Greenleaf Health

Comprehensive Quality, Manufacturing & Compliance Services

Our experience. Your success.

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

ABOUT GREENLEAF HEALTH

Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical and medical device companies researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

Founded in 2007, Greenleaf's team of experts includes former leaders and regulatory experts from the FDA, Capitol Hill, top global pharmaceutical companies, leading law firms, and the top U.S. biotechnology trade organization.

With decades of experience in senior positions at the FDA and throughout industry, Greenleaf's team of respected professionals provides unmatched expertise that companies need when navigating today's changing FDA regulatory environment.

UNMATCHED REGULATORY EXPERIENCE

Greenleaf's robust blend of regulatory expertise and FDA institutional knowledge allows the firm to provide unmatched guidance to companies developing medical products for the U.S. market.

Greenleaf experts draw on a combined total of more than 200 years of FDA experience to provide reliable, objective advice to FDA-regulated companies.

This wealth of experience allows Greenleaf to understand the broad health care industry and provide expert guidance throughout the product lifecycle.

GREENLEAF'S REGULATORY TEAMS

Greenleaf's experts lead teams specializing in product quality, manufacturing, and compliance; medical devices and combination products; and drug and biological products.

The firm's experts specialize in the following areas:

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.

DRUG & BIOLOGICAL PRODUCTS

Greenleaf serves as a trusted regulatory partner by advising companies on the complex process of bringing new therapeutics to market and guiding companies through product lifecycle management decisions.

MEDICAL DEVICES & COMBINATION PRODUCTS

Greenleaf applies extensive regulatory expertise to guide medical device clients from early stage development to marketing authorization and throughout the product lifecycle.

PRODUCT SUBMISSIONS

Greenleaf offers strategic and technical guidance on all aspects of the medical device submissions process, including the preparation of 510(k) and PMA submissions, 513(g) requests, de novo petitions, HUD, HDE and IDE applications, pre-submissions, and requests for designation of a combination product.

ADVISORY SERVICES

Greenleaf understands the complex environment within which life science transactions take place and frequently advises investors to evaluate potential issues and regulatory risks that may be identified during life science transactions.

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE SERVICES

In today's dynamic regulatory environment, keeping pace is not enough. Success is achieved by staying one step ahead of the pack. That's easier said than done, which is why successful companies recognize the need for a trusted regulatory partner to help navigate the challenging FDA landscape.

Greenleaf's 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. Greenleaf's compliance experts combine their depth of knowledge and breadth of expertise to guide companies through the evolving quality, compliance, and regulatory environment. Team members include:

JOHN TAYLOR

President

Principal, Compliance & Regulatory Affairs

Former FDA senior official held many high-profile positions at the Agency, as well as a senior leadership roles within industry.

DAVID ELDER

Executive Vice President, Regulatory Compliance

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

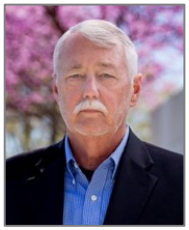
TARYN FRITZ WALPOLE

Executive Vice President, Corporate & Regulatory Affairs

15+ years of leadership experience on Capitol Hill and at the FDA, including service as Deputy Chief of Staff.

ADDITIONAL TEAM MEMBERS

Liz Oestreich | Samantha Eakes | Brittany Milby



MICHAEL CHAPPELL

Principal, Regulatory Compliance

Former FDA Acting Associate Commissioner for Regulatory Affairs, where he served as head of the FDA field force.

CYNTHIA SCHNEDAR

Executive Vice President, Regulatory Compliance

25-year compliance career, including role as Director of the FDA's drug compliance office.

KALAH AUCHINCLOSS

Senior VP, Regulatory Compliance & Deputy General Counsel

10+ years of experience on Capitol Hill, in the private sector and at the FDA, including Deputy Chief of Staff.

KRISTEN GRUMET

Senior VP, Regulatory Compliance

25-year compliance career, including role as an FDA Field Investigator specializing in medical devices.

EXPANDED QUALITY & COMPLIANCE SERVICES

The FDA's continued emphasis on proactive quality management and CGMP compliance presents new challenges and opportunities for the life science industry, making it essential for companies to build quality, safety, and integrity into their products.

Recognizing this, Greenleaf has expanded its portfolio of services to include comprehensive on-site compliance assessments, remediation, and inspection readiness. Greenleaf's expanded strategic capacity and capabilities include the following quality, compliance, and manufacturing services:

Compliance Assessments

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

Consultation, Training & Regulatory Guidance

Greenleaf partners with companies to deliver insight and guidance that helps companies achieve their business and regulatory objectives. The team also develops and delivers training in a variety of regulatory areas.

Inspection Readiness

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

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 Greenleaf team has the FDA experience and insight to guide companies along the remediation pathway.

THE GREENLEAF APPROACH

Members of the Greenleaf team work cross-functionally to ensure a full-service experience when navigating the challenging FDA regulatory environment.

The combined knowledge and extensive experience of the full Greenleaf team ensures clients can count on expert assistance through complex regulatory challenges.

FULL-SERVICE REGULATORY EXPERIENCE

In addition to comprehensive quality, manufacturing, and compliance services, Greenleaf's regulatory services include:

- Strategic and technical guidance for medical product development and regulatory review
- Product quality, manufacturing, and compliance
- Advisory services
- FDA meeting preparation and communication
- Medical device product submissions - 510(k), PMA, DeNovo, HDE, IDE and 513(g) requests
- Medical product labeling and promotion
- Regulatory policy guidance
- Strategic planning, communications, and engagement
- Best practices and benchmarking
- Product lifecycle management

THE GREENLEAF DIFFERENCE

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