



# 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 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. By expanding Greenleaf's core regulatory consulting services, the firm is now capable of providing a full-service experience for companies navigating today's evolving regulatory environment.

Greenleaf's expanded strategic capacity and capabilities include the following comprehensive quality, compliance, and manufacturing services:

- **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 the 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 the 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 navigating today's changing FDA 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.

## 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 breadth 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 towards optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.



### Inspection Readiness

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



### 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 in a variety of regulatory areas.



### Compliance Remediation

The Greenleaf team of experts brings 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.



### 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.



### 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.

## 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.



### 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.



### 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 FDA Deputy Chief of Staff.



### Kalah Auchincloss

*Senior Vice President,  
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.

### Additional Team Members

Liz Oestreich | Samantha Eakes | Brittany Milby