Greenleaf Health

SUPPLY CHAIN OPTIMIZATION

As documented by the United States Food and Drug Administration (FDA) and its regulatory peers, the pharmaceutical supply chain has become increasingly global and complex due to many factors, including globalization, cost reduction pressures, lapses in product quality, the intricacies of the interactions between various health care industry stakeholders, public health and environmental crises and catastrophes, and product shortages.

Threats to the supply chain such as counterfeit products, diversion, cargo theft, poorly manufactured drugs, and the importation of unapproved or otherwise substandard drugs can result in unsafe, ineffective, or poor-quality drugs in U.S. distribution. To secure the supply chain against these threats, industry stakeholders must proactively strengthen their supply chain management practices.

The Drug Quality and Security Act (DQSA) was enacted by Congress in 2013. Title II of the DQSA, the Drug Supply Chain Security Act (DSCSA), outlines critical steps to enhance the security of the U.S. drug supply chain by strengthening accountability throughout the system. This includes requirements for manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers (trading partners).

The FDA has so far released more than a dozen DSCSA-related guidance and policy documents addressing aspects of the law such as annual reporting by wholesale distributors and third-party logistics providers and identification of trading partners.

The FDA is on track to fully implement the DSCSA by 2023. Will your supply chain be ready?

www.greenleafhealth.com

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.

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

SUPPLY CHAIN MANAGEMENT SERVICES

Greenleaf's compliance services are recognized as best in class by companies seeking strategic and technical expertise to strengthen and safeguard the integrity of their supply chain management practices. Greenleaf services include:

Good Supply Practices

Greenleaf works with life science entities to evaluate and strengthen good supply practices using a systemic approach to 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.

Auditing Services

Greenleaf's skilled professionals provide auditing services that include the review and audit of good manufacturing, good distribution, good import/export, and product security practices.

Responsive Services

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 facing compliance issues and addressing potential and actual supply chain breaches.

Consultation, Training & Regulatory Guidance

Greenleaf delivers insight and guidance that help companies strengthen their supply chains and comply with regulatory requirements included in the Drug Supply Chain Security Act.

Inspection Readiness

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

EXPERT TEAM

Greenleaf's Product Quality, Manufacturing, and Compliance Team is guided by decades of regulatory expertise.

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.

LIZ OESTREICH

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

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.