



# GOOD CLINICAL PRACTICE SERVICES

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The development of innovative therapies and associated clinical complexities further emphasize the importance of high-integrity, reliable data.

For companies designing and executing clinical trials, the FDA's trust is paramount. Greenleaf experts understand firsthand the importance of accurate and reliable clinical data and work with clients to build quality research programs.

## STRATEGIC & TECHNICAL CAPABILITIES

Greenleaf's compliance services are recognized as best in class by companies seeking strategic and technical expertise to strengthen their quality management systems and guide them through the challenging FDA regulatory landscape.

Greenleaf's Product Quality, Manufacturing, and Compliance Team works with clients to build good clinical practices (GCP) that will align a client's approach with the FDA's quality, safety, and compliance expectations.

Greenleaf's team of highly experienced specialists uses a risk-based methodology to develop and improve clinical quality systems. Because there is no one-size-fits-all approach to GCP compliance, each solution is built to fit the targeted needs of the client.

## EXPERT TEAMS

Members of Greenleaf's Product Quality, Manufacturing, and Compliance Team specialize in corporate quality and compliance systems; FDA inspections, compliance, and enforcement processes; FDA organization and structure as they relate to compliance functions and decisions; FDA communications, including enforcement letters and facility and supply chain audit reports; and the complete spectrum of compliance- and enforcement-related actions.

The collective knowledge and extensive experience of the Greenleaf team is enhanced by Greenleaf's network of specialized technical experts who can be deployed to provide on-site services at entities that manufacture FDA-regulated products.

[www.GreenleafHealth.com](http://www.GreenleafHealth.com)

*Adherence to the principles of good clinical practice is not an option - it is essential.*

## ABOUT GREENLEAF

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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 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.

## UNMATCHED EXPERTISE

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

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

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

## GCP SERVICES

The Greenleaf Product Quality, Manufacturing, and Compliance Team uses its combined depth of knowledge and breadth of skill to provide the following GCP services:



### Compliance Assessments

Greenleaf works with life science entities to evaluate and strengthen clinical quality systems with an eye toward optimizing processes, mitigating risks, and creating a culture of compliance, while continuing to meet business objectives.



### FDA Communications

Greenleaf's best-in-class experts bring value to any communication with the FDA, including formal regulatory communications, 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 team has the experience and insight to successfully guide companies along the remediation pathway.



### Auditing Services

Greenleaf's skilled professionals provide auditing services that include the review and audit of GCP documents, sponsor and laboratory sites, and vendors for areas of nonconformance.



### Consultation, Training & Regulatory Guidance

Greenleaf delivers insight and guidance that help clients achieve business and regulatory objectives. The team also develops and delivers training on a variety of regulatory subjects.



### Inspection Readiness

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

## EXPERT TEAM



### JOHN TAYLOR

**President and Principal, Compliance & Regulatory Affairs**

Former FDA senior official held high-profile positions at the Agency and senior leadership roles within industry.



### DAVID ELDER

**Principal, Regulatory Compliance**

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



### CYNTHIA SCHNEDAR

**Principal, Regulatory Compliance**

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



### KALAH AUCHINCLOSS

**Exec. Vice President, Regulatory Compliance**

15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.



### DAWN WYDNER

**Senior Vice President, Regulatory Compliance**

10-year quality and compliance career in the FDA's Office of Regulatory Affairs.



### MARIA BONNER

**Vice President, Regulatory Compliance**

Policy and legal experience in both the public and private sectors provides deep understanding of regulatory policy.

## 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:

### Drugs & 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.

### Medical Devices & Combination Products

Greenleaf's Medical Device and Combination Products Team guides clients through the complete 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.

### 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.