Greenleaf Health

DRUG & BIOLOGICAL PRODUCT PIPELINE REVIEW

Successful life sciences companies understand the value that a multidisciplinary team of experts brings to critical pipeline decisions. With access to experienced judgment and a diversity of perspectives, companies can build and maintain a strong pipeline throughout all the complexities of drug development. Greenleaf Health offers decades of regulatory experience and insight across a wide range of therapeutic areas, enabling clients to make timely, informed decisions to optimize and strategically manage their drug and biological product development pipelines.

COMPREHENSIVE SERVICES

Greenleaf helps reduce regulatory uncertainties by providing the following services:

PIPELINE REVIEW

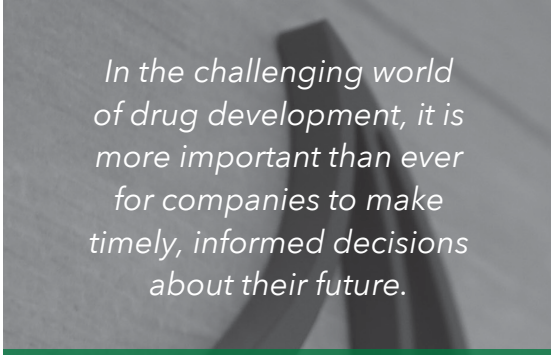
Greenleaf experts evaluate the various components critical to a drug development pipeline's clinical and regulatory success. With experience across a range of therapeutic areas and therapeutic modalities, Greenleaf is able to provide guidance on a variety of clinical indications and drug development issues, including proof-of-concept and pivotal study design and endpoints; preclinical toxicology and pharmacokinetics testing; evaluation of scientific and clinical data; FDA submissions and regulatory requirements; and potential postmarket requirements.

GAP ANALYSIS

Greenleaf's team helps guide drug development programs forward by working with the client's technical experts to perform a systematic review of factors that may impact the success of a product, including trial design and duration; patient population and selection strategy; clinical validation, stability, and testing specifications; and communication with regulators. Our experts then evaluate the collected data and information, identify missing elements, and help the client develop a plan to prioritize and address programmatic needs for individual therapeutic candidates and across the portfolio. Early identification of gaps allows companies to address issues proactively and make informed decisions about a program's viability, timing, and resources.

STRATEGY DEVELOPMENT

Greenleaf works with companies to create customized drug development strategies, from early-phase to late-stage development. Greenleaf's advisors provide realistic direction by determining the strengths and weaknesses of the pipeline, highlighting potential catalysts that could impact product development, assessing the competitive landscape, and considering study concept and clinical development plan design alternatives. The result is an actionable strategy that identifies development options and meaningful benchmarks to measure success and optimizes factors such as clinical positioning, product differentiation, and regulatory approval.



In the challenging world of drug development, it is more important than ever for companies to make timely, informed decisions about their future.

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.

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

STRATEGIC & TECHNICAL CAPABILITIES

Greenleaf Health serves as a trusted partner to companies evaluating and prioritizing their drug development pipeline. The firm works with clients to identify valuable portfolio opportunities and to understand and effectively manage regulatory risks. By assessing regulatory risk early in the drug development process, companies can allocate resources more efficiently and plan their development strategy with greater confidence.

Greenleaf's pipeline review services are tailored to fit a company's needs. Prior to initiating a pipeline assessment, Greenleaf professionals communicate with clients to gain perspective on the underlying science, data generated to date, and future development plans. Our experts carefully review these components and analyze other clinical and regulatory variables critical to success, then provide recommendations and guidance based on the client's specific objectives.

EXPERT TEAMS & UNMATCHED EXPERIENCE

Greenleaf experts draw on a combined total of more than 300 years of FDA experience to deliver reliable, objective advice to FDA-regulated companies. Further, the Drug and Biological Products Team offers a rare fusion of perspectives developed as leaders in the public and private sectors and in academia. This wealth of context enables Greenleaf to contribute unique direction to companies as they make business decisions about their pipeline.

Synchronizing their multidisciplinary skills and drawing on deep FDA institutional knowledge, Greenleaf professionals provide analysis and guidance on an array of questions affecting life science product development, including clinical trial design, scientific data, the regulatory review process, and postmarket requirements. The collective expertise and experience of Greenleaf's Drug and Biological Products Team ensures that clients can count on unmatched insight when managing their drug development strategy.

DISTINGUISHED LEADERSHIP

Greenleaf's regulatory experts demonstrate unmatched levels of skill in their specialties within the field of drug and biological products. The combined knowledge and substantial qualifications of the Greenleaf team enable a cross-functional, full-service engagement that delivers best-in-class insight for companies evaluating and prioritizing life science pipelines.

JOHN JENKINS, M.D.
Principal, Drug & Biological Products
Former Director of the Office of New Drugs within the FDA's Center for Drug Evaluation and Research (CDER).

KAREN MIDTHUN, M.D.
Principal, Drug & Biological Products
28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research (CBER).

JOSEPH GRIFFIN
Executive VP, Drug & Biological Products
20+ years of FDA service with a vast knowledge of the drug regulatory process, promotion, and labeling.

JULIA BARRETT, M.D.
Executive VP, Drug & Biological Products
23-year career in clinical regulatory consulting for biologics and drugs and 5 years with the FDA's CBER.

BOB MEYER, M.D.
Principal, Drug & Biological Products
A leader in drug and biological product lifecycle management with 25+ years of regulatory and academic leadership.

KATE COOK
Principal, Regulatory Policy
20 years of FDA experience in policy development and as legal counsel on biological, medical device, and drug issues.

BRIAN CORRIGAN
Executive VP, Regulatory Policy
10+ years of experience in the biopharmaceutical industry provides in-depth knowledge of the U.S. health care system.

CHRIS LEPTAK, M.D., Ph.D.
Senior VP, Drug & Biological Products
14-year FDA tenure, including service as Acting Office Director of CDER's Office of Drug Evaluation Science.