Greenleaf Health

Madeleine Giaquinto, J.D.

Director, Regulatory Affairs

BACKGROUND

- 9+ years in public health policy and regulatory compliance professional services

SPECIALTY

- FDA regulation of drugs, biologics, medical devices, dietary supplements, cannabis-derived products, cosmetics, and tobacco-related products

EXPERIENCE

- FDA regulatory consulting and strategic engagement
- Federal health care legislation and public health policy research & analysis

Madeleine Giaquinto offers a robust portfolio of public health policy and regulatory compliance expertise that spans a career of nearly 10 years working across legal, government/legislative affairs, and hospital administrative environments.

At Greenleaf Health, Madeleine helps clients navigate complex landscapes of FDA regulation, policy, guidance, and GXP standards for drugs, biologics, medical devices, dietary supplements, cannabidiol (CBD) and cannabis-derived products, cosmetics, and tobacco-related products. She advises clients through strategic engagement with the FDA on wide-ranging compliance issues, such as remediating deficiencies identified in FDA Form 483s and warning letters and building mature quality management systems.

Madeleine has spoken on panels and published articles analyzing the regulatory impacts of a host of timely topics, including root causes of drug shortages, FDA warning letter trends, implementation of the Drug Supply Chain Security Act (DSCSA), advanced and continuous drug manufacturing technologies, and the development of a regulatory framework for CBD and cannabis-derived products. She serves on the Food and Drug Law Institute's (FDLI) Austern Writing Awards Committee, focused on fostering the next generation of professionals in the food and drug law field.

Prior to joining Greenleaf Health, Madeleine worked on legal and government relations teams at 340B Health, a membership organization of hospitals and health care systems that participate in the federal 340B drug pricing program. Her role involved researching and analyzing implications of 340B program development, and educating members on program compliance, implementation, and advocacy strategies. Madeleine also previously worked at Mintz Levin Strategies, LLC, where she tracked and analyzed development of various federal and state health care bills and policies. She has also spent time in health care practices managing compliance with practitioner credentialing requirements of federal, state, and local regulatory authorities.

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