Greenleaf Health

Maura M. Norden, J.D.

Senior Vice President, Medical Devices & Combination Products General Counsel

BACKGROUND	• 10+ years advising clients on a broad range of FDA regulatory matters
SPECIALTY	• Specialist in FDA statutes, regulations, and policy, as well as product development, clearance and approval, and marketing • Specialist in FDA regulatory due diligence
EXPERIENCE	• Several years experience working in the food, drug, and medical device practice group at a large, multinational law firm

Maura Norden joined Greenleaf from the law firm Sidley Austin LLP (Sidley) in January 2015, following nearly a decade of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

Maura uses her comprehensive and in-depth understanding of FDA regulatory requirements and regulatory processes to provide strategic advice to medical device and drug companies throughout the product lifecycle, from development to FDA premarket review and postmarket regulation. Maura advises a broad range of clients from early-stage companies to large, multinational industry leaders on developing optimal regulatory solutions and successfully navigating FDA regulatory processes. Maura also regularly assists medical device and drug clients on FDA regulation of cutting-edge technologies, such as companion diagnostics and combination products.

Maura works with clients to develop and implement regulatory strategies to bring products to market. Maura also advises companies on all aspects of clinical trials and compliance with Good Clinical Practices, including investigational device exemption (IDE) and investigational new drug (IND) requirements.

Maura also has extensive experience advising clients on postmarket regulation, including compliance with FDA promotional requirements. She has assisted manufacturers in responding to regulatory letters and inquiries involving promotional materials. Her promotion expertise is bolstered by experience gained during temporary assignments to multinational pharmaceutical companies, where she sat on copy review committees. Maura also has experience advising on MDR and adverse event reporting requirements.

In addition, Maura advises clients developing positions on various FDA reports and guidance documents and has drafted comments on behalf of clients. She also regularly conducts targeted regulatory due diligence for transactions involving public and private FDA-regulated firms and provides strategic counseling for post-acquisition risk mitigation.

Maura received her J.D., with honors, from the George Washington University Law School where she was an associate of The George Washington International Law Review. She received her B.A. from the University of Virginia where she was a Jefferson Scholar.