Greenleaf Health

OUR EXPERIENCE. YOUR SUCCESS.

COMPREHENSIVE SERVICES & SUPPORT

Greenleaf's comprehensive services and wealth of experience ensure that clients can count on expert direction as they encounter complex regulatory challenges. Greenleaf professionals work as teams specializing in product quality, manufacturing, and compliance; medical devices and combination products; and drug and biological products.

Product Quality, Manufacturing & Compliance

Greenleaf's Product Quality, Manufacturing, and Compliance Team provides assistance and support to companies, trade associations, and other stakeholders regulated by the U.S. Food and Drug Administration (FDA). Greenleaf experts identify and promote practices that will align a client's approach with the FDA's quality, safety, and compliance expectations.

Medical Device & Combination Products

Greenleaf's Medical Device and Combination Products Team 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.

Drug & Biological Products

Greenleaf serves as a trusted partner when maneuvering the sophisticated process of bringing new therapeutics to market. The Drug and Biological Products Team specializes in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements.

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 APPROACH

Greenleaf is committed to serving our clients' needs with extensive expertise, unwavering integrity, and strategic insight in a manner that supports availability of safe, effective, and high-quality drugs, biologics, and devices.

TEAM OF EXPERTS

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.

REGULATORY SERVICES

The firm's targeted regulatory capabilities include:

- Strategic and technical guidance for medical product development and regulatory review
- Product quality, manufacturing, and compliance
- FDA meeting preparation and communication
- Advisory services
- Medical product labeling and promotion
- Regulatory policy consultation, strategic planning, and communications
- Compliance assessments, remediation, and inspection readiness

Greenleaf is a regulatory consulting firm and does not provide legal advice or legal services.

DISTINGUISHED LEADERSHIP

Greenleaf's team of experts includes former leaders and regulatory professionals from the FDA, Capitol Hill, top global pharmaceutical and medical device companies, leading law firms, and the top U.S. biotechnology trade organization.

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

John Taylor joined Greenleaf following a distinguished FDA career of more than 20 years. Taylor served in many high-profile positions at the FDA, as well as in senior leadership roles within industry.

KATHLEEN SONNTAG

Chief Operating Officer

Kathleen Sonntag is a veteran in the financial services field, with a broad career emphasizing information technology, data analysis, and the use of technology to enable business processes.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

With a 25-year career at the FDA, including 15 years in senior leadership positions within the Center for Drugs, Dr. Jenkins is an expert in the statutes and regulations that guide drug development.

DANIEL SCHULTZ, M.D.

Principal, Medical Devices & Combination Products

Dr. Schultz's distinguished 35-year public service career includes his role as a member of the U.S. Public Health Service and as Director of the FDA's Center for Devices.

BOB MEYER, M.D.

Principal, Drug & Biological Products

Dr. Meyer brings more than 25 years of regulatory, industry, and academic leadership to Greenleaf, including roles at the FDA, Merck, and the University of Virginia.

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

An infectious disease physician by training, Dr. Midthun's 28-year career in public service includes her role as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

Cynthia Schnedar's 25-year compliance career includes her role as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research (CDER).

DAVID ELDER

Principal, Regulatory Compliance

A 23-year veteran of the FDA, David Elder served as a senior FDA official with prominent roles in domestic and foreign inspections, recalls and emergencies, and compliance actions.

SANDRA KWEDER, M.D.

Principal, Drug & Biological Products

Dr. Kweder served for six years as Deputy Director of the FDA's Europe Office and the Agency's Liaison to EMA following 14 years as Deputy Director of CDER's Office of New Drugs.

COMPREHENSIVE SERVICES

Members of the Greenleaf team work cross-functionally to provide a full-service engagement that ensures clients can count on expert direction as they encounter regulatory challenges. Greenleaf's collaborative services include:

Advisory Services

Life sciences transactions involve a key component not found in other commercial transactions – the product or company of interest is regulated by the FDA, and regulatory issues therefore must be carefully considered. Greenleaf applies vast FDA institutional knowledge to equip investors with the thorough and focused due diligence needed to ensure that decisions and transactions reflect regulatory risk.

Cell & Gene Therapy

New cell and gene therapies are now available for patients, some after decades of research. The culmination of these efforts will be novel treatments, and perhaps ultimately cures, for devastating and intractable illnesses. Greenleaf assists sponsors by optimizing FDA interactions and submissions to support development, manufacturing, quality, compliance, and regulatory review.

Regulatory Policy Services

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.

Digital Health

Players in the digital health space face unique challenges in navigating an ever-changing regulatory landscape, as FDA regulators try to keep up with the pace of digital health technology development. 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.

Litigation Support Services

Greenleaf's litigation support services include an outside network of experienced and knowledgeable FDA experts who were thoughtfully selected by Greenleaf and are adept at advising litigators representing FDA-regulated clients. The firm's deep bench and network provide authoritative, objective expert opinions that may make a difference in how disputes are resolved.