Greenleaf Health

Madeleine Giaquinto, J.D.

Manager, Regulatory Affairs

SPECIALTY

- FDA Regulation of Drugs, Biologics, Medical Devices, Dietary Supplements, and Cannabidiol (CBD)
- Quality and Compliance Oversight of FDA-Regulated Products
- FDA Strategic Engagement

EXPERIENCE

- Regulatory Compliance Consulting
- Federal Healthcare Policy Advocacy

BACKGROUND

- Legal, Nonprofit, Government Affairs, and Public Health Policy Sectors

Madeleine Giaquinto offers a robust portfolio of regulatory compliance and federal healthcare advocacy experience, spanning legal, nonprofit, government affairs, and public health policy settings.

In her role as Manager of Regulatory Affairs at Greenleaf Health, Madeleine provides clients with timely analysis of FDA regulations, policies, and guidance documents related to good practice standards for drugs, biologics, medical devices, dietary supplements, and CBD. In addition, she advises clients on strategic engagement with FDA regarding a range of compliance issues, such as remediating deficiencies identified in FDA Form 483 observations and FDA Warning Letters, as well as building cultures of quality within mature quality management systems.

She has published articles on topics ranging from the root causes of drug shortages along global supply chains, DOJ's evaluation of corporate compliance programs in the context of FDA-regulated products, and FDA's regulatory activities in response to COVID-19 and in future pandemic preparedness efforts.

Before joining Greenleaf Health, Madeleine gained legal and government relations experience at 340B Health, a membership organization of hospitals and health systems within the federal 340B drug pricing program. Her role involved researching and analyzing implications of 340B development and educating members on issues involving program compliance, implementation, and advocacy strategies. Madeleine also worked at Mintz Levin Strategies, where she tracked and analyzed development of various federal and state healthcare policies.

Before earning her law degree, Madeleine worked at MedStar Georgetown University Hospital managing the Department of Pediatrics' compliance with healthcare provider credentialing requirements of various regulatory authorities.

Madeleine received a B.S. in Biology from Georgetown University and a J.D. from George Mason University School of Law.