Greenleaf Health

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

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.

A TRUSTED PARTNER

Greenleaf Health provides services that are recognized as best in class by companies seeking strategic and technical expertise to strengthen their quality management systems and guide them through challenging quality and compliance matters.

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.

STRATEGIC & TECHNICAL CAPABILITIES

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

Recognizing this, Greenleaf has expanded the firm's strategic capacity and capabilities to support comprehensive quality, compliance, and manufacturing services. In addition to Greenleaf's core regulatory consulting services, the firm's capabilities now include:

- **Inspection Readiness**: Strengthen clients' readiness for FDA pre-approval and surveillance inspections through consulting, training, audits and mock inspections.
- **Compliance Assessments**: Perform objective audits and assessments of a clients' operations to identify strengths and areas of needed improvement.
- **Compliance Remediation**: Develop strategy and support implementation of clients' remediation plans and responses to enforcement actions.

Members of the Greenleaf Compliance Team work cross-functionally to ensure a full-service experience that identifies and promotes practices and procedures that align a client's approach with FDA's quality, safety, and compliance expectations.

WHY GREENLEAF

Greenleaf is committed to serving 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.

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 working directly with the FDA and when navigating today's evolving regulatory environment.

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

ABOUT GREENLEAF

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.

greenleafhealth.com

COMPREHENSIVE SERVICES

Greenleaf experts lead teams specializing in product quality, manufacturing and compliance; medical devices and combination products; and drug and biological products. The Greenleaf Product Quality, Manufacturing and Compliance Team uses their combined depth of knowledge and breath of experience to provide the following compliance services:

Compliance Assessments

Greenleaf works with life science firms 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.

Consultation, Training & Regulatory Guidance

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

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.

Inspection Readiness

An FDA inspection is a critical moment for any regulated company. Greenleaf experts strengthen clients' readiness for FDA pre-approval and surveillance inspections through consulting, training, audits and mock inspections.

Compliance Remediation

The Greenleaf team of 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 on the remediation pathway.

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 compliance.

UNMATCHED REGULATORY EXPERIENCE

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 Greenleaf's expanded services, the team now includes additional technical experts who can be deployed to support the firm's robust strategic and technical expertise. Members of the Greenleaf Product Quality, Manufacturing & Compliance Team include:

John Taylor

President,
Principal, Compliance & Regulatory Affairs
Former FDA senior official held many high-profile positions at the agency, as well as senior leadership roles within industry.

Cynthia Schnedar

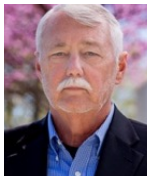
Executive Vice President,
Regulatory Compliance
25-year compliance career, including role as Director of FDA's drug compliance office.

Taryn Fritz Walpole

Executive Vice President,
Corporate & Regulatory Affairs
15+ years of leadership experience on Capitol Hill and at the FDA, including service as FDA's Deputy Chief of Staff.

Kristen Grumet

Senior Vice President, Reguatory Compliance
25-year compliance career, including role as an FDA Field Investigator specializing in medical devices.



Michael Chappell

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

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.

Kalah Auchincloss

Senior Vice President,
Regulatory Compliance & Deputy General Counsel
10+ years of experience on Capitol Hill, in the private sector and at FDA, including Deputy Chief of Staff.

Additional Team Members

Liz Oestreich | Samantha Eakes | Brittany Milby