Greenleaf Health

GREENLEAF HEALTH

DRUG & BIOLOGICAL PRODUCTS 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.


Greenleaf Health
DRUG & BIOLOGICAL
PRODUCT SERVICES

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 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).

KATE COOK

Principal, Regulatory Policy

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

JOSEPH GRIFFIN

EVP, Drug & Biological Products

20+ years of FDA service with a vast knowledge of the drug regulatory process, promotion, and labeling.

BRIAN CORRIGAN

EVP, Regulatory Policy

10+ years of experience in the biopharmaceutical industry provides in-depth knowledge of the U.S. health care system.

JULIA BARRETT, M.D.

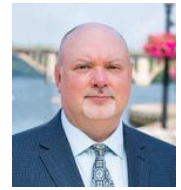
EVP, Drug & Biological Products

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

STEPHEN MASON

EVP, Regulatory Policy

Accomplished and diverse career specializing in regulatory and legislative policy development and analysis.



CHRIS LEPTAK, M.D., Ph.D.

SVP, Drug & Biological Products

14-year FDA tenure, including service as Acting Office Director of CDER's Office of Drug Evaluation Science.

SEAN HILSCHER

VP, Regulatory Policy

More than 10 years of experience as a consultant and product manager 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.

BECCA HUNT

Associate Director of Operations, Drug & Biological Products

Expertise in program management, facilitation, assessment, and reporting.

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.

DRUG & BIOLOGICAL PRODUCT PIPELINE REVIEW SERVICES

Greenleaf works with companies to identify valuable portfolio opportunities and to understand and effectively manage regulatory risks. By assessing regulatory risk early in the drug development process, companies can allocate resources more efficiently and plan their development strategy with greater confidence.

The expansive knowledge and diverse perspectives of the collective Greenleaf team enable clients to make timely, informed decisions to optimize and strategically manage their pipelines.

The Drug and Biological Products Team helps reduce regulatory uncertainties by providing the following services:

PIPELINE REVIEW

Greenleaf experts evaluate the various components critical to a drug development pipeline's clinical and regulatory success. The team's assessments span the drug development continuum from preclinical and clinical milestones through postapproval considerations. With experience across a wide range of therapeutic areas and therapeutic modalities, Greenleaf is able to provide guidance on a variety of clinical indications and drug development issues.

GAP ANALYSIS

Greenleaf's team helps guide drug development programs forward by working with the client's technical experts to perform a systematic review of factors that may impact the success of a product. Our experts then evaluate the collected data and information, identify missing elements, and help the client develop a plan to prioritize and address programmatic needs for individual therapeutic candidates and across the portfolio. Early identification of gaps allows companies to address issues proactively and make informed decisions about a program's viability, timing, and resources.

STRATEGY DEVELOPMENT

Greenleaf works with companies to create customized drug development strategies, from early-phase to late-stage development. Greenleaf's advisors provide realistic direction by determining the strengths and weaknesses of the pipeline, highlighting potential catalysts that could impact product development, assessing the competitive landscape, and considering study concept and clinical development plan design alternatives. The result is an actionable strategy that identifies development options and meaningful benchmarks to measure success and optimizes factors such as clinical positioning, product differentiation, and regulatory approval.

CELL & GENE THERAPY SERVICES

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

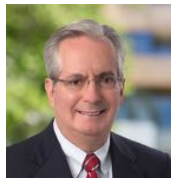
Principal, Regulatory Policy

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.



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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.

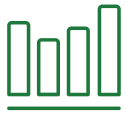
MADELEINE GIAQUINTO

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

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
DIGITAL HEALTH
SERVICES

DIGITAL HEALTH SERVICES TEAM

Greenleaf Health serves as a trusted partner to both large and small clients developing and commercializing innovative digital health technologies as they navigate the complex landscape of FDA regulations and policies. The firm's team of experts provides guidance to medical device and combination product manufacturers, pharmaceutical and biotechnology companies, trade associations, and other stakeholders implementing and complying with the FDA's digital health requirements.

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combination Products

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

BRIAN CORRIGAN

EVP, Regulatory Policy

10+ years of experience in the biopharmaceutical industry provides in-depth knowledge of the U.S. health care system.

SEAN HILSCHER

VP, Regulatory Policy

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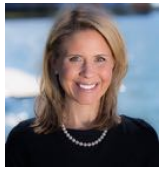

MAURA NORDEN

EVP, Medical Device & Combination Products

15 years of experience advising leading medical device and drug companies on FDA regulatory matters.

KALAH AUCHINCLOSS

EVP, Regulatory Compliance

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

MARIA BONNER

VP, Regulatory Compliance

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

DIGITAL HEALTH AREAS OF EXPERTISE

Greenleaf's digital health clients vary greatly in nature, scope, and levels of experience. Because there is no one-size-fits-all approach, each solution is built to fit the targeted needs of the client. Greenleaf regularly provides expertise to the following types of clients:

- Start-up and mid-sized software companies developing digital health mobile apps
- Drug companies entering the digital health space to enhance the patient or health care provider experience of their products
- Diagnostic testing companies developing applications to read diagnostic test results
- Consumer product companies entering the digital health space with limited FDA regulatory experience
- Health policy and research organizations developing, tracking, and responding to digital health policies, legislation, and initiatives
- Investors identifying and evaluating regulatory risks in potential digital health investments
- Trade associations and global drug and medical device companies developing digital health policy strategies
- Artificial intelligence (AI) program developers seeking FDA regulatory insight and clarity
- Telehealth companies partnering with clinical practitioners and life science companies to offer online access to medical products
- Drug and device companies using digital tools to conduct decentralized clinical trials

DIGITAL HEALTH SERVICES

The combined knowledge and substantial qualifications of the Greenleaf team ensure best-in-class insight for companies navigating digital health regulations. Greenleaf offers the following digital health-focused services:

REGULATORY STRATEGY & COMPLIANCE

Provide insight, clarity, and strategic consultation on digital health topics

- Advise clients on FDA regulatory policies, programs, and procedures, including questions related to jurisdiction to regulate, device classification, and potential pathways to market
- Partner with clients to design strategies for product development and premarket review
- Assist with marketing application preparation and submission
- Provide advice regarding FDA communications, including compliance and regulatory correspondence
- Advise on FDA labeling and postmarket safety requirements

ADVISORY SERVICES

Assist entities involved in digital health technology investments and transactions

- Perform due diligence and regulatory risk assessments of potential targets
- Advise investors on opportunities to manage and mitigate risks in order to achieve desired regulatory outcomes
- Research and analyze regulatory data sources

REGULATORY POLICY

Help clients keep pace with developments and navigate the emerging regulatory landscape

- Identify novel regulatory tools and approaches to optimize the development process
- Support clients in structuring their regulatory policy capabilities to effectively advance priorities
- Design and implement strategies that engage stakeholders, leverage alliances, and advance regulatory policy


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.

OUR EXPERIENCE.
YOUR SUCCESS.