Greenleaf Health

GREENLEAF HEALTH
COSMETICS REGULATORY 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.

COSMETICS REGULATORY SERVICES

COSMETICS REGULATORY SERVICES TEAM

Greenleaf experts draw on decades of FDA and industry experience to provide best-in-class insight on all aspects of the FDA's regulation of cosmetics. Our wide-ranging expertise enables us to advise companies:

- entering the cosmetics space with limited FDA regulatory experience and/or knowledge;
- with existing products in the cosmetics space, that now need to interpret and comply with new FDA regulatory requirements under the Modernization of Cosmetics Regulation Act;
- marketing cannabis-derived consumer products (e.g., CBD-containing products) in the cosmetics space; and
- marketing novel products, such as innovative products or combination products that include a cosmetic with an over-the-counter drug or device, that are seeking assistance in complying with the most appropriate regulatory framework.

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

Former FDA senior official held high-profile positions at the Agency and senior leadership roles within industry.

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 (CDER).

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.

MAURA NORDEN

EVP, Medical Device & Combination Products

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

LIZ OESTREICH

SVP, Regulatory Compliance

Diverse background provides critical expertise within legal, public policy, regulatory advocacy, and non-profit sectors.

SAMANTHA EAKES

VP, Regulatory Affairs

Master's in Public Health from the Boston University School of Public Health provides critical public health, advocacy, and regulatory knowledge.

MADELEINE GIAQUINTO

Director, Regulatory Affairs

Legal and policy expertise and experience advising on compliance with federal health programs and regulations.

COSMETICS REGULATORY SERVICES

Greenleaf provides guidance to cosmetics and aesthetic product manufacturers, beauty and personal care product companies, trade associations, and other stakeholders implementing and complying with FDA regulations and policies under the Federal Food, Drug, and Cosmetic (FD&C) Act, including new requirements stemming from the Modernization of Cosmetics Regulation Act (MoCRA), the Federal Fair Packaging and Labeling Act, and related statutes and regulations. Our services include:

REGULATORY POLICY

Helping clients keep pace with, and better navigate, the emerging regulatory landscape

- Advising clients on new FDA rules and reports mandated by MoCRA and their underlying impact on the broader regulatory framework
- Providing regulatory intelligence gathering and supporting clients in developing and implementing regulatory policy capabilities and strategies to effectively advance their priorities
- Identifying opportunities for clients to engage with the FDA and other stakeholders and leverage alliances to influence regulatory policy

REGULATORY STRATEGY & COMPLIANCE

Working with clients to clarify and support compliance with the regulatory requirements for consumer products marketed in the cosmetics space

- Providing guidance on FDA regulatory policies, programs, and procedures, including advising on the anticipated FDA jurisdictional determination for the product
- Advising on all aspects of MoCRA, including:
  - New marketing, facility registration, and product listing requirements
  - Small business accommodations under MoCRA
  - FDA's expanded enforcement authorities under MoCRA, and relevant FDA enforcement trends
- Providing compliance services, such as:
  - Helping clients understand applicable FDA manufacturing and quality controls, including GXP regulations for cosmetics
  - Conducting compliance assessments and gap analyses of manufacturing and quality practices and systems, and providing inspection readiness services
  - Assistance evaluating and responding to FDA communications related to enforcement actions and other regulatory correspondence
- Advising on FDA labeling requirements and product claims made on packaging and marketing materials
- Counseling on postmarket safety and reporting requirements


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

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 (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
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.

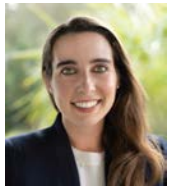
KRISTEN GRUMET
SVP, Regulatory Compliance
25-year compliance career, including role as an FDA field investigator specializing in medical devices.

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 and experience advising on compliance with federal health programs and regulations.

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.

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

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

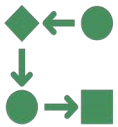
Greenleaf works with life science entities to evaluate and strengthen compliance functions with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.

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.

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

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

Master's in Public Health from the Boston University School of Public Health provides critical public health, advocacy, and regulatory knowledge.

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 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.

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). Our experts have extensive experience with drug-coated devices and a wide range of drug delivery systems including subcutaneous, inhaled, injected, topical, intrathecal, and closed loop. We also have knowledge of, and experience with, designation and development of companion diagnostics.

Additionally, Greenleaf has expertise to help sponsors determine the regulatory identity (classification) of their product as a drug, device, biological product, or combination product and can prepare Requests for Designation (RFDs) and pre-RFDs to determine the regulatory identity and responsible FDA Center.

PREMARKET STRATEGY & SUBMISSIONS

- Preparation and/or assistance with preparation of RFDs and pre-RFDs to determine primary mode of action (PMOA) and lead FDA Center assignment for combination products; strategies to help 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 help avoid the need for cross-labeling of constituent parts and advice on post-approval changes and bridging strategies for combination products
- 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

- Advice on communicating with the FDA, including help translating between "CDER speak" and "CDRH speak"
- Strategies to break logjams or obtain assistance navigating Centers
- Advice on working effectively with the Office of Combination Products (OCP)
- Review of/recommendations for responses to FDA deficiencies to investigational/marketing applications and responses to OCP questions on pre-RFD submissions

CGMP & POSTMARKET COMPLIANCE

- Review of/advice on company procedures to comply with regulatory requirements for combination products
- Advice on cGMP requirements for single-entity, co-packaged, and cross-labeled combination products, including compliance with quality system "call-out" requirements for drugs, devices, and biological products
- Audits of company facilities for compliance with cGMP requirements for combination products
- Advice on postmarket reporting requirements for single-entity, co-packaged, or cross-labeled combination products
- Training on both cGMP and postmarket reporting requirements for combination products

MEDICAL DEVICE & COMBINATION PRODUCTS SERVICES

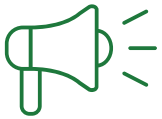
Greenleaf's Medical Device and Combination Products Team applies extensive FDA experience to determine the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

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.

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).

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

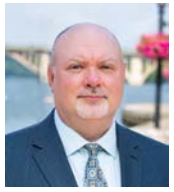
EVP, Drug & Biological Products

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

BRIAN CORRIGAN

EVP, Regulatory Policy

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



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

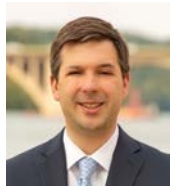
EVP, Drug & Biological Products

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.



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.

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 18 years of private sector marketing and project management experience.

BECCA HUNT Associate Director of Operations, Drug & Biological Products

STEPHEN POWER Associate 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 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.

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

10+ years of experience in the international and U.S. health care markets.

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 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

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

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

JOHN TAYLOR

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JOHN JENKINS, M.D.

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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).

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combo. Products

35-year career includes service as a physician and Director of the FDA's Center for Devices and Radiological Health (CDRH).

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Principal, Regulatory Compliance

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

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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.

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

25-year compliance career includes serving as Director of the Office of Compliance for the FDA's CDER.

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.

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.

OUR EXPERIENCE.
YOUR SUCCESS.