GREENLEAF HEALTH
DIGITAL HEALTH 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 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.

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

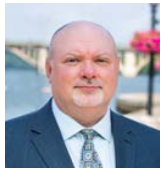
EVP, Regulatory Policy

15+ years in the biopharmaceutical industry focused on regulatory policy development and strategic clinical development support.

SEAN HILSCHER

VP, Regulatory Policy

Deep experience in regulatory intelligence and policy analysis, with specific expertise in real-world evidence (RWE) and digital health.



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

EVP, Drug & Biological Products

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

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

More than 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

MEDICAL DEVICE & COMBINATION PRODUCT SERVICES

MEDICAL DEVICE & COMBINATION PRODUCTS TEAM

Guided by decades of experience, Greenleaf's Medical Device and Combination Products Team provides unmatched knowledge of the life sciences regulatory process and serves as a trusted partner for companies navigating the complexities of product lifecycle management.

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combination Products

Former Director of the FDA's Center for Devices and Radiological Health (CDRH); 35-year career includes service as a physician, senior FDA official, and member of the U.S. Public Health Service.

MAURA NORDEN

EVP, Medical Device & Combination Products
General Counsel

More than 15 years of experience advising FDA-regulated entities, investors, and public health organizations on a broad range of FDA regulatory matters.

SAMANTHA EAKES

VP, Regulatory Affairs

More than seven years of FDA regulatory consulting experience and a diverse background in public health, public policy, and the nonprofit sector.

HEATHER ROSECRANS

EVP, Medical Device & Combination Products

One of the nation's leading 510(k) experts, with an FDA career that spanned more than 30 years and included a pivotal role in developing the FDA's 510(k) program.

MARK KRAMER

EVP, Medical Device & Combination Products

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

CATHERINE ROWE

Executive Director of Operations,
Medical Device & Combination Products

More than 20 years of professional experience in marketing, sales, and project management.

MEDICAL DEVICE & COMBINATION PRODUCTS SERVICES

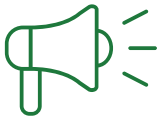
Greenleaf's Medical Device and Combination Products Team applies extensive FDA experience to determine the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

UNMATCHED REGULATORY EXPERIENCE

Greenleaf guides clients through the complex regulatory process, from the earliest stages of product development, through the FDA review process, to marketing authorization and compliance with postmarket requirements and quality systems.

PREMARKET REVIEW PROCESS

Greenleaf provides expert direction on scientific and regulatory strategies for clinical programs and regulatory submissions. Experts also provide recommendations and preparation for FDA meetings, including medical device advisory panel meetings, and FDA communications.



MARKETING & PROMOTIONAL PRACTICES

Greenleaf provides strategic guidance to medical device firms on labeling requirements, promotional materials, direct-to-consumer advertising review processes, and use of social media. Experts also guide companies in remediation of untitled and warning letters.

LITIGATION SUPPORT SERVICES

Greenleaf's deep bench 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 product types across the product lifecycle. Greenleaf professionals have experience preparing expert declarations, drafting professional expert reports and depositions, and testifying at trial, and have worked with litigators representing FDA-regulated clients in a wide array of disputes involving complex FDA issues.

COMBINATION PRODUCT SUPPORT SERVICES

Greenleaf provides strategic advice throughout the combination product lifecycle, including all potential premarket pathways (NDA, ANDA, BLA, PMA, 510(k), De Novo). Additionally, Greenleaf has expertise to help sponsors determine the regulatory identity (classification) of their product as a drug, device, biological product, or combination product.

PRODUCT EXPERTISE

Our experts have extensive experience with:

- Drug-coated devices
- A wide range of drug delivery systems including subcutaneous, inhaled, injected, topical, intrathecal, and closed loop
- Designation and development of companion diagnostics
- Single-entity, co-packaged, and cross-labeled combination products

PREMARKET STRATEGY & SUBMISSIONS

Greenleaf works with clients to support an effective and efficient development and submission process, offering:

- Preparation and assistance with requests for designation (RFDs) and pre-RFDs to determine primary mode of action (PMOA) and lead FDA Center, and strategies to influence PMOA determination in line with company's objectives
- Strategic considerations in filing single vs. separate marketing application(s) for the drug, biological product, and/or device constituent parts of a combination product
- Strategies to avoid the need for cross-labeling of constituent parts
- Advice on post-approval changes and bridging strategies
- Review of/recommendations for sufficiency of device design control documentation, including verification and validation plans, protocols, and reports for the device constituent part and combination product as a whole
- Review of/recommendations for human factors plans, protocols, and reports, including comparative use protocols for generic combination products
- Training in combination product statutory requirements, regulations, policies, and procedures
- Assessment of regulatory precedents and guidance to inform desired regulatory outcomes

FDA INTERACTIONS

As former FDA leaders, Greenleaf consultants can provide insight and strategies to:

- Enhance communication with the FDA, including translating between "CDER speak" and "CDRH speak"
- Break logjams or obtain assistance navigating Centers
- Work effectively with the Office of Combination Products (OCP)
- Respond to FDA deficiencies to investigational/marketing applications and OCP questions on pre-RFD submissions

CGMP & POSTMARKET COMPLIANCE

Greenleaf assists companies in complying with regulatory requirements for combination products through:

- Review of/advice on company procedures
- Advice on cGMP and postmarket reporting requirements for single-entity, co-packaged, and cross-labeled combination products, including quality system "call-out" requirements for drugs, devices, and biological products
- cGMP audits
- Training on both cGMP and postmarket reporting requirements for combination products

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 30 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), 2009-2016.

SANDRA KWEDER, M.D.

Principal, Drug & Biological Products

Former Deputy Director of the FDA's Office of New Drugs and Deputy Director of the FDA's Europe Office and Liaison to the EMA.

JOSEPH GRIFFIN

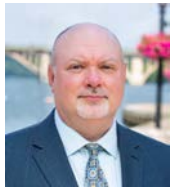
EVP, Drug & Biological Products

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

BRIAN CORRIGAN

EVP, Regulatory Policy

15+ years in the biopharmaceutical industry focused on regulatory policy development and strategic clinical development support.



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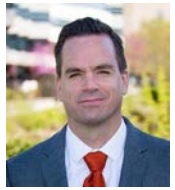


STEPHEN MASON

EVP, Regulatory Policy

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

WILSON BRYAN, M.D.

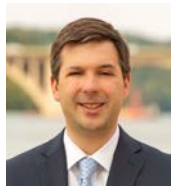
EVP, Drug & Biological Products

FDA career of 19 years, serving as Director of CBER's Office of Tissues and Advanced Therapies (OTAT) from 2016-2023.

SARAH MCGARRY, M.D.

SVP, Drug & Biological Products

During 18 years with FDA CDER and CBER, led review teams for many significant approvals and served as expert advisor on drug review process.



SEAN HILSCHER

VP, Regulatory Policy

Deep experience in regulatory intelligence and policy analysis, with specific expertise in RWE and digital health.

TANVI MEHTA

Manager, Regulatory Affairs & Policy

Brings analytical approach to regulatory policy from background in financial services and health care business.

RHONA BANIQUED Exec. Director of Operations, Drug & Biological Products

BECCA HUNT Assoc. Director of Operations, Drug & Biological Products

STEPHEN POWER Assoc. Director of Operations, Drug & Biological Products

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 expedited programs (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 helps sponsors of cell and gene therapies understand and respond to FDA requirements and guidance for these products and optimize FDA interactions and submissions at all stages of development and review. The team also provides guidance on clinical trial design for cell and gene therapies to treat rare and ultra-rare diseases and assists sponsors preparing requests for orphan drug, RMAT, breakthrough therapy, fast track, and rare pediatric disease designations.

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.


Greenleaf Health
QUALITY & COMPLIANCE
SERVICES

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, acting in high-profile positions at the Agency and senior leadership roles within industry.

CYNTHIA SCHNEDAR
Principal, Regulatory Compliance
30-year career as a compliance expert; formerly 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
EVP, Regulatory Compliance
More than 15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

DONALD D. ASHLEY
EVP, Regulatory Compliance
25-year compliance and enforcement career, including six years at FDA as Director of CDER's Office of Compliance.

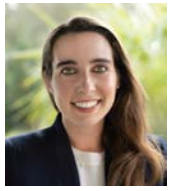
KRISTEN GRUMET
SVP, Regulatory Compliance
35-year compliance career, including role as an FDA field investigator specializing in medical devices.

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

LIZ OESTREICH
SVP, Regulatory Compliance
Diverse background provides critical expertise within legal, public policy, regulatory advocacy, and non-profit sectors.

TOM BERRY
SVP, Regulatory Compliance
Extensive regulatory experience includes 20 years with the FDA and 10 years as a clinical/hospital pharmacist.

DAWN WYDNER
SVP, Regulatory Compliance
10-year global quality and compliance career in the FDA's Office of Regulatory Affairs.



MARIA BONNER
VP, Regulatory Compliance
Policy and legal experience in both the public and private sectors provides deep understanding of regulatory policy.

MADELEINE GIAQUINTO
Director, Regulatory Affairs
Legal and policy expertise, with a robust portfolio of advising on FDA regulatory compliance for a range of product types.

BRITTANY MILBY Exec. Director of Operations, Regulatory Compliance
LAURA BARTEE Exec. Director of Operations, Regulatory Compliance
ELLEIGH MORRIS Assoc. Director of Operations, Regulatory Compliance & Finance

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

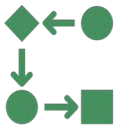
Greenleaf works with life science entities to evaluate and strengthen compliance functions with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.

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.

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

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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.

Greenleaf Health

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

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

Deep experience in regulatory intelligence and policy analysis, with specific expertise in real-world evidence (RWE) and digital health.

TANVI MEHTA

Manager, Regulatory Affairs & Policy

Brings analytical approach to regulatory policy from background in financial services and health care business.

RHONA BANIQUED

Executive Director of Operations, Drug & Biological Products

More than 20 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

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

EVP, Regulatory Policy

15+ years in the biopharmaceutical industry focused on regulatory policy development and strategic clinical development support.

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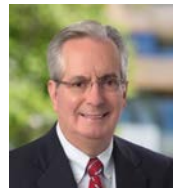

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A leader in drug and biological product lifecycle management with 30 years of regulatory and academic leadership.

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CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

30-year career as a compliance expert; formerly Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER).

KALAH AUCHINCLOSS

EVP, Regulatory Compliance

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

MAURA NORDEN

EVP, Medical Device & Combo. Products

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

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.

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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