Greenleaf Health

CELL & GENE THERAPY

GREENLEAF'S APPROACH

Companies striving to introduce cell and gene therapy products to market need a trusted partner to advance treatments through the rapidly evolving FDA regulatory landscape.

Greenleaf's strategic approach, firmly grounded in established principles of public health, is guided by our decades of regulatory experience working in senior FDA positions, international public health organizations, academia, and industry. Our advisors have a robust blend of technical skills and FDA institutional knowledge that spans all therapeutic areas and quality, manufacturing, and compliance systems. Working cross-functionally, Greenleaf experts ensure that clients benefit from the specialized insight and perspectives of our full multidisciplinary team.

Product Development & Review

Greenleaf's Drug and Biological Products Team helps sponsors understand and respond to the FDA requirements applicable to cell and gene therapy products and optimize FDA interactions and submissions to support development and regulatory review.

As development of cell and gene therapies often involves consideration of aspects of medical device and combination product regulation – another area of deep FDA experience and expertise at Greenleaf – experts from the Medical Device and Combination Products Team and the Drug and Biological Products Team collaborate regularly on such matters.

Quality, Manufacturing & Compliance

Greenleaf's Product Quality, Manufacturing, and Compliance Team, along with its network of independent compliance experts, offer 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

After decades of research, cell and gene therapies offer new hope to patients with diseases and conditions previously considered untreatable. While there have been tremendous advances, companies still face a complex and changing regulatory environment.

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

Regulatory Strategy & FDA Interactions

Greenleaf experts specialize in strategic FDA communications at every stage – early INTERACT meetings, pre-IND and other formal meetings throughout development, correspondence, clinical trial design, submissions, FDA review communications and labeling discussions, and postmarket requirements. Greenleaf also assists clients in interpreting and properly applying FDA guidance to ensure effective, efficient product development.

Regulatory Landscape Analysis & Diligence

Greenleaf monitors and analyzes the regulatory environment for emerging trends in cell and gene therapy that could potentially impact development programs, as well as changes to the competitive landscape for cell and gene therapies. Our Advisory Services Team also offers focused due diligence and regulatory risk assessment in this space.

Rare Disease Guidance

For sponsors developing cell and gene therapies to treat rare and ultra-rare diseases, Greenleaf offers guidance on maximizing trial design using appropriate clinical endpoints and natural history study data in support of efficient product development. Our experts also assist sponsors preparing requests for orphan drug and rare pediatric disease designations.

Expedited Program Expertise

Greenleaf advises sponsors on the FDA's expedited programs for development and review, including regenerative medicine advanced therapy (RMAT), breakthrough therapy, fast track, priority review, and accelerated approval and confirmatory studies.

Manufacturing Technology

Greenleaf works with the FDA to support the development and implementation of cell and gene therapy manufacturing technology. Our team has effectively engaged with the FDA on behalf of clients to identify and resolve potential technical and regulatory challenges related to emerging manufacturing technologies prior to regulatory submissions.

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.

Regulatory Response Support

Greenleaf helps clients prepare for and respond to identified GXP compliance problems with knowledgeable, objective analysis of FDA Form 483s, warning letters, untitled letters, audit reports, establishment inspection reports, CAPAs, and other critical regulatory correspondence and documentation. Greenleaf also offers FDA meeting preparation.

Inspection Readiness

Greenleaf experts strengthen clients' readiness for FDA pre- and postapproval and surveillance inspections through consulting, training, audits, and mock inspections to align the organization with regulators' expectations.

EXPERT TEAM

Greenleaf's team is comprised of the foremost experts in the regulatory field, including former leaders in the FDA's offices overseeing cell and gene therapy review, drug product quality, and compliance, as well as medical devices and combination products.

JOHN TAYLOR

President
Principal, Compliance & Regulatory Affairs
Former FDA senior official, acting in high-profile positions at the Agency and in senior leadership roles within industry.

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance
30-year career as a compliance expert, serving as Director of the Office of Compliance for the FDA's Center for Drug Evaluation and Research.

KALAH AUCHINCLOSS

Executive VP, Regulatory Compliance
More than 15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

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

SANDRA KWEDER, M.D.

Principal, Drug & Biological Products
Former Deputy Director of the FDA's Office of New Drugs and Deputy Director of the FDA's Europe Office and EMA Liaison.

MADELEINE GIAQUINTO

Director, Regulatory Affairs
Legal and policy expertise, with robust portfolio of advising on FDA regulatory compliance for a range of product types.

WILSON BRYAN, M.D.

Executive VP, Drug & Biological Products
FDA career of 19 years, serving as Director of CBER's Office of Tissues and Advanced Therapies (OTAT) from 2016-2023.