Greenleaf Health

ADVISORY SERVICES

Life sciences transactions involve a key component not found in other, more routine commercial transactions – the product or company of interest is regulated by the U.S. Food & Drug Administration (FDA), and regulatory issues therefore must be carefully considered. Greenleaf Health's in-depth knowledge and understanding of the FDA equips clients with a trusted partner when considering life sciences transactions.

GREENLEAF'S APPROACH

Thorough and focused due diligence allows companies to identify and assess both expected and unexpected regulatory risks. Greenleaf's comprehensive approach ensures that such risks are reflected in the transaction's structure and timing, purchase agreements, and disclosure schedules.

Greenleaf experts provide investors with extensive research and due diligence on potential deals that require regulatory risk analyses before and after decisions and transactions. By working cross-functionally across our areas of expertise, the Greenleaf team is able to offer insights on the FDA's current thinking in multiple areas and set appropriate expectations for investors.

COMPREHENSIVE SERVICES

The firm's multidisciplinary team uses its extensive expertise to perform risk assessments that take into account business objectives, transaction timelines, and the industry landscape. Greenleaf's comprehensive due diligence services evaluate a company's pipeline, or a specific asset, in the following areas:

Product Development & Review: Analysis of the target company's regulatory filings and product development plans, including approvals and clearances, special designations, advisory committee decisions, labeling review, and investigational products.

Identification of Regulatory Risk: Evaluation of the target company's compliance with FDA regulations and identification of issues that may require attention and resources for remediation.

Quality Manufacturing: Assessment of the target company's manufacturing practices, compliance with quality system regulations (QSRs), good manufacturing practices (GMPs), and identification of inconsistencies that may affect the regulatory risk of a product or the company.

The end result is an unbiased analysis identifying a target company's key regulatory risks, likelihood of the risks materializing, potential impact on the business, and opportunities to manage and mitigate risks in order to achieve desired regulatory outcomes.

A strong due diligence effort is vital to ensuring successful life sciences transactions.

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.

EXPERT TEAMS

Greenleaf's team of advisors offers a rare blend of perspectives developed as leaders in both the public and private sectors. This wealth of experience informs Greenleaf's understanding of the broad life sciences industry and enables us to deliver valuable insight throughout the product lifecycle.

DRUGS & BIOLOGICAL PRODUCTS

Greenleaf experts specialize in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements. The team's approach, firmly grounded in established principles of public health, is guided by decades of regulatory experience in drug and biological product development, spanning all therapeutic areas.

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.

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

Greenleaf's Compliance Team provides services that are recognized as best in class by companies seeking to strengthen their quality management systems. Experts specialize in corporate quality and compliance systems; FDA inspections, communication, and enforcement processes; and the complete spectrum of compliance- and enforcement-related actions.

STRATEGIC & TECHNICAL GUIDANCE

Greenleaf regularly partners with investors to evaluate potential issues and regulatory risks that may be identified during life sciences transactions. Greenleaf's advisory services include research and analysis of the following potential data sources:

Medical Product Development

Evaluation of clinical development plans to assess alignment with FDA regulations and product-specific guidance through review of clinical and nonclinical data, FDA correspondence, safety reporting, and sponsor proposals for future clinical studies.

Assessment of FDA Submissions

Review of pending product submissions to assess completeness and approval prospects. Review includes interactions during the course of the FDA's review, such as information requests, mid- and late-cycle meetings, advisory committee outcomes, labeling negotiations, and inspectional results.

Distribution and Supply Chain

Assessment of import-export practices, supply chain audit reports, outsourcing arrangements, and distribution procedures.

Compliance With Reporting Requirements

Confirm that the target company has complied with all requirements for registration, authorization, filing, and listing associated with approved products, including user fee payments and fulfillment of postmarket obligations.

Adverse Event Reporting

Review of adverse event reports (AERs) and good manufacturing practice (GMP) complaints to ensure that the target company has taken appropriate measures for review and investigation.

Regulatory Pathway Evaluation

Determine opportunity for special designation(s) for early-stage assets, including requests for priority review, fast track, accelerated approval, breakthrough therapy designation (BTD), and regenerative medicine advanced therapy (RMAT) designation.

Compliance Status

Research and summarize the target company's FDA compliance and enforcement history, including a review of FDA correspondence relating to compliance matters and identification of outstanding or pending compliance and remediation actions.

Preclinical and Clinical Quality Systems

Assessment of compliance with FDA current good laboratory practice (GLP) and good clinical practice (GCP) regulations.

Quality Manufacturing

Evaluation of the target company's compliance with FDA quality and manufacturing regulations related to inspections, standard operating procedures, quality assurance activities, and relevant contract manufacturers.

Marketing and Promotion

Evaluation of promotional practices and marketing materials, including labeling claims, promotion of unapproved products or off-label uses, and related FDA correspondence or enforcement actions.