Greenleaf Health

GREENLEAF HEALTH
CELL & GENE THERAPY 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.

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.

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.

COMPLIANCE AUDIT, TRAINING & REMEDIATION

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

DIGITAL HEALTH SERVICES

Greenleaf experts provide guidance to clients developing, commercializing, utilizing, and investing in innovative digital health technologies as they navigate the evolving landscape of FDA digital health requirements.

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.

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.

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.

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, as well as 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

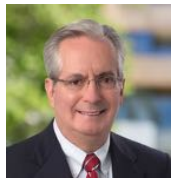
Principal, Regulatory Policy

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.

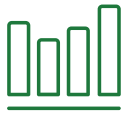
MADELEINE GIAQUINTO

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.

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.

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, working closely with clients to navigate today's evolving FDA regulatory environment.

UNMATCHED REGULATORY EXPERIENCE

Greenleaf serves as a trusted regulatory partner, advising clients on the complex process of bringing new therapies to market. The team's multidisciplinary expertise helps companies evaluating and prioritizing their drug development pipeline to understand and effectively manage regulatory risk.

PREMARKET REVIEW PROCESS

Greenleaf's team of experts provides strategic and technical consultation on: scientific and regulatory practices for clinical programs and regulatory submissions, including endpoint and biomarker selection and development; identification of and eligibility for special designations (e.g., breakthrough therapy designation, fast track, and accelerated approval); use of real-world evidence in regulatory submissions; and preparation for FDA milestone meetings (e.g., EOP2, pre-filing, mid-cycle, and end-of-review meetings).

REGULATORY POLICY SERVICES

Greenleaf offers strategic regulatory policy insight to support stakeholders' participation in and compliance with FDA programs and improve patient access to innovative medical products. Our team draws on deep expertise and institutional knowledge related to FDA regulatory policy, including novel programs; product designations and access to expedited programs; regulatory issues arising both pre and post market; regulatory intelligence and scientific policy; and building clients' capacity to effectively advance their regulatory policy priorities.

CELL & GENE THERAPY

The Drug and Biological Products Team assists sponsors of cell and gene therapies with FDA interactions and submissions — including early INTERACT and pre-IND meetings; requests for orphan drug, RMAT, and rare pediatric disease designations; and data comparability questions — and helps to clarify FDA requirements for specific types of cellular products. The team also provides guidance on how to maximize clinical trial design for cell and gene therapies to treat rare and ultra-rare diseases.

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
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

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

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.

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