Greenleaf Health

OUR EXPERIENCE. YOUR SUCCESS.

GREENLEAF HEALTH IS A LEADING REGULATORY CONSULTING FIRM GUIDING COMPANIES THROUGH THE CHANGING FDA LANDSCAPE.

ABOUT GREENLEAF HEALTH

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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.

Greenleaf is guided by experts with a combined total of more than 200 years of FDA experience. This wealth of experience allows Greenleaf to understand the broad health care industry and provide strategic and technical guidance throughout a product's lifecycle.

Greenleaf consults on strategic regulatory matters for a select group of health care sector clients, including pharmaceutical, biotechnology and medical device companies.

GREENLEAF LEADERSHIP – UNMATCHED REGULATORY EXPERIENCE

Greenleaf comprises a team of experts including former leaders and regulatory experts from the FDA, Capitol Hill, top global pharmaceutical companies, leading law firms and the top U.S. biotechnology trade organization.

PATRICK RONAN

Chief Executive Officer

Greenleaf's founder is the former FDA Chief of Staff and Global Regulatory Affairs executive at a leading pharmaceutical manufacturer.

JOHN TAYLOR

President

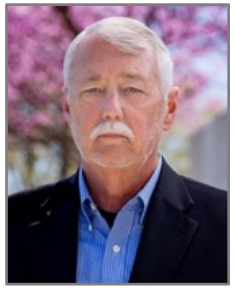
Principal, Compliance & Regulatory Affairs

Former FDA Counselor to the Commissioner, Acting Principal Deputy Commissioner and Associate Commissioner for Regulatory Affairs, as well as a senior leadership role at Abbott.

KATHLEEN SONNTAG

Chief Financial Officer

Expert in the financial services field with unique experience in information technology and data analysis.



MICHAEL CHAPPELL

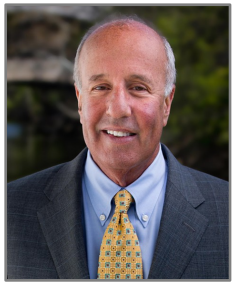
Principal, Regulatory Compliance

Former FDA Acting Associate Commissioner for Regulatory Affairs, where he served as head of the FDA field force.

JOHN JENKINS, MD

Principal, Drug and Biological Products

Former Director of the Office of New Drugs within the FDA's Center for Drug Evaluation and Research.



DANIEL SCHULTZ, MD

Principal, Medical Devices & Combination Products

Former Director of FDA's Center for Devices and Radiological Health (CDRH).

THE GREENLEAF APPROACH

Greenleaf's hands-on experience in the regulatory space is unmatched. This expert knowledge enables the firm to guide companies through the changing FDA landscape.

- Team approach enables inclusive regulatory support
- Public and private experience directs comprehensive guidance to clients
- Medical background guides clinical/regulatory strategy
- Extensive network includes well-respected external FDA consultants
- Experience level accelerates support process
- Institutional knowledge of FDA organization and personnel strengthens Greenleaf's ability to provide meaningful insight to clients
- Experts evaluate new and impending legislation
- Experience level facilitates productive communications with FDA
- Real-time information provides insight on FDA's regulatory environment

GREENLEAF SERVICES

REGULATORY SERVICES

Greenleaf's robust blend of regulatory expertise and FDA institutional knowledge allows the firm's team of experts to provide strategic and technical guidance in an array of areas.

The firm's comprehensive services and wealth of experience ensure that clients can count on expert guidance as they navigate complex regulatory challenges.

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
- Advisory services
- FDA meeting preparation and communication
- Medical Device Product Submissions - 510(k), PMA, 513(g) requests, HUD, HDE and IDE
- Medical product labeling and promotion
- Regulatory policy guidance
- Strategic planning and communications

GREENLEAF'S REGULATORY TEAMS

Greenleaf's experts specialize in the following areas:

Product Quality, Manufacturing & Compliance

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

Drug & Biological Products

Greenleaf serves as a trusted regulatory partner by advising companies on the complex process of bringing new therapeutics to market and guiding companies through product lifecycle management decisions.

Medical Devices & Combination Products

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

Product Submissions

Greenleaf serves as a trusted regulatory partner by advising companies on the complex process of bringing new therapeutics to market and assisting companies with product management decisions.

Advisory Services

Greenleaf regularly partners with investors to evaluate potential issues and regulatory risks that may be identified during life sciences transactions, including product development, compliance, enforcement and manufacturing.

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE TEAM

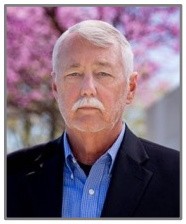
Greenleaf's Product Quality, Manufacturing & Compliance Team assists companies, trade associations and other key stakeholders engaged with FDA on regulatory matters affected by new legislation and FDA policies.

JOHN TAYLOR

President

Principal, Compliance & Regulatory Affairs

Former FDA senior official held many high-profile positions at the Agency, as well as a senior leadership roles within industry.



MICHAEL CHAPPELL

Principal, Regulatory Compliance

Former FDA Acting Associate Commissioner for Regulatory Affairs, where he served as head of the FDA field force.

DAVID ELDER

Executive VP, Regulatory Compliance

23-year veteran of the FDA with prominent roles in domestic and foreign inspections; recalls and emergencies; and compliance actions.

CYNTHIA SCHNEDAR

Executive VP, Regulatory Compliance

25-year compliance career, including role as Director of FDA's drug compliance office.

TARYN FRITZ WALPOLE

Executive VP, Corporate & Regulatory Affairs

15+ years of leadership experience on Capitol Hill and at the FDA, including service as FDA's Deputy Chief of Staff.

ADDITIONAL TEAM MEMBERS

Liz Stevulak | Samantha Eakes | Brittany Milby

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE SERVICES

FDA's continuing shift from reactive to proactive compliance presents new challenges and opportunities for the private sector, making it essential for companies to build quality, safety and integrity into their products.

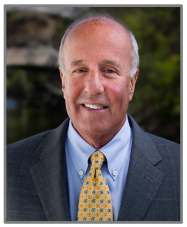
By analyzing compliance actions and tracking FDA trends, Greenleaf's Product Quality, Manufacturing and Compliance Team helps companies navigate FDA's regulatory environment through every step in the process.

PRODUCT QUALITY, MANUFACTURING & COMPLIANCE SERVICES INCLUDE:

- Analysis of FDA trends and priorities
- Analysis of industry trends as they relate to company performance
- Review and analysis of FDA correspondence and enforcement actions
- Assessment of company quality management systems and compliance strategies
- Expertise in FDA’s compliance, inspection and enforcement processes
- Proactive participation in the Agency’s Quality Initiative
- Experience responding to FDA regulatory correspondence, compliance and enforcement actions

MEDICAL DEVICES & COMBINATION PRODUCTS TEAM

Guided by decades of experience, Greenleaf's Medical Devices and Combination Products Team provides unmatched knowledge of the life sciences regulatory process and serves as a trusted partner for companies navigating the complexities of product lifecycle management.



DANIEL SCHULTZ, MD

Principal,
Medical Devices & Combination Products

Former Director of FDA's Center for Devices and Radiological Health (CDRH).

HEATHER ROSECRANS

Executive Vice President,
Medical Devices & Combination Products

One of the nation's leading 510(k) experts with an FDA career that spanned more than 30 years and included a pivotal role in developing FDA's 510(k) program.

LAURIE CLARK

Executive Vice President,
Medical Devices & Combination Products

25 years of leadership as an FDA attorney, including experience as a partner at three leading Washington, DC law firms.

MAURA NORDEN

Senior Vice President,
Medical Devices & Combination Products

Nearly a decade of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

ADDITIONAL TEAM MEMBERS

Jason Campbell | Catherine Rowe

MEDICAL DEVICES & COMBINATION PRODUCT SERVICES

Greenleaf's Devices & Combination Products Team applies extensive FDA experience to determine the best regulatory approach for a product and provide a comprehensive strategy to achieve a successful result.

MEDICAL DEVICE & COMBINATION PRODUCT SERVICES INCLUDE:

- Strategic and technical guidance on regulatory matters
- FDA's review process
- Regulatory policy guidance
- Marketing and promotional practices
- Postmarket requirements, such as safety monitoring and quality systems
- Regulatory policy guidance
- Monitoring and assessing regulatory trends and competitive landscape

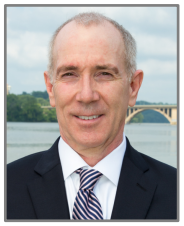
DRUG & BIOLOGICAL PRODUCTS TEAM

Greenleaf's Drug and Biological Products Team has a robust blend of regulatory expertise and FDA institutional knowledge, providing strategic and technical guidance in a variety of areas.

JOHN JENKINS, MD

Principal, Drug and Biological Products

Former Director of the Office of New Drugs within FDA's Center for Drug Evaluation and Research.



JOSEPH GRIFFIN

Executive VP, Drug & Biological Products

20+ years of FDA service with a vast institutional knowledge of the drug regulatory process and prescription drug promotion and labeling.

KATE COOK

Executive VP, Drug & Biological Products

Two decades of experience in policy development, including as legal counsel on biological products, medical devices and drug issues.

STEPHEN MASON

Senior VP, Regulatory Policy

Accomplished and diverse career specializing in regulatory and legislative policy development and analysis.

BRIAN CORRIGAN

Senior VP, Regulatory Policy

More than a decade of experience in the bio-pharmaceutical industry provides in-depth understanding of the U.S. health care system.

ADDITIONAL TEAM MEMBERS

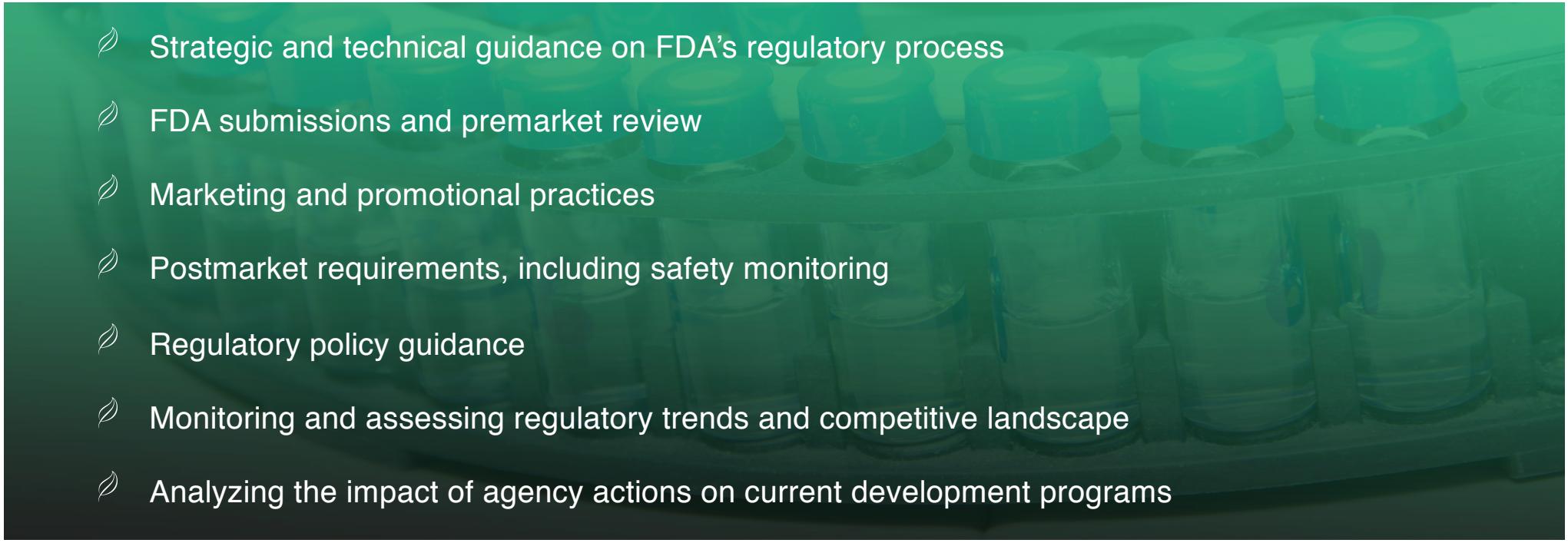
Katie McCarthy | Christina Karas | Rhona Baniqued

DRUG & BIOLOGICAL PRODUCT SERVICES

Greenleaf's in-depth knowledge and understanding of FDA as a regulator provides clients with a trusted partner when navigating the complex process of bringing new therapeutics to market.

The Drug and Biological Products Team delivers a variety of services from the earliest stages of product development through post-approval commitments.

DRUG & BIOLOGICAL PRODUCT SERVICES INCLUDE:



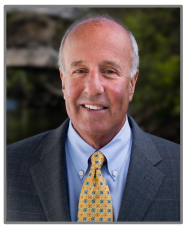
- Strategic and technical guidance on FDA's regulatory process
- FDA submissions and premarket review
- Marketing and promotional practices
- Postmarket requirements, including safety monitoring
- Regulatory policy guidance
- Monitoring and assessing regulatory trends and competitive landscape
- Analyzing the impact of agency actions on current development programs

MEDICAL DEVICE PRODUCT SUBMISSIONS TEAM

To ensure success in today's rapidly evolving medical technology industry, companies must recognize and be prepared for a dynamic regulatory landscape.

Greenleaf's team of experts delivers services that guide clients from early stage development to marketing authorization and throughout a product's lifecycle.

Greenleaf's Product Submissions Team includes the following team members:



DANIEL SCHULTZ, MD

Principal,
Medical Devices & Combination Products

Former Director of FDA's Center for Devices and Radiological Health (CDRH).

LAURIE CLARK

Executive Vice President,
Medical Devices & Combination Products

25 years of leadership as an FDA attorney, including experience as a partner at three leading Washington, DC law firms.

JASON CAMPBELL

Director, Medical Devices & Combination Products

Extensive experience at three prestigious international law firms assisting clients in the FDA sector.

HEATHER ROSECRANS

Executive Vice President,
Medical Devices & Combination Products

One of the nation's leading 510(k) experts with an FDA career that spanned more than 30 years and included a pivotal role in developing the FDA's 510(k) program.

MAURA NORDEN

Senior Vice President,
Medical Devices & Combination Products

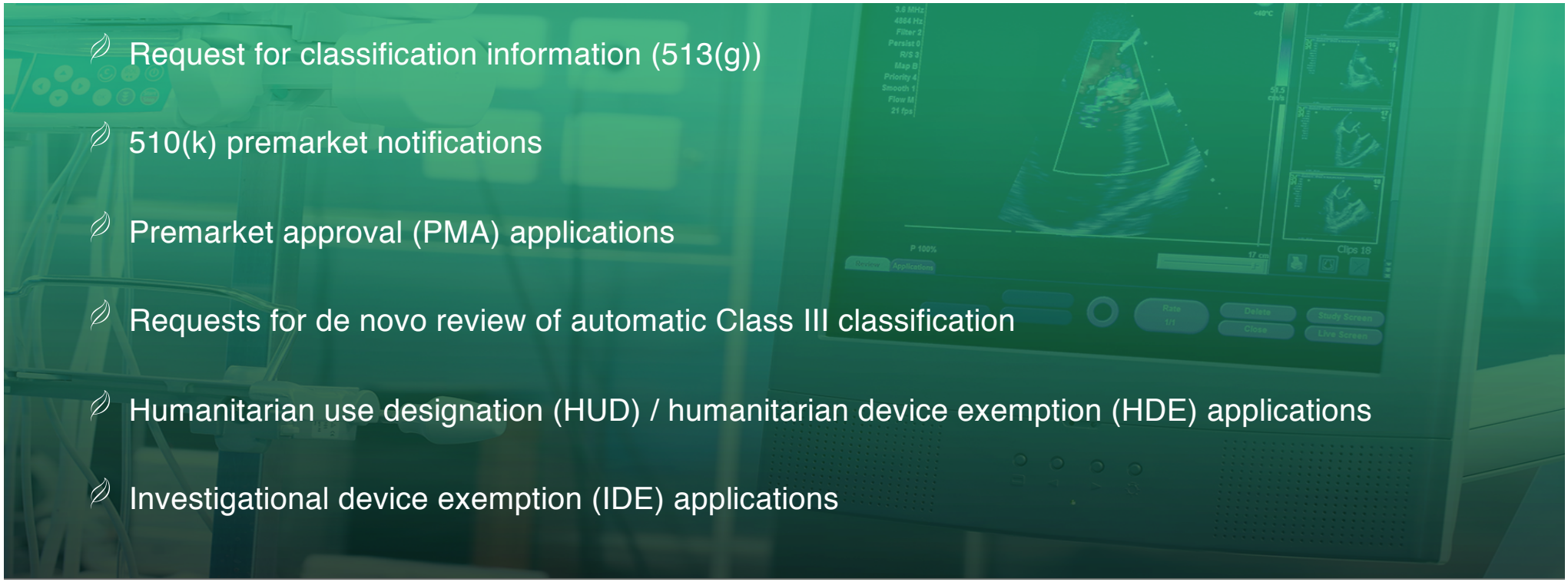
Nearly a decade of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

MEDICAL DEVICE PRODUCT SUBMISSION SERVICES

In a constantly changing regulatory environment, medical device companies need a comprehensive, forward-looking strategy and a well-versed strategic partner to support the growth of their innovative technologies and successfully bring new products to market.

Greenleaf's Medical Devices and Combination Products Team offers strategic and technical guidance on all aspects of the medical device submission process.

PRODUCT SUBMISSION SERVICES INCLUDE:



- Request for classification information (513(g))
- 510(k) premarket notifications
- Premarket approval (PMA) applications
- Requests for de novo review of automatic Class III classification
- Humanitarian use designation (HUD) / humanitarian device exemption (HDE) applications
- Investigational device exemption (IDE) applications

ADVISORY SERVICES

Greenleaf's in-depth knowledge and understanding of FDA as a regulator provides clients with a trusted partner when considering life sciences transactions.

Greenleaf understands the complex environment within which life science transactions take place. This is why the firm considers multiple aspects of a business when performing advisory services, including product development, compliance, enforcement, and manufacturing.

GREENLEAF EXPERTS WORK TOGETHER TO PROVIDE GUIDANCE IN THE FOLLOWING ARENAS:

Drugs & Biological Products

Product Quality, Manufacturing & Compliance

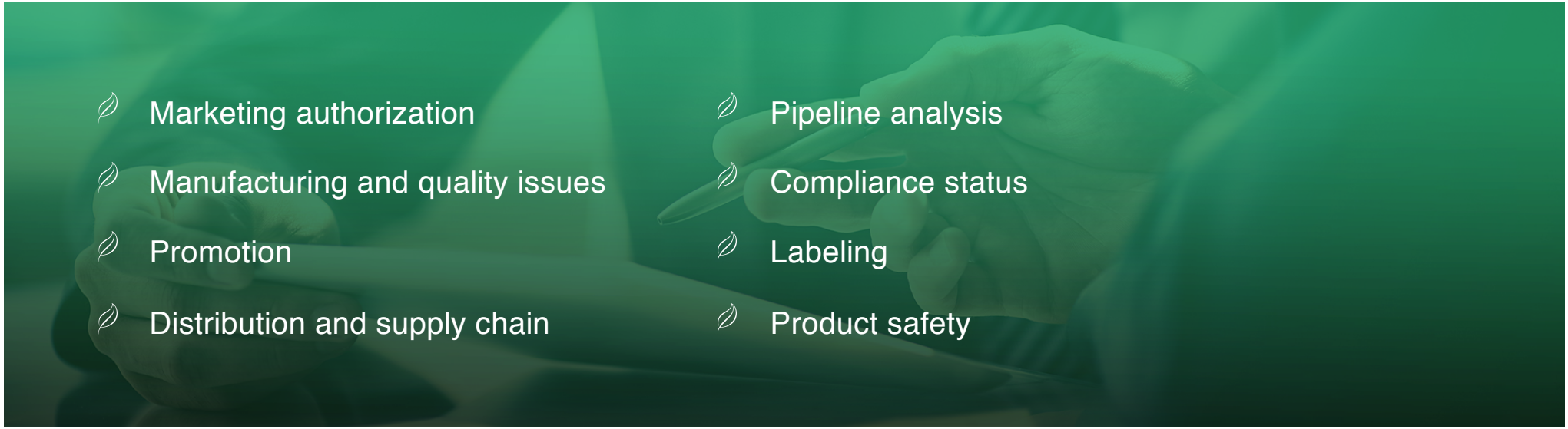
Medical Devices & Combination Products

By using cross-functional areas of expertise, the Greenleaf team is able to set appropriate expectations for investors and provide insights on FDA's current thinking in key areas.

ADVISORY SERVICES

Greenleaf's advisory services apply the firm's vast institutional knowledge to provide tailored, in-depth assessments that fit client-specific needs.

Greenleaf's Advisory Services include research and analysis of the following potential sources of regulatory risk:



- Marketing authorization
- Manufacturing and quality issues
- Promotion
- Distribution and supply chain
- Pipeline analysis
- Compliance status
- Labeling
- Product safety

Greenleaf also advises clients post-transaction regarding how to successfully manage and mitigate existing regulatory risk.