Greenleaf Health

# PRODUCT QUALITY, MANUFACTURING & COMPLIANCE

To meet FDA's mission of promoting and protecting public health, manufacturers are responsible for ensuring safe, high-quality medical products. With strong quality management systems, industry can avoid lapses in quality and instead provide high-quality ingredients and components, rigorous manufacturing practices and processes and a consistently reliable supply chain.

## GREENLEAF'S APPROACH

- The U.S. Food and Drug Administration's (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.
- Greenleaf experts identify and promote practices and procedures that will align a client's approach with FDA's regulatory expectations. Robust quality management systems ensure premium-quality ingredients and components, stringent manufacturing practices and processes and a uniformly reliable supply chain to meet patient and consumer needs.
- By analyzing compliance issues and tracking FDA trends, Greenleaf assists companies navigate this new FDA regulatory environment throughout every step in the process.
- Experts from Greenleaf's Compliance Team also provide advisory services that include extensive research and due diligence for firms engaged in potential mergers and acquisitions that require regulatory risk assessments before and after a life sciences transaction.

## ABOUT GREENLEAF

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

Greenleaf's Product Quality, Manufacturing and Compliance Team assists companies, trade associations and other stakeholders affected by new legislation and FDA policies. This includes clients aiming to actively participate in future policy initiatives relating to FDA's regulatory and statutory authorities.

# GREENLEAF'S COMPLIANCE SERVICES

**Analysis & Expert Consultation**

*Greenleaf provides regulatory analysis for strengthening:*

- Corporate quality systems
- Corporate training programs
- Corporate compliance strategies
- Inspection readiness
- Corporate quality and compliance organization

**Regulatory Guidance**

*Greenleaf provides corporate insight on:*

- FDA inspection, compliance and enforcement processes
- FDA organization and structure as they relate to compliance functions and decisions
- Impact of compliance-related legislation, regulations and guidance
- FDA trends and priorities

**Corporate Training & Development**

*Greenleaf provides training and development for:*

- Issuing technical reports, determining policies and procedures, and revising company standard operating procedures
- Preparing for FDA meetings and facilitating effective interactions with FDA
- Training in cGMP (current Good Manufacturing Practices), quality system regulation compliance and other compliance-related issues
- Developing responses to compliance-related proposals
- Assisting legal counsel on compliance-related issues
- Engaging with a firm's inspection team

**FDA Communications**

*Greenleaf provides evaluation and response recommendations for:*

- Facility and supply chain audit reports
- cGMP deficiency letters
- Establishment inspection reports (EIRs)
- FDA Form 483s
- Warning letters
- Untitled letters
- Other compliance- and enforcement-related actions

**Advisory Services**

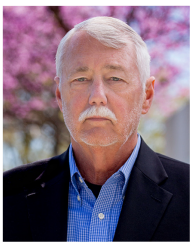
- Greenleaf regularly partners with investors to evaluate potential issues and regulatory risks identified during life sciences transactions.
- Greenleaf's advisory services include evaluations of the following potential sources of risk: marketing authorization, manufacturing, product safety, labeling, promotion, research and development, and distribution and supply chain.

# LEADERSHIP

## John Taylor

***President and Principal, Compliance & Regulatory Affairs***

John joined Greenleaf following a distinguished career of more than 20 years at FDA. During John's time at the agency, he led several of its priority initiatives and served such senior roles as Counselor to the Commissioner and as Principal Deputy Commissioner.



## Michael Chappell

***Principal, Regulatory Compliance***

Michael's extensive FDA experience brings a unique understanding of how industry is affected by FDA enforcement operations. At Greenleaf, Michael works closely with clients, providing strategic consulting services on regulatory, enforcement and compliance issues.

## David Elder

***Executive Vice President, Regulatory Compliance***

A 23-year veteran of FDA and the U.S. Public Health Service, David served as a senior FDA official with prominent roles in domestic and foreign inspections; recalls and emergencies; and compliance actions involving hundreds of situations.

## Cynthia Schnedar

***Executive Vice President, Regulatory Compliance***

Cynthia's 25-year compliance career includes more than 20 years of leadership positions in the government. Before joining Greenleaf, Cynthia served as Director of FDA's drug compliance office.

## Taryn Fritz Walpole

***Executive Vice President, Corporate & Regulatory Affairs***

Taryn is a strategic regulatory advisor and senior communications executive who brings nearly two decades of leadership experience on Capitol Hill and at FDA. While at FDA, Taryn served as Deputy Chief of Staff.

## Kalah Auchincloss

***Senior Vice President, Regulatory Compliance & Deputy General Counsel***

Kalah brings over 10 years of regulatory experience from Capitol Hill, the private sector and FDA, including Deputy Chief of Staff for two FDA Commissioners.

## ADDITIONAL TEAM MEMBERS

Liz Oestreich | Maria Bonner | Brittany Milby

Greenleaf Health

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