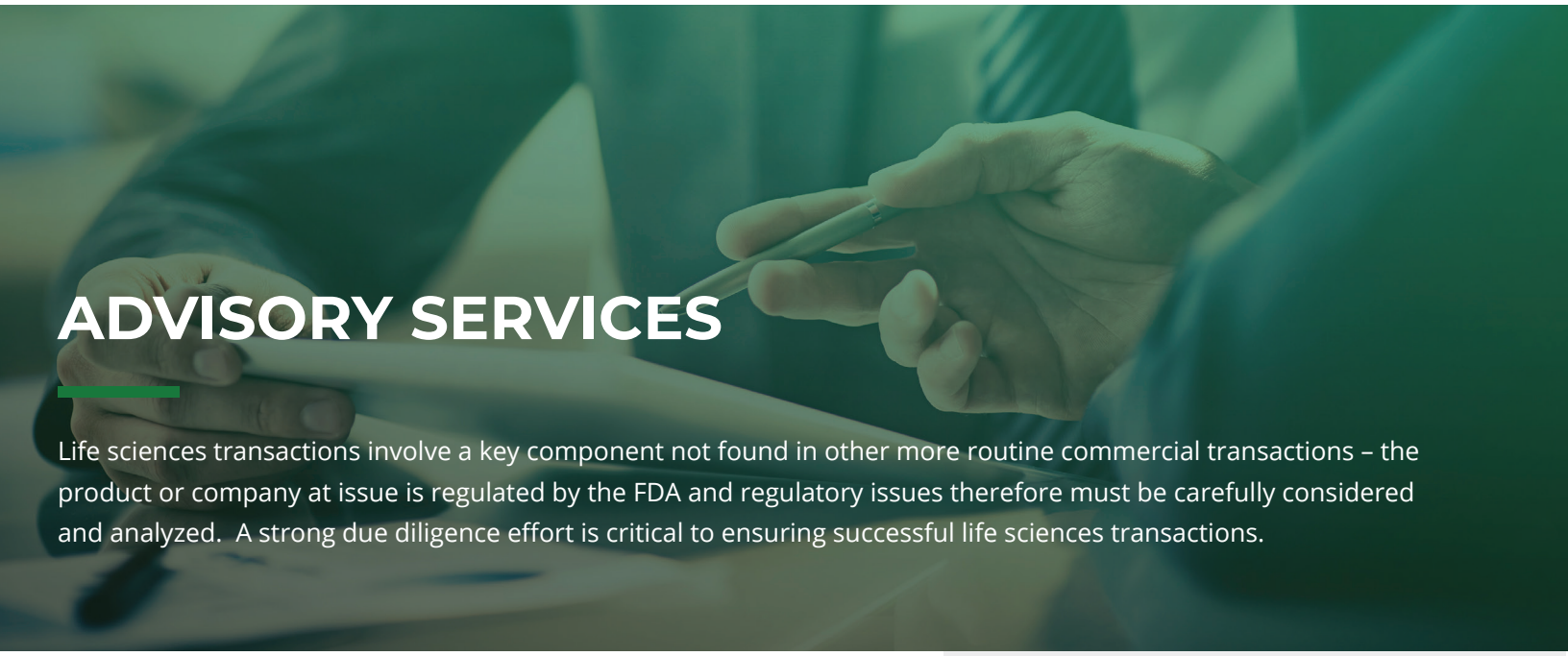
Greenleaf Health



ADVISORY SERVICES

Life sciences transactions involve a key component not found in other more routine commercial transactions – the product or company at issue is regulated by the FDA and regulatory issues therefore must be carefully considered and analyzed. A strong due diligence effort is critical to ensuring successful life sciences transactions.

GREENLEAF'S APPROACH

- Thorough and focused due diligence allows companies to identify and assess both expected and unexpected regulatory risks. This comprehensive approach ensures that such risks are reflected in the transaction's structure and timing, the target's valuation, purchase agreements and disclosure schedules.
- Greenleaf's in-depth knowledge and understanding of the U.S. Food and Drug Administration (FDA) as a regulator provides clients with a trusted partner when considering life sciences transactions.
- Greenleaf's decades of hands-on experience in the regulatory space is unmatched. The firm is comprised of a team of experts including former leaders and regulatory experts from FDA, Capitol Hill, top global pharmaceutical companies and the leading U.S. biotechnology trade organization.
- Greenleaf experts work together to provide advisory services that include extensive research and due diligence for investors engaged in potential mergers and acquisitions that require regulatory risk assessments before and after a life sciences transaction.
- By using cross-functional areas of expertise, the Greenleaf team is able to set appropriate expectations for investors and provide insights on the FDA's current thinking in key areas.

ABOUT GREENLEAF

Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic guidance to pharmaceutical and medical device companies researching, developing and manufacturing innovative solutions to pressing global public health challenges.

COMPREHENSIVE SERVICES

Greenleaf's advisory services are more than a compilation of public data. Greenleaf goes a step further by using the firm's vast institutional knowledge to provide tailored, in-depth assessments that fit client-specific needs.

GREENLEAF'S ADVISORY SERVICES

Greenleaf regularly partners with investors to evaluate potential issues and regulatory risks that may be identified during life sciences transactions.

Greenleaf understands the complex environment within which life sciences transactions take place. This is why the firm considers multiple aspects of a business when performing advisory services, including product development, compliance, enforcement, manufacturing and regulatory submissions.

Greenleaf's advisory services include research and analysis of the following potential sources of risk:

- Marketing authorization
- Manufacturing and Quality Issues
- Promotion
- Distribution and Supply Chain
- Pipeline Analysis
- Compliance Status
- Labeling
- Product safety

Greenleaf also advises clients regarding how to mitigate regulatory risks once the deal is completed.

EXPERT TEAMS

Greenleaf's team of experts provides a rare blend of leadership experience in both the private and public sector. This wealth of expertise allows Greenleaf to understand the broad health care industry and provide strategic and technical guidance.

Product Quality, Manufacturing & Compliance

Greenleaf's Product Quality, Manufacturing and Compliance Practice provides assistance and support to companies, trade associations, and other stakeholders affected by new legislation and FDA policies. This includes clients aiming to actively participate in future policy initiatives relating to FDA's regulatory and statutory authorities.

Compliance Practice 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, facility and supply chain audit reports; and many additional compliance and enforcement related actions.

Drug & Biological Products

Greenleaf's Drug and Biological Products Practice has a robust blend of regulatory expertise and FDA institutional knowledge, providing regulatory guidance in an array of areas, including clinical trial design, FDA filings, the regulatory review process and post-market requirements such as safety monitoring.

Services from this team include analysis and guidance during the earliest stages of product development through post-approval commitments. In addition, Greenleaf's Drug and Biological Products Practice monitors and analyzes the regulatory environment for emerging trends, potential impacts of agency actions on current development programs and the competitive landscape for specific therapeutic areas.

Medical Devices & Combination Products

Greenleaf delivers services that guide clients from early stage development to marketing authorization and throughout a product's lifecycle. The firm's Medical Devices and Combination Products Practice makes this possible by applying extensive regulatory expertise, determining the best regulatory approach for a product and providing a comprehensive strategy to achieve a successful result.

Greenleaf assists clients with all aspects of the regulatory review process for medical devices and combination products. Greenleaf's portfolio of services also includes medical device submission support for 510(k) and PMA submissions, as well as 513(g) requests, de novo petitions and HUD, HDE and IDE applications.