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

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.

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

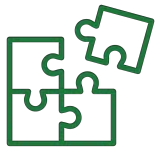
Greenleaf applies extensive regulatory expertise to guide medical device clients from early-stage development to marketing authorization and throughout the product lifecycle.

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.

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.



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.

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.

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.

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

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

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

25-year compliance career includes serving as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER).

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.

KALAH AUCHINCLOSS

Executive VP, Regulatory Compliance

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

KRISTEN GRUMET

Senior VP, Regulatory Compliance

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

GRACE MCNALLY

Senior VP, Regulatory Compliance

33-year FDA career, including experience as an investigator and leadership of many pharmaceutical cGMP and quality initiatives.

LIZ OESTREICH

VP, Regulatory Compliance

Diverse background provides critical expertise within legal, public policy, regulatory advocacy, and non-profit sectors.

MARIA BONNER

VP, Regulatory Compliance

Policy and legal experience in both the public and private sectors provides deep understanding of regulatory policy.

MADELEINE GIAQUINTO

Manager, Regulatory Affairs

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

BRITTANY MILBY

Exec. Director of Operations, Regulatory Compliance

9+ years of experience in pharmaceutical marketing, communications, and planning.

LAURA BARTEE

Director of Operations, Regulatory Compliance

10+ years of private sector operational and administrative experience.

To enhance the firm's robust quality and compliance services, Greenleaf works with an Independent Contractor Network of additional technical experts who can be deployed to provide on-site services at entities that manufacture FDA-regulated products.

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

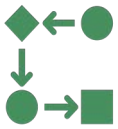
Greenleaf works with life science entities to evaluate and strengthen compliance functions with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.

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

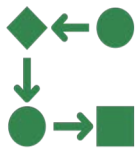
Greenleaf's skilled professionals provide auditing services that include the review and audit of GCP documents, sponsor and laboratory sites, and vendors for areas of nonconformance.

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 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.

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

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

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).

KATE COOK

Principal, Regulatory Policy

20 years of FDA experience in policy development and as legal counsel on biological, medical device, and drug issues.

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

25-year compliance career includes serving as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research.

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.

BOB MEYER, M.D.

Principal, Drug & Biological Products

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

JULIA BARRETT, M.D.

EVP, Drug & Biological Products

23-year career in clinical regulatory consulting for biologics and drugs and 5 years with the FDA's CBER.

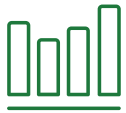
MADELEINE GIAQUINTO

Manager, Regulatory Affairs

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

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.

REGULATORY POLICY SERVICES TEAM

Greenleaf's Regulatory Policy Services Team offers a rare blend of perspectives developed as leaders in both the public and private sectors. This wealth of experience equips clients with a trusted partner when seeking guidance on implementing, complying with, and communicating about FDA regulatory policy.

The team's areas of expertise include:

- Insight into FDA regulatory policy, including novel programs
- Regulatory intelligence and scientific policy
- Effective communication on regulatory policy issues
- Product designations and access to expedited programs
- Regulatory issues arising both pre and post market
- Building client capacity and understanding of regulatory policy issues

KATE COOK

Principal, Regulatory Policy

20 years of FDA experience in policy development and as legal counsel on biological, medical device, and drug issues.

STEPHEN MASON

Executive Vice President, Regulatory Policy

Accomplished and diverse career of 20+ years specializing in regulatory and legislative policy development and analysis.

SEAN HILSCHER

Vice President, Regulatory Policy

10+ years of experience in the international and U.S. health care markets.

RHONA BANIQUED

Director of Operations, Drug & Biological Products

More than 18 years of private sector marketing and project management experience.

REGULATORY POLICY SERVICES

Regulatory policy is an essential component of the FDA regulatory landscape – it helps shape how regulators make decisions about the development, approval, and marketing of drugs, biological products, medical devices, and combination products. These policy decisions determine the feasibility of the development and use of new technologies and directly affect patient access to medical products.

Greenleaf's regulatory policy services are designed to support the needs of large and small clients as they navigate FDA regulations and regulatory policies. The firm's team of experts works cross-functionally to assist pharmaceutical and biotechnology companies, medical device manufacturers, patient groups, trade associations, and other stakeholders in communicating effectively about FDA regulatory policy issues and in understanding, implementing, and complying with the FDA's regulatory programs.

EXPERT INSIGHT

Greenleaf's well-regarded professionals have each spent decades working in leadership roles at regulatory agencies and within regulated industry. The Regulatory Policy Services Team provides advice and recommendations based on extensive institutional knowledge of the FDA's overarching regulatory approach, as well as deep and granular expertise regarding FDA regulation of medical product types across the product lifecycle.

TARGETED CAPABILITIES

Greenleaf offers unmatched insight on pre- and postmarket regulatory policy issues, product designations, expedited programs, regulatory intelligence, and scientific policy. Clients utilize our depth and breadth of knowledge to understand regulatory policy issues and build their capacity to implement, comply with, and communicate about FDA regulatory policy.

COMPREHENSIVE SERVICES

Greenleaf's regulatory policy services address FDA regulations and regulatory policies to support clients' participation in FDA programs and regulatory compliance and to enhance patient access to innovative medical products. Comprehensive services include:

- Assistance with designing and implementing regulatory policy strategies to effectively advance priorities
- Guidance on policy issues related to development programs, combination products, submissions for marketing authorization, and the postapproval phase
- Stakeholder engagement and alliance development to achieve regulatory policy goals
- User fee negotiation support, impact assessment, and program development
- Strategic regulatory guidance for sponsors seeking access to FDA programs and designations, including orphan drug, breakthrough therapy, RMAT, and other expedited pathways
- Advice on incorporating novel tools and approaches into development programs


Greenleaf Health
LITIGATION SUPPORT SERVICES

LITIGATION SUPPORT SERVICES NETWORK

The combined capabilities of Greenleaf professionals and our firm's network of FDA experts offer litigators enhanced guidance when grappling with FDA regulatory issues.

MAURA NORDEN

EVP, Medical Device & Combo. Products General Counsel

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

KALAH AUCHINCLOSS

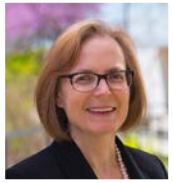
EVP, Regulatory Compliance Deputy General Counsel

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

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combo. Products

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



CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

25-year compliance career includes serving as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER).

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.

HEATHER ROSECRANS

EVP, Medical Device & Combo. Products

One of the nation's leading 510(k) experts, with an FDA career that spanned more than 30 years.

MARK KRAMER

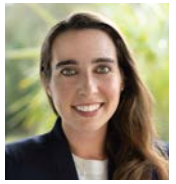
EVP, Medical Device & Combo. Products

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

KATHERINE MUELLER

Deputy General Counsel

10+ years of legal experience in the private sector, including national litigation management and guidance risk mitigation.



MARIA BONNER

VP, Regulatory Compliance

Policy and legal experience in both the public and private sectors provides deep understanding of regulatory policy.

MADELEINE GIAQUINTO

Manager, Regulatory Affairs

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

SAMANTHA EAKES

Director, Regulatory Affairs

Master's in Public Health provides critical public health, advocacy, and regulatory knowledge.

LITIGATION SUPPORT NETWORK

Greenleaf's litigation support capabilities include an outside network of experienced and knowledgeable FDA experts who were thoughtfully selected by Greenleaf and are adept at advising litigators representing FDA-regulated clients.

LITIGATION SUPPORT SERVICES

In legal actions involving FDA-regulated entities, complex FDA regulatory issues are often critical components of disputes.

Greenleaf's deep bench and network of experienced and knowledgeable FDA experts can advise litigators grappling with FDA regulatory issues and provide authoritative, objective expert opinions that may make a difference in how disputes are resolved.

Greenleaf and our network of experts work closely with litigators representing FDA-regulated clients in a wide array of disputes related to medical devices, drug and biological products, and product quality, manufacturing, and compliance.

Greenleaf is a regulatory consulting firm and does not provide legal advice or legal services.

EXTENSIVE KNOWLEDGE

Greenleaf and our network of experts can offer litigators a high-level institutional knowledge of the FDA as well as more granular expertise regarding FDA regulation of a variety of medical product types across the product lifecycle. Greenleaf's well-regarded professionals have spent decades working at the FDA in senior positions, allowing them to render thoughtful advice and authoritative opinions.

TARGETED EXPERTISE

The Greenleaf team and network have extensive, in-depth expertise regarding medical product development and the premarket review process, as well as manufacturing, product quality and safety, compliance, and enforcement of all FDA-regulated products. Our experts have the knowledge, qualifications, and experience required to explain and clarify these and other issues to our clients, the courts, or juries and are credible, persuasive expert witnesses.

COMPREHENSIVE SERVICES

Greenleaf and our network have experience advising litigators on the nuances of FDA regulation, preparing expert declarations or reports, and testifying during depositions and at trial. Greenleaf's team has worked with litigators engaged in a variety of disputes, including complex commercial litigation, unfair competition and false advertising cases, intellectual property litigation, product liability class actions, and securities class actions.


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

Executive Vice President, 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

Exec. Vice President, 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

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MARK KRAMER

Exec. Vice President, 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.

OUR EXPERIENCE.
YOUR SUCCESS.