Greenleaf Health

REMOTE COMPLIANCE SERVICES

Entities regulated by the U.S. Food & Drug Administration (FDA) encounter challenges on a regular basis. But no recent challenge has placed as great of a strain on the life sciences industry as COVID-19. The impact of this global pandemic is experienced by companies of every size, and increased effort and adaptability are required from all parties to preserve the integrity of the supply chain and ensure a consistent supply of safe, high-quality products.

Greenleaf Health recognizes that quality and compliance activities cannot be stalled. Despite global disruptions in surveillance inspections and other regulatory operations, Greenleaf's work on behalf of our clients continues. The firm's team of experts has identified opportunities to assist clients remotely while continuing to support all public health measures in effect throughout the course of the pandemic.

Greenleaf's remote compliance services concentrate on the FDA's evolving alternative approaches to on-site inspections that may exist for many months to come. Although not a full substitution for on-site work, the remote opportunities provided by Greenleaf enable companies to continue essential quality and compliance activities while preparing for the time when on-site activities fully or partially resume.

STRATEGIC & TECHNICAL GUIDANCE

Greenleaf's Product Quality, Manufacturing, and Compliance Team identifies and promotes practices and procedures that will align a client's approach with the FDA's quality, safety, and compliance expectations. Greenleaf also engages a network of independent contractors to provide technical expertise, both on site and remotely.

While companies face the complexities of navigating today's challenging public health landscape, Greenleaf and our network of independent compliance experts are prepared to assist clients with the following remote quality and compliance services:

- **Procedural and Record Review.** Review of Standard Operating Procedures (SOPs) for acceptability and compliance with requirements and evaluation of selected records for accuracy, completeness, and compliance with requirements.
- **Data and Trending Review.** Examination of documents and objective feedback on key quality data and metrics, and trending reports prepared for quality or management reviews.
- **Corrective Action Assessment.** Evaluation of responses, corrective action records, and change control records related to issues identified by the client, or identified during previous inspections by the FDA and other health authorities, and determination of whether the actions are appropriate, complete, and effective.
- **Regulatory Response Support.** Objective review and expert guidance on providing effective responses to FDA 483s, warning letters, requests for additional information, and other critical regulatory correspondence.
- **Issue-Specific Information.** Review of information relating to a specific issue of interest identified by the client to provide an objective assessment and feedback to help with resolution, documentation, and communication.
- **Training.** Live video training on specific topics such as inspection preparedness, design controls, CAPA, etc.

During global disruptions, a culture of quality is an expectation and an asset.

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

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

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.

COMPREHENSIVE SERVICES

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

Compliance Assessments
Greenleaf works with life science entities 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.

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 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
An FDA inspection is a noteworthy moment for any regulated company. Greenleaf experts strengthen clients' readiness for FDA preapproval 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.

GCP Services
Greenleaf specialists use 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 TEAM

Greenleaf's regulatory experts demonstrate unmatched levels of skill in their specialties of quality and compliance. The combined achievements and substantial qualifications of the Greenleaf team enable a cross-functional, full-service engagement that delivers best-in-class insight and consultations.

JOHN TAYLOR
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
EVP, Regulatory Compliance
25-year compliance career, including serving as director of the FDA's drug compliance office.

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

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

KRISTEN GRUMET
SVP, Regulatory Compliance
25-year compliance career, including role as an FDA field investigator specializing in medical devices.

ADDITIONAL TEAM MEMBERS
Liz Oestreich
Madeleine Giaquinto
Maria Bonner
Brittany Milby
Laura Bartee