

# **GREENLEAF HEALTH**

## **REGULATORY POLICY CAPABILITIES**

**OUR EXPERIENCE.  
YOUR SUCCESS.**

Greenleaf Health is a leading FDA regulatory consulting firm guiding companies through the changing FDA landscape.

# ABOUT GREENLEAF HEALTH



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## 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.

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## 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 product development, manufacturing, quality, compliance, 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.





# REGULATORY POLICY SERVICES

# REGULATORY POLICY SERVICES TEAM

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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 BANIQUEUED

### 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





# 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

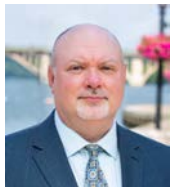
20+ years of FDA service, with a vast knowledge of the drug regulatory process, promotion, and labeling.



## BRIAN CORRIGAN

### EVP, Regulatory Policy

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



## 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.



## 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.



# QUALITY & COMPLIANCE SERVICES



# PRODUCT QUALITY, MANUFACTURING & COMPLIANCE TEAM

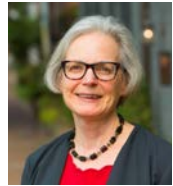


Greenleaf's Product Quality, Manufacturing, and Compliance Team has a proven track record of achieving success and providing services that are recognized as best in class by companies seeking to strengthen their quality management systems.



**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.



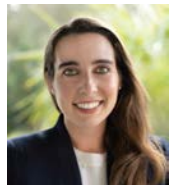
**TOM BERRY**

**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.



## 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.



## COMPLIANCE REMEDIATION

Greenleaf experts bring an unmatched level of credibility and trust when interacting with the FDA. The team has the experience and insight to successfully guide companies along the remediation pathway.



## CONSULTATION, TRAINING & REGULATORY GUIDANCE

Greenleaf delivers insight and guidance that help clients achieve business and regulatory objectives. The team also develops and delivers training on a variety of regulatory subjects.



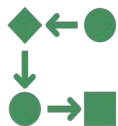
## INSPECTION READINESS

Greenleaf experts strengthen clients' readiness for FDA preapproval and surveillance inspections through consulting, training, audits, and mock inspections.



## 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.



## 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.



## 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.

A woman with blonde hair tied back, wearing a light-colored top and a pearl necklace, is seated at a desk. She is looking towards a large Apple iMac computer monitor. The scene is dimly lit, with light coming from a window with blinds in the background. A green semi-transparent banner is overlaid across the middle of the image, containing the text.

# 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.



## 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.



## MAURA NORDEN

### EVP, Medical Device & Combination Products

#### General Counsel

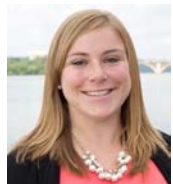
More than 15 years of experience advising FDA-regulated entities, investors, and public health organizations on a broad range of FDA regulatory matters.



## 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.



## 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.



## 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



# CELL & GENE THERAPY SERVICES



# CELL & GENE THERAPY TEAM



Greenleaf is comprised of the foremost experts in the regulatory field, including former leaders in the FDA's offices overseeing cell and gene therapies, drugs and biologics, drug product quality, and compliance, as well as medical devices and combination products. The Cell and Gene Therapy Team draws on decades of regulatory experience in senior FDA positions, international public health organizations, academia, and industry.



## 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.



## 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) from 2009-2016.



## WILSON BRYAN, M.D.

### Executive VP, Drug & Biological Products

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



## 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.



## CYNTHIA SCHNEDAR

### Principal, Regulatory Compliance

30-year career as a compliance expert; formerly Director of the Office of Compliance for the FDA's CDER.



## KALAH AUCHINCLOSS

### Executive VP, 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.



## 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.



## MADELEINE GIAQUINTO

### Director, Regulatory Affairs

Legal and policy expertise, with a robust portfolio of experience advising on FDA regulatory compliance for a range of product types.

# CELL & GENE THERAPY SERVICES

Greenleaf assists sponsors of cell and gene therapy products by optimizing FDA interactions, submissions, manufacturing technology, and quality systems. Working cross-functionally, Greenleaf's experts ensure that clients have the specialized strategic insight and multidisciplinary perspective needed to navigate the rapidly evolving regulatory landscape for cell and gene therapies.



## PRODUCT DEVELOPMENT & REVIEW

Greenleaf helps sponsors understand and respond to the FDA requirements and guidance applicable to cell and gene therapies, including aspects of device and combination product regulation when relevant. Our experts specialize in:

- strategic FDA interactions throughout development, including formal meetings
- clinical trial design
- submissions and expedited programs
- FDA review communications and labeling discussions
- postmarket requirements



## MANUFACTURING & QUALITY CONTROLS

Greenleaf experts provide clients with strategic and technical support for establishing manufacturing and quality controls and complying with the FDA's multiple current GXP regulations, in addition to:

- pre- and postapproval inspection readiness
- compliance assessments
- evaluating and responding to FDA regulatory correspondence
- engaging with CBER's Advanced Technologies Team



## RARE DISEASE GUIDANCE

For sponsors developing cell and gene therapies to treat rare and ultra-rare diseases, Greenleaf offers guidance on maximizing trial design using appropriate clinical endpoints and natural history study data in support of efficient product development. Our experts also assist sponsors preparing requests for orphan drug and rare pediatric disease designations.



## REGULATORY LANDSCAPE

Greenleaf monitors and analyzes the regulatory environment for emerging trends in cell and gene therapy regulation that could potentially impact current development programs, as well as changes to the competitive landscape.

Our Advisory Services Team also offers focused due diligence and regulatory risk assessment in this space.





# 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.



## MAURA NORDEN

### EVP, Medical Device & Combination Products

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



## BRIAN CORRIGAN

### EVP, Regulatory Policy

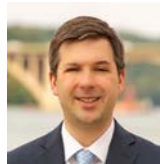
15+ years in the biopharmaceutical industry focused on regulatory policy development and strategic clinical development support.



## 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.



## SEAN HILSCHER

### VP, Regulatory Policy

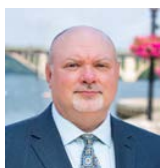
Deep experience in regulatory intelligence and policy analysis, with specific expertise in real-world evidence (RWE) and digital health.



## MARIA BONNER

### VP, Regulatory Compliance

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



## 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.



# 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



**OUR EXPERIENCE.**  
**YOUR SUCCESS.**