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

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.

DRUG & BIOLOGICAL PRODUCTS TEAM

Greenleaf's Drug and Biological Products Team has a robust blend of regulatory and policy expertise and FDA institutional knowledge. The team's approach is guided by decades of regulatory experience in drug and biological product development, spanning all therapeutic areas.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

Former Director of the Office of New Drugs within the FDA's Center for Drug Evaluation and Research (CDER).

BOB MEYER, M.D.

Principal, Drug & Biological Products

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

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

An infectious disease physician by training, with a 28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

JOSEPH GRIFFIN

Executive Vice President, Drug & Biological Products

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

KATE COOK

Executive Vice President, Drug & Biological Products

Two decades of experience in policy development and as legal counsel on biological, medical device, and drug issues.

STEPHEN MASON

Senior Vice President, Regulatory Policy

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

BRIAN CORRIGAN

Senior Vice President, Regulatory Policy

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

KATIE MCCARTHY

Senior Vice President, Regulatory Policy

10+ years of policy experience specializing in scientific and regulatory issues impacting drug and biotechnology companies.

ADDITIONAL TEAM MEMBERS: **Rhona Baniqued, Colleen Vivaldi, Sean Hilscher**

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; identification of and eligibility for special designations, such as breakthrough therapy designation, RMAT, fast track, and accelerated approval; and preparation for FDA milestone meetings, such as EOP2, pre-filing meetings, mid-cycle review, and end-of-review meetings.

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.

REAL-WORLD EVIDENCE (RWE)

Greenleaf's exclusive agreement with Trio Health, a leading provider of real-time data on real-world patients, gives clients the advantage of Trio's groundbreaking Multi-Disease Platform (MDX) integrated with Greenleaf's unrivaled regulatory knowledge. Greenleaf's team of experts provides end-to-end guidance to companies utilizing MDX data on how to optimize and validate the information to drive effective regulatory strategies.

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

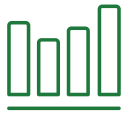
Greenleaf's team helps guide drug development programs forward by working with the client's technical experts to perform a systematic review of factors that may impact the success of a product. Our experts then evaluate the collected data and information, identify missing elements, and help the client 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

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.

REAL-WORLD EVIDENCE SERVICES

Trio Health

Real-world evidence — the concept of using real-world data (RWD) to improve clinical evidence — has the potential to transform the drug development landscape.

The Food and Drug Administration recognizes the opportunities presented by RWE and is developing a new paradigm for its use in regulatory decision-making.

Companies prepared to employ the power of RWE will require more than just raw data — that's why Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight.

GREENLEAF + TRIO

Greenleaf's exclusive agreement with Trio Health, a leading provider of real-time data on real-world patients, gives clients the advantage of Trio's groundbreaking Multi-Disease Platform (MDX) technology integrated with Greenleaf's unrivaled regulatory knowledge. The result is a comprehensive resource for enhancing and contextualizing evidence derived from RWD.

MDX PLATFORM

The first-of-its-kind MDX platform tracks patients throughout the course of their treatment by combining disparate information from the physician, pharmacy, and payer 'trio.' MDX offers life science customers best-in-class speed, data certainty, and unparalleled visibility across the clinical and commercial lifecycle.

Trio's comprehensive and high-quality databases are on caliber with FDA-level rigor, giving pharmaceutical and biotechnology companies, specialty pharmacies, and physicians access to information and opportunities that can be leveraged to support pre- and postmarketing activities.

UNRIVALED INSIGHT

When integrated with Greenleaf's regulatory expertise, Trio's advanced analytics MDX platform delivers unrivaled insights to the industry. Clients gain the ability to transform real-world data into actionable intelligence to innovate and make better decisions, with greater confidence, throughout the product lifecycle. Greenleaf's team of regulatory experts provides end-to-end guidance to companies utilizing MDX data on how to optimize and validate the information to drive effective regulatory strategies.

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).

KATE COOK

EVP, Drug & Biological Products

Two decades of experience in policy development and as legal counsel on biological, medical device, and drug issues.

MAURA NORDEN

SVP, Medical Device & Combination Products

More than a decade of experience advising medical device and drug companies 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.

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