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.

ABOUT GREENLEAF

Greenleaf Health is a full-service regulatory consulting firm guiding companies through the changing FDA landscape.

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

UNMATCHED REGULATORY EXPERTISE

Greenleaf's decades of hands-on experience in the regulatory space is unmatched. The firm'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.

DISTINGUISHED EXPERIENCE & LEADERSHIP

Greenleaf's team is comprised of experts with a combined total of more than 300 years of FDA experience.

JOHN TAYLOR

President
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.

DANIEL SCHULTZ, M.D.

Principal, Medical Device & Combination Products

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

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.

BOB MEYER, M.D.

Principal,
Drug & Biological Products

Dr. Meyer brings more than 25 years of regulatory, industry, and academic leadership to Greenleaf, including prominent 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 spent 28 years in public service, including her leadership as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

MAURA NORDEN, J.D.

General Counsel
SVP, Medical Device & Combination Products

Maura Norden brings 15 years of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

TARYN WALPOLE

Chief of Staff
EVP, Regulatory Affairs

Taryn Walpole is a strategic regulatory advisor and senior communications executive who brings to Greenleaf more than 20 years of leadership experience on Capitol Hill and at the FDA.

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:

Real-World Evidence

Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight via Trio's groundbreaking real-world evidence (RWE) technology platform.

Advisory Services

Greenleaf understands the complex environment within which life sciences transactions take place and advises investors on potential issues and regulatory risks that may be identified during such transactions.

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.