Greenleaf Health

CELL & GENE THERAPY

GREENLEAF'S APPROACH

Companies striving to introduce cell and gene therapy products to market need a trusted partner when maneuvering the sophisticated FDA regulatory landscape.

Greenleaf advisors have a robust blend of technical skill and FDA institutional knowledge that spans all therapeutic areas and quality, manufacturing, and compliance systems. The team's approach, firmly grounded in established principles of public health, is guided by decades of regulatory experience working in senior FDA positions, in global public health organizations, in academia, and in industry.

FULL-SERVICE EXPERIENCE

Greenleaf experts work cross-functionally to ensure clients benefit from the extensive qualifications of the full Greenleaf team. Members of Greenleaf's Drug and Biological Products Team work together with the firm's Product Quality, Manufacturing, and Compliance Team to deliver expert direction on cell and gene therapy products.

Product Development & Review

Greenleaf's Drug and Biological Products Team assists sponsors of cell and gene therapies by optimizing FDA interactions and submissions to support development and regulatory review. Greenleaf helps sponsors understand and respond to the FDA requirements applicable to various cellular products.

Quality, Manufacturing & Compliance

Greenleaf's Product Quality, Manufacturing, and Compliance Team, along with its network of independent compliance experts, offers credible, informed guidance to help manufacturers of cell and gene therapies comply with the FDA's multiple current GXP regulations.

Greenleaf experts provide strategic and technical support for establishing manufacturing and quality controls; pre- and postapproval inspection readiness; compliance assessments; evaluating and responding to FDA regulatory correspondence; and engaging with CBER's Advanced Technologies Team.

www.greenleafhealth.com

New cell and gene therapies are now available for patients, some after decades of research. The culmination of these efforts will be novel treatments, and perhaps ultimately cures, for devastating and intractable illnesses.

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.

COMPREHENSIVE SERVICES

The Greenleaf team uses its combined depth of knowledge and breadth of skill to provide the following cell and gene therapy services:

FDA Interactions

Greenleaf experts specialize in strategic FDA communications at every stage in product development - early INTERACT meetings, pre-IND and meetings throughout development, correspondence, clinical trial design, submissions, FDA review communications and labeling discussions, and postmarket requirements.

Consultation & Regulatory Guidance

Greenleaf monitors and analyzes the regulatory environment for emerging trends in cell and gene therapy that could potentially impact current development programs, as well as changes to the competitive landscape for cell and gene therapies.

Targeted Specialties

For sponsors developing cell and gene therapies to treat rare and ultra-rare diseases, the team helps clients maximize trial design using appropriate clinical endpoints and natural history study data in support of efficient product development.

Premarket Expertise

The team also assists sponsors developing requests for designations, including orphan drug, fast track, regenerative medicine advanced therapy, breakthrough therapy, and rare pediatric disease.

Manufacturing Technology

Greenleaf works with CBER's Advanced Technologies Team to support development and implementation of cell and gene therapy manufacturing technology and has effectively engaged with the FDA to resolve potential technical and regulatory challenges related to emerging technologies.

Inspection Readiness

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

Compliance Assessments

Greenleaf experts conduct compliance assessments and gap analyses at both the facility and corporate levels for manufacturing and quality practices and systems - including GMP, GCP, GTP, and QSR - and deliver recommendations for implementing system-wide quality enhancements.

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.

EXPERT TEAM

Greenleaf experts demonstrate unmatched levels of skill in their specialties of drug and biological products and product quality, manufacturing, and compliance.

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.

CYNTHIA SCHNEDAR

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

MADELEINE GIAQUINTO

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

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).

KATE COOK

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

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.