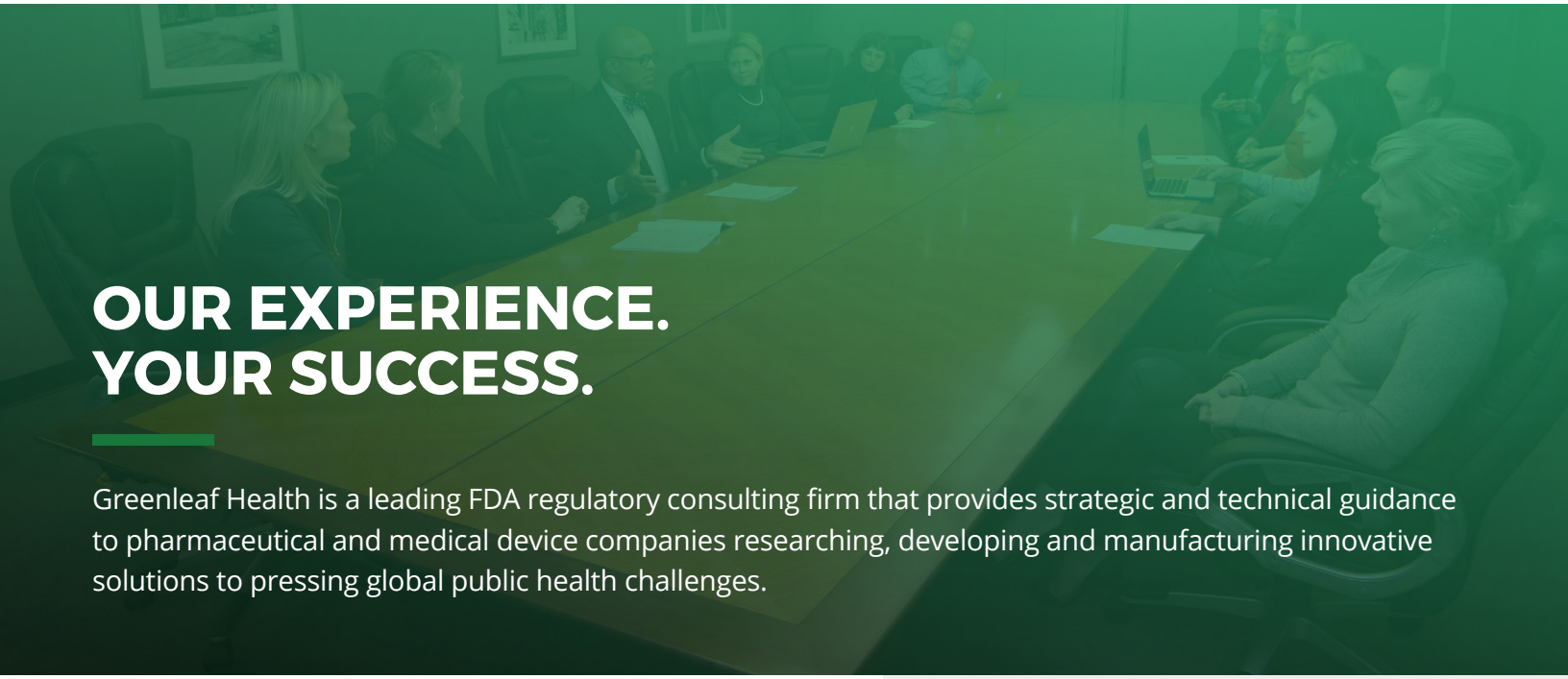
Greenleaf Health



OUR EXPERIENCE. YOUR SUCCESS.

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

COMPREHENSIVE SERVICES & SUPPORT

Greenleaf's comprehensive services and wealth of experience ensure that clients can count on expert guidance as they navigate complex regulatory challenges. Greenleaf's experts specialize in product quality, manufacturing and compliance; medical devices and combination products; and drug and biological products.

Product Quality, Manufacturing & Compliance

Greenleaf's Product Quality, Manufacturing and Compliance Team assists companies, trade associations and other stakeholders regulated by the U.S. Food and Drug Administration (FDA). Greenleaf experts identify and promote practices that will align a client's approach with FDA's quality, safety and compliance expectations.

Medical Devices & Combination Products

Greenleaf's Medical Devices and Combination Products Team delivers services that guide clients from early stage development to marketing authorization and throughout a product's lifecycle. Greenleaf applies extensive regulatory expertise, determines the best regulatory approach for a product and develops a comprehensive strategy to achieve a successful result.

Drug & Biological Products

Greenleaf serves as a trusted partner for companies navigating the complex process of bringing new therapeutic products to market. The Drug and Biological Products Team specializes in advising on the full product lifecycle, including clinical trial design, FDA filings, the FDA review process, postmarket requirements and more.

ABOUT GREENLEAF

Greenleaf Health is a full-service regulatory consulting firm guiding companies through the changing FDA landscape.

TEAM OF EXPERTS

Greenleaf's team of experts offers a rare blend of leadership experience in both the public and private sectors. This wealth of experience allows Greenleaf to understand the broad health care industry and provide strategic and technical guidance throughout a product's lifecycle.

REGULATORY SERVICES

The firm's targeted regulatory services include:

- Strategic and technical guidance for medical product development and regulatory review
- Product lifecycle management
- Product quality, manufacturing and compliance
- 510(k), PMA, 513(g) requests and HUD, HDE and IDE applications
- FDA meeting preparation and communication
- Advisory services
- Medical product labeling and promotion
- Regulatory policy guidance, strategic planning and communications
- Regulatory benchmarking

UNMATCHED REGULATORY EXPERTISE

Greenleaf's decades of hands-on experience in the regulatory process is unmatched. The firm comprises a team of experts including former leaders and regulatory experts from FDA, Capitol Hill, top global pharmaceutical companies, leading law-firms and the leading U.S. biotechnology trade organization.

DISTINGUISHED EXPERIENCE & LEADERSHIP

Greenleaf is guided by experts with a combined total of more than 200 years of FDA experience.

Patrick Ronan

Chief Executive Officer

Greenleaf is led by regulatory veteran Patrick Ronan, whose 20+ years of experience includes leadership positions at FDA, on Capitol Hill and at a leading global pharmaceutical company. Patrick founded Greenleaf in 2007 following his role as Vice President of Regulatory Policy and External Affairs at Novartis Pharmaceuticals. Prior to joining Novartis, Patrick served as FDA's Chief of Staff where he was the principal advisor on all issues to a number of FDA Commissioners.

John Taylor

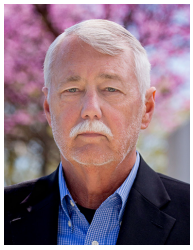
President and Principal, Compliance & Regulatory Affairs

John Taylor joined Greenleaf following a distinguished FDA career of more than 20 years. During John's time at the agency, he served in multiple high-profile roles, including FDA Counsel to the Commissioner, Acting Principal Deputy Commissioner, Acting Deputy Commissioner for Global Regulatory Operations and Policy and Associate Commissioner for Regulatory Affairs. John's experience also includes time spent in senior leadership roles within regulated industry.

Kathleen Sonntag

Chief Financial Officer

Kathleen Sonntag is a specialist in the financial services field. Kathleen's broad career spans financial services and the legal profession, with an emphasis on information technology, data analysis and the use of technology to enable business processes. This unique blend of more than 20 years of industry experience brings strong analytical, technical and business skills to her role as Greenleaf's Chief Financial Officer.



Michael Chappell

Principal, Regulatory Compliance

Michael Chappell's extensive FDA experience gives him a unique understanding of how the industry is affected by FDA's enforcement operations and compliance priorities. Michael's 38-year FDA career included service as Acting Associate Commissioner for Regulatory Affairs, where he managed a 4,000-person staff in five regional offices responsible for imports, inspections and enforcement policy.

John Jenkins, MD

Principal, Drug and Biological Products

During his 25 years with FDA, John Jenkins oversaw drug regulations across all therapeutic areas within FDA's Center for Drug Evaluation and Research (CDER). As Director of the Office of New Drugs, he was responsible for 19 product review divisions and was a critical figure in the development and implementation of programs under the Prescription Drug User Fee Act. He also played a leading role in implementing the biosimilars program in CDER.

Daniel Schultz, MD

Principal, Medical Devices & Combination Products

Dan Schultz joined Greenleaf following a 35-year career devoted to supporting and advancing Americans' public health as a physician, senior FDA official and member of the U.S. Public Health Service. Most recently, Dan served as Director of FDA's Center for Devices and Radiological Health where he led the development, implementation, and evaluation of regulatory policies concerning medical devices and radiation-emitting products.