Greenleaf Health

GOOD CLINICAL PRACTICE SERVICES

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.

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

ABOUT GREENLEAF

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

Greenleaf's team is comprised of experts with a combined total of more than 250 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.

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.

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.

Consultation, Training & Regulatory Guidance
Greenleaf partners with companies to deliver insight and guidance that help achieve business and regulatory objectives. The team also develops and delivers training on a variety of regulatory subjects.

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.

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.

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

TEAM

JOHN TAYLOR
Principal,
Compliance & Regulatory Affairs
Former senior FDA official held many high-profile positions at the Agency, as well as 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.

CYNTHIA SCHNEDAR
Executive Vice President,
Regulatory Compliance
25-year compliance career, including serving as director of the FDA's drug compliance office.

KALAH AUCHINCLOSS
Senior Vice President,
Regulatory Compliance
10+ years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

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 product lifecycle, from the earliest stages of product development, through the FDA review process, to marketing authorization, postmarket requirements, and quality systems.

Advisory Serivces

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