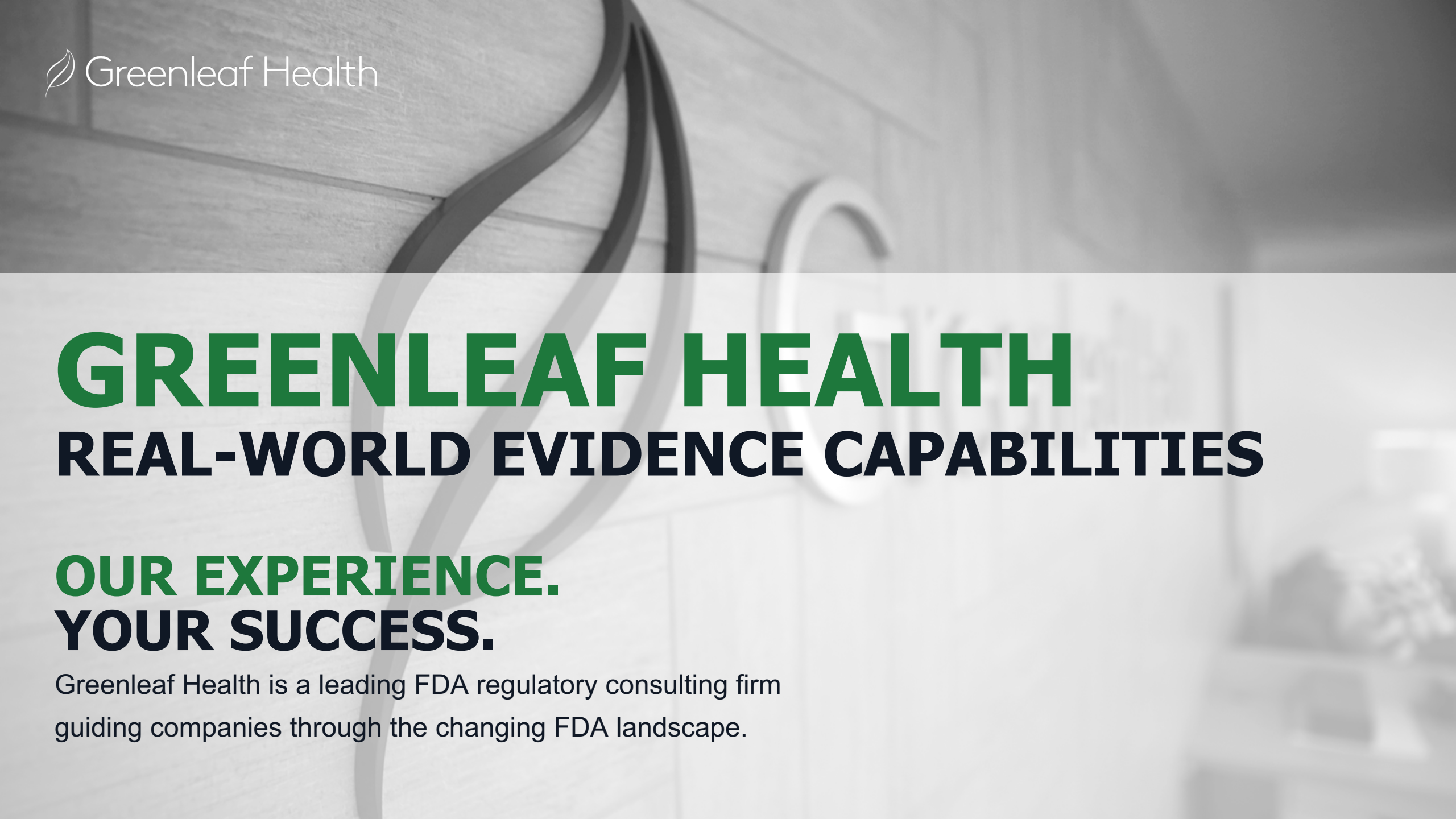

GREENLEAF HEALTH

REAL-WORLD EVIDENCE CAPABILITIES

OUR EXPERIENCE.
YOUR SUCCESS.

Greenleaf Health is a leading FDA regulatory consulting firm guiding companies through the changing FDA landscape.

ABOUT GREENLEAF HEALTH

250+ YEARS
OF COMBINED FDA EXPERIENCE

WHY GREENLEAF

Founded in 2007, 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's robust blend of technical skill and FDA institutional knowledge enables the firm to provide reliable, objective guidance to companies developing medical products for the U.S. market.

UNMATCHED EXPERTISE

Greenleaf's team brings unmatched expertise that companies need when navigating today's evolving FDA regulatory environment. 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 U.S. biotechnology trade organization.

Greenleaf experts draw on a combined total of more than 250 years of FDA experience and a network of technical specialists. This wealth of experience informs Greenleaf's understanding of the broad life sciences industry and allows us to deliver valuable insight throughout the product lifecycle.

COMPREHENSIVE SERVICES

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

Greenleaf experts identify and promote practices and procedures that will align a client's approach with the FDA's quality, safety, and compliance expectations.

COMPLIANCE AUDIT, TRAINING & REMEDIATION

Greenleaf works with a network of independent technical experts who provide comprehensive on-site compliance assessments, remediation, and inspection readiness.

DRUG & BIOLOGICAL PRODUCTS

Greenleaf serves as a trusted regulatory partner, advising companies on the complex process of bringing new therapeutics to market in today's evolving FDA environment.

MEDICAL DEVICE & COMBINATION PRODUCTS

Greenleaf applies extensive regulatory expertise to guide medical device clients from early-stage development to marketing authorization and throughout the product lifecycle.

CELL & GENE THERAPY

Greenleaf assists sponsors of cell and gene therapies by optimizing FDA interactions and submissions to support development, manufacturing, quality, and regulatory review.

REAL-WORLD EVIDENCE (RWE)

Greenleaf Health and Trio Health have united to provide a cutting-edge combination of technology and regulatory insight via Trio's groundbreaking real-world evidence technology platform.

ADVISORY SERVICES

Greenleaf understands the complex environment within which life sciences transactions take place and performs in-depth regulatory risk assessments tailored to investors' needs.

LITIGATION SUPPORT

Greenleaf works closely with litigators representing FDA-regulated clients in a wide array of disputes related to medical devices and product quality, manufacturing, and compliance.

REAL-WORLD EVIDENCE TEAM

Greenleaf's team of regulatory experts provides unmatched insight and consultation on all aspects of the FDA's regulatory application of real-world evidence (RWE).

The combined achievements and substantial qualifications of the full Greenleaf team enable a cross-functional, full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges.

JOHN JENKINS, M.D.

Principal, Drug & Biological Products

A 25-year career at the FDA, with 15 years in senior leadership positions within the Center for Drug Evaluation and Research, including as Director of the Office of New Drugs.

BOB MEYER, M.D.

Principal, Drug & Biological Products

More than 25 years of regulatory, industry, and academic leadership, including prominent roles at the FDA, Merck, and the University of Virginia.

KAREN MIDTHUN, M.D.

Principal, Drug & Biological Products

An infectious disease physician by training, with a 28-year career in public service, including as Director of the FDA's Center for Biologics Evaluation and Research.

SEAN HILSCHER

Associate Vice President, Regulatory Affairs

More than 10 years of experience as a consultant and product manager in the international and U.S. health care markets.

PATRICK RONAN

Chief Executive Officer

25+ years of leadership experience that includes positions on Capitol Hill, at a leading global pharmaceutical company, and at the FDA, serving as a principal advisor to a number of FDA commissioners.

REAL-WORLD EVIDENCE SERVICES

Trio Health

Real-world evidence — the concept of using real-world data (RWD) to improve clinical evidence — has the potential to transform the drug development landscape.

The Food and Drug Administration recognizes the opportunities presented by RWE and is developing a new paradigm for its use in regulatory decision-making.

Companies prepared to employ the power of RWE will require more than just raw data — that's why Greenleaf has partnered with Trio Health to provide a cutting-edge combination of technology and regulatory insight.

GREENLEAF + TRIO

Greenleaf's exclusive agreement with Trio Health, a leading provider of real-time data on real-world patients, gives clients the advantage of Trio's groundbreaking Multi-Disease Platform (MDX) technology integrated with Greenleaf's unrivaled regulatory knowledge. The result is a comprehensive resource for enhancing and contextualizing evidence derived from RWD.

MDX PLATFORM

The first-of-its-kind MDX platform tracks patients throughout the course of their treatment by combining disparate information from the physician, pharmacy, and payer 'trio.' MDX offers life science customers best-in-class speed, data certainty, and unparalleled visibility across the clinical and commercial lifecycle.

Trio's comprehensive and high-quality databases are on caliber with FDA-level rigor, giving pharmaceutical and biotechnology companies, specialty pharmacies, and physicians access to information and opportunities that can be leveraged to support pre- and postmarketing activities.

UNRIVALED INSIGHT

When integrated with Greenleaf's regulatory expertise, Trio's advanced analytics MDX platform delivers unrivaled insights to the industry. Clients gain the ability to transform real-world data into actionable intelligence to innovate and make better decisions, with greater confidence, throughout the product lifecycle. Greenleaf's team of regulatory experts provides end-to-end guidance to companies utilizing MDX data on how to optimize and validate the information to drive effective regulatory strategies.

OUR EXPERIENCE.
YOUR SUCCESS.