

Samantha Eakes

Vice President, Regulatory Affairs



BACKGROUND

- Public health, public policy, and nonprofit sector

SPECIALTY

- FDA regulation of medical devices and combination products
- Premarket medical device submissions

EXPERIENCE

- 7+ years of FDA regulatory consulting experience
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Samantha brings more than seven years of FDA regulatory consulting experience and a diverse background in public health, public policy, and the nonprofit sector to her position as Vice President of Regulatory Affairs.

Through her public health studies and prior experience, Samantha acquired critical public health knowledge that allows her to effectively assist clients with developing communications and advocacy strategies, stay informed on evolving regulatory requirements, and provide strategic insight on critical regulatory challenges.

In her role at Greenleaf, Samantha advises clients regarding potential FDA regulatory pathways for their devices and assists clients with their FDA submissions and correspondence. She reviews, drafts, and files FDA premarket submissions for medical device clients, including: Pre-Submissions (Pre-Subs); Submission Issue Requests (SIRs); Requests for Designation (RFDs); Breakthrough Device Designation Requests; Investigational Device Exemptions (IDEs); 510(k) Premarket Notifications; Premarket Approval Applications (PMAs); and Emergency Use Authorizations (EUAs). Samantha also conducts research for medical device clients to use in strategic planning and analyzes the regulatory landscape using FDA databases, regulations, policies, and guidance documents.

Samantha has published articles on medical device-related topics such as cybersecurity and the FDA's least burdensome provisions.

Prior to joining Greenleaf, Samantha gained policy and advocacy experience at Management Sciences for Health (MSH). She also previously volunteered with Arts for Dementia, an organization in London, England, that provides art and music therapy for individuals living with dementia and Alzheimer's disease.

Samantha earned a B.A. in psychology from Boston University and an M.P.H. from Boston University's School of Public Health.