Greenleaf Health

# DIGITAL HEALTH SERVICES

The increasing adoption and use of digital health technologies, including wearable devices, mobile applications, software as a medical device (SaMD), and artificial intelligence (AI) programs, have opened new and innovative ways to improve patient health and health care delivery. Digital health technologies are driving a major evolution in drug and medical device development, empowering patients to make better-informed decisions while managing their own health and wellness, and allowing health care providers to care for patients with greater effectiveness and efficiency.

Players in the digital health space face unique challenges in navigating an ever-changing regulatory landscape, as Food and Drug Administration (FDA) regulators try to keep up with the pace of digital health technology development.

## TARGETED CAPABILITIES

Greenleaf Health serves as a trusted partner to both large and small clients developing and commercializing innovative digital health technologies as they navigate the complex landscape of FDA regulations and policies.

The firm's team of experts provides guidance to medical device and combination product manufacturers, pharmaceutical and biotechnology companies, trade associations, and other stakeholders implementing and complying with FDA's digital health requirements.

## FULL-SERVICE SUPPORT

Greenleaf professionals work as teams specializing in product quality, manufacturing, and compliance; medical devices and combination products; and drug and biological products. Greenleaf's comprehensive approach provides a full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges. Greenleaf's collaborative services include:

### Medical Devices & Combination Products

Greenleaf guides clients through the complete regulatory process, from the earliest stages of product development, through the FDA review process, to marketing authorization and compliance with postmarket requirements and quality systems.

### Drugs & Biological Products

Greenleaf supports clients maneuvering the sophisticated process of bringing new therapeutics to market. Experts specialize in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements.

### Product Quality, Manufacturing, and Compliance

Greenleaf provides expertise to companies seeking to strengthen their quality management systems. Experts specialize in corporate quality and compliance systems; FDA inspections, communication, and enforcement processes; and the complete spectrum of compliance and enforcement-related actions.

## ABOUT GREENLEAF

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.

## COMPREHENSIVE SERVICES

Greenleaf's robust blend of technical skill and FDA institutional knowledge enables the firm's team to provide unmatched guidance to companies developing medical products for the U.S. market.

This wealth of experience allows the Greenleaf team to work cross-functionally to provide a full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges.

# AREAS OF EXPERTISE

Greenleaf's digital health clients vary greatly in nature, scope, and levels of experience. Because there is no one-size-fits-all approach, each solution is built to fit the targeted needs of the client. Greenleaf regularly provides expertise to the following types of clients:

- Start-up and mid-sized software companies developing digital health mobile apps
- Drug companies entering the digital health space to enhance the patient or health care provider experience of their products
- Diagnostic testing companies developing applications to read diagnostic test results
- Consumer product companies entering the digital health space with limited FDA regulatory experience
- Investors identifying and evaluating regulatory risks in potential digital health investments
- Trade associations and global drug and medical device companies developing digital health policy strategies
- Artificial intelligence (AI) program developers seeking FDA regulatory insight and clarity
- Telehealth companies partnering with clinical practitioners and life science companies to offer online access to medical products
- Health policy and research organizations developing, tracking, and responding to digital health policies, legislation, and initiatives
- Drug and device companies using digital tools to conduct decentralized clinical trials

# STRATEGIC & TECHNICAL GUIDANCE

The combined knowledge and substantial qualifications of the Greenleaf team ensure best-in-class insight for companies navigating digital health regulations. Greenleaf offers the following digital health-focused services:

## REGULATORY STRATEGY & COMPLIANCE

***Provide insight, clarity, and strategic consultation on digital health topics***

Advise clients on FDA regulatory policies, programs, and procedures, including questions related to jurisdiction to regulate, device classification, and potential pathways to market

Partner with clients to design strategies for product development and premarket review

Assist with marketing application preparation and submission

Provide advice regarding FDA communications, including compliance and regulatory correspondence

Advise on FDA labeling and postmarket safety requirements

## ADVISORY SERVICES

***Assist entities involved in digital health technology investments and transactions***

Perform due diligence and regulatory risk assessments of potential targets

Advise investors on opportunities to manage and mitigate risks in order to achieve desired regulatory outcomes

Research and analyze regulatory data sources

## REGULATORY POLICY

***Help clients keep pace with developments and navigate the emerging regulatory landscape***

Identify novel regulatory tools and approaches to optimize the development process

Support clients in structuring their regulatory policy capabilities to effectively advance priorities

Design and implement strategies that engage stakeholders, leverage alliances, and advance regulatory policy

# EXPERT TEAM

### DAN SCHULTZ, M.D.

***Principal, Medical Device & Combo Products***

Distinguished 35-year career includes service as Director of the FDA's Center for Devices and Radiological Health.

### MAURA NORDEN

***EVP, Medical Device & Combo Products***

15 years of experience advising leading medical device and drug companies on FDA regulatory matters.

### KALAH AUCHINCLOSS

***EVP, Regulatory Compliance***

15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff.

### BRIAN CORRIGAN

***EVP, Regulatory Policy***

10+ years of experience in the biopharmaceutical industry provides in-depth knowledge of the U.S. health care system.

### SEAN HILSCHER

***VP, Regulatory Policy***

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

### MARIA BONNER

***VP, Regulatory Compliance***

Policy and legal experience in both the public and private sectors provides deep understanding of regulatory policy.