Greenleaf Health

PRODUCT QUALITY MANUFACTURING & COMPLIANCE

The U.S. Food and Drug Administration's (FDA's) continued emphasis on proactive quality management and compliance with current good manufacturing practices (cGMPs) presents new challenges and opportunities for the private sector, making it essential for companies to build quality, safety, and integrity into their products.

Greenleaf's in-depth knowledge and understanding of the FDA provides clients with the technical and strategic support needed to align their approach with the FDA's quality, safety, and compliance expectations.

STRATEGIC & TECHNICAL CAPABILITIES

Greenleaf's Product Quality, Manufacturing, and Compliance Team has a proven track record of achieving success and providing services that are recognized as best in class by companies seeking to strengthen their quality management systems.

Greenleaf professionals work as teams specializing in product quality, manufacturing, and compliance; medical devices and combination products; and drug and biological products. Greenleaf's comprehensive approach provides a full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges.

Greenleaf's compliance experts 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.

To further enhance the firm's robust compliance services, Greenleaf has developed an Independent Contractor (IC) Network of additional technical experts who can be deployed to provide on-site services at entities that manufacture FDA-regulated products.

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.

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 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.

QUALITY & COMPLIANCE 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.

Inspection Readiness

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

Supply Chain Optimization

Greenleaf uses a systemic approach to help clients strengthen and safeguard the integrity of their supply chain management practices and comply with the regulatory requirements of the Drug Supply Chain Security Act.

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.

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.

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 CGP compliance, each solution is built to fit the targeted needs of the client.

Cell & Gene Therapy

Greenleaf helps sponsors establish manufacturing and quality controls and engage with the FDA to address potential technical and regulatory challenges related to emerging manufacturing technologies.

TEAM

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

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

KALAH AUCHINCLOSS
Executive 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.

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

GRACE MCNALLY
Senior Vice President, Regulatory Compliance
33-year FDA career, including experience as an investigator and leadership of many drug cGMP and quality initiatives.

LIZ OESTREICH
Vice President, Regulatory Compliance
Diverse background and knowledge of legal, public policy, and non-profit sectors.

MARIA BONNER
Vice President, Regulatory Compliance
Policy and legal experience in both the public and private sectors provides deep understanding of regulatory policy.

MADELEINE GIAQUINTO
Manager, Regulatory Affairs
Robust portfolio of regulatory compliance and federal health care advocacy experience.

BRITTANY MILBY
Exec. Director of Operations, Regulatory Compliance
Close to a decade of experience in pharmaceutical marketing, communications, and event planning.

LAURA BARTEE
Director of Operations, Regulatory Compliance
More than 10 years of private sector operational and administrative experience.

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:

Litigation Support

Greenleaf and our network of experts work closely with litigators representing FDA-regulated clients in disputes related to medical devices, drug and biological products, and product quality, manufacturing, and compliance.

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

Advisory Services

Experts from Greenleaf's Product Quality, Manufacturing, and Compliance Team also provide advisory services that include extensive research and due diligence for investors engaged in potential deals that require regulatory risk analyses before and after decisions and transactions.

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