

GREENLEAF HEALTH LLC.



A Full Service Regulatory Consulting Firm
Helping Your Company Navigate the FDA Landscape

OUR EXPERIENCE — YOUR SUCCESS

ABOUT GREENLEAF HEALTH



- Greenleaf Health, LLC. is a full service regulatory consulting firm that provides strategic guidance to companies regulated by the Food and Drug Administration (FDA) that are developing innovative solutions to pressing public health challenges around the globe.
- Founded in 2007 by Mr. Patrick Ronan, Greenleaf is based in Washington, D.C with offices in Portola Valley, CA. Greenleaf is led by Mr. Ronan and comprised of a team of experts including other former, high-level FDA officials.
- Greenleaf Health consults on strategic regulatory matters for a select group of healthcare sector clients, including pharmaceutical, biotechnology and medical device companies.
- Greenleaf's regulatory guidance services include product lifecycle management, product approval, product labeling, manufacturing & compliance, marketing & promotional practices, and regulatory policy.

EXPERIENCE



- Clients choose Greenleaf for strategic guidance because the firm has a rare blend of experience in both the public and private sectors, equipping it with the expertise and insights necessary to assist health care clients in making critical, real-time business decisions.
- The Greenleaf team includes former leaders from FDA, Capitol Hill, top global pharmaceutical companies and the leading U.S. biotechnology trade organization.
- This wealth of experience allows the Greenleaf team to understand the broad health care industry, while appreciating the business challenges facing health care companies in a rapidly changing environment.

THE GREENLEAF TEAM



PATRICK RONAN, *Founder and President*

With 15 years of leadership experience at the FDA, on Capitol Hill and a leading global pharmaceutical company, Patrick Ronan brings a keen understanding of the regulatory climate of the health care sector to Greenleaf Health. Prior to founding Greenleaf, Patrick served as Vice President of Regulatory Policy & External Affairs at Novartis Pharmaceutical Corporation and Chief of Staff at FDA.

DR. DANIEL SCHULTZ, *Senior Vice President, Medical Devices & Combination Products*

Dr. Schultz joined Greenleaf following a distinguished 35-year career of supporting and advancing the public health of Americans. He served for 15 years at the FDA, most recently as Director of the Center for Devices and Radiological Health (CDRH). Prior to his time at FDA, Dr. Schultz was a member of the U.S. Public Health Service (USPHS). He has been recognized many times for his contributions and dedication to public health.

TARYN FRITZ WALPOLE, *Vice President of Corporate Affairs*

A senior communications executive and strategic advisor, Walpole brings more than a decade of leadership experience on Capitol Hill and the FDA. Most recently, Walpole served as Deputy Chief of Staff at FDA where she planned and executed all of the FDA's priority announcement and medical product crisis actions on a wide variety of issues.

HEATHER ROSECRANS, *Senior Regulatory Advisor*

Heather Rosecrans brings more than 30 years of public health and medical device experience to Greenleaf Health LLC. Prior to joining Greenleaf, Rosecrans served as Director of the 510(k) Pre-Market Notification Staff at CDRH. Rosecrans' extensive experience at CDRH, and specifically the 510(k) office, enabled her to become one of the nation's leading experts on the program.

PHARMACEUTICAL & BIOTECHNOLOGY SERVICES



- **Product Lifecycle Management:** Strategic guidance regarding the FDA regulatory process, including, post-market safety requirements and assessing the regulatory process for generic competition.
- **Product Approval:** Strategic guidance for official and unofficial FDA meetings, analysis of “Complete Response” letters, preparation for FDA Drug Advisory Committee Meetings, scientific and medical guidance for clinical programs and regulatory filings.
- **Medical Product Labeling:** Strategic guidance on new labeling requirements, including Risk Evaluation and Mitigation Strategy (REMS) safety plans, guidance on patient-related outcomes (PRO) studies and expertise on all non-prescription (OTC) products.
- **Manufacturing and Compliance:** Expertise in the FDA inspection process, assessment of Form 483 and EIRs, Current Good Manufacturing Process (cGMP) deficiency letters and analysis of Corporate Warning letters.
- **Adverse Event Reporting:** Guidance on new adverse event reporting requirements for non-prescription drugs.
- **Marketing and Promotional Practices:** Direct-to-consumer (DTC) advertising review process, remediation of untitled and warning letters and use of social media.

MEDICAL DEVICE SERVICES



- **Product Lifecycle Management:** Strategic guidance regarding the FDA regulatory process, including all aspects of pre-market review and post-market safety requirements.
- **Product Approval:** Strategic guidance for official and unofficial FDA meetings, analysis of “Request for Additional Information” letters, preparation for FDA device panel meetings, scientific and medical guidance for clinical programs and regulatory filings.
- **Manufacturing and Compliance:** Expertise in the FDA inspection process, assessment of Form 483 and EIRs, Current Good Manufacturing Process (cGMP) deficiency letters and analysis of Corporate Warning letters.
- **Changing Regulatory Environment:** Insight regarding new proposals for post-market safety requirements and potential regulatory actions in the area of medical devices.
- **Marketing and Promotional Practices:** Direct-to-consumer (DTC) advertising review process, remediation of untitled and warning letters and use of social media.

OTHER SERVICES



In addition to regulatory guidance, Greenleaf Health also offers the following services:

- **Strategic Planning:** Assessment and analysis of regulatory structure, processes and people. Formulation of strategic plan to increase likelihood of regulatory success.
- **Strategic Communications:** Formulation of strategic communications plans, analysis of FDA enforcement actions in the area of media and public affairs and process expertise with respect to FDA's Risk Communications strategy.

SUMMARY



- As a leader in the life sciences arena, Greenleaf Health utilizes its experience in both the private and public sectors to advise their clients in order to achieve desirable regulatory outcomes.
- Greenleaf's wealth of experience is unparalleled. This combined set of skills and understandings of the Food and Drug Administration enables the team to provide the most up-to-date and dynamic regulatory consulting for their clients.
- For more information on how Greenleaf Health can help your company navigate the FDA landscape and assist with smart business decisions, please call 202-351-6168 or contact Greenleaf at info@greenleafhealthllc.com

www.GreenleafHealthLLC.com