using a systemic approach to optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.

RESPONSIVE SERVICES

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 facing compliance issues and addressing potential and actual supply chain breaches.

AUDITING SERVICES

Greenleaf's skilled professionals provide auditing services that include the review and audit of good manufacturing, good distribution, good import/export, and product security practices.

INSPECTION READINESS

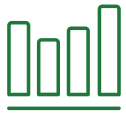
Greenleaf experts strengthen clients' readiness for FDA preapproval and surveillance inspections through consulting, training, audits, and mock inspections.

REGULATORY GUIDANCE

Greenleaf delivers insight and guidance that help companies strengthen their supply chains and comply with regulatory requirements included in the Drug Supply Chain Security Act.

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.


Greenleaf Health
ADVISORY SERVICES

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

SVP, Regulatory Policy

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

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

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

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

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).

PATRICK RONAN

Chief Executive Officer

25+ 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.

MAURA NORDEN

SVP, 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.

DAVID ELDER

EVP, Regulatory Compliance

23-year veteran of the FDA with prominent roles in global inspections, emergencies, and compliance actions.

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.

OUR EXPERIENCE.
YOUR SUCCESS.