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Jessica L. Vaughn, Ph.D.

Associate

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Jessica provides clients with legal and regulatory support needed to design and implement regulatory strategies to advance products, including pharmaceuticals, medical devices, cosmetics, food products, and dietary supplements, through the premarket approval regimen of the U.S. Food and Drug Administration (FDA). With an advanced scientific degree and experience in-house at a global biotechnology company, Jessica provides a unique insight into pharmaceutical and medical device matters.

Representative Matters

- Advises clients on early drug development programs, including assistance with the drafting and technical review of preclinical testing protocols.
- Counsels clients on clinical development of new drugs, including review and design of clinical trial protocols and endpoint development, and interactions with contract research organizations.
- Assisted multiple private and publicly traded companies in developing a relationship with regulators, navigating the planning, drafting, and submission of FDA meeting and information requests, and accompanying clients to meetings with regulatory agencies.
- Assists clients with short- and long-term regulatory strategy planning and execution for pharmaceuticals, including drafting Investigational New Drug Applications and New Drug Applications.
- Advises clients on FDA requirements for expedited development and review programs such as orphan drug

Practice Areas

Food & Drug
Pharmaceuticals, Biologics, and Life Sciences
Medical Devices
Digital Health
Enforcement & Recalls
Environment & Product Regulation
FDA and USDA Regulatory Compliance
Food & Drug Due Diligence and Transactional Support
Food and Food Ingredients
Labeling, Advertising, and Promotion
Litigation and Administrative Advocacy

Credentials

Education
J.D., *cum laude*, The Catholic University of America Columbus School of Law
Ph.D., New York University
M.S., New York University
B.A., Ithaca College

Bar and Court Memberships
District of Columbia Bar

designations, fast track, breakthrough therapy, and priority review designations, as well as accelerated approval, with a proven track record of successful applications.

- Represents and guides clients in responding to FDA information requests as well as enforcement actions such as Warning Letters, Untitled Letters, Complete Response Letters, recalls, import detentions, and alerts.
- Provides technical expertise and support in due diligence involving the sale and acquisition of companies that produce FDA-regulated products, and provides support to litigation and discovery matters.
- Provides regulatory strategy planning and support for medical devices, including the design and drafting of premarket applications such as 510(k) applications and De Novo classification requests, and provides technical support for medical device development issues.
- Reviews agreements and contracts associated with pharmaceutical and medical device activities.

Professional Experience

- Executive Director, Legal/Regulatory/Compliance, CorMedix Inc. (2019-2021)
- Law Clerk (2019), Regulatory Scientist (2012-2019), Private law practice
- Graduate Assistant, New York University School of Medicine, Department of Environmental Medicine (2006-2012)
- Clinical Information Manager, Alpha Physicians Resources (Emergency Medical Associates of NJ) (2004-2012)

Affiliations

- American Bar Association
- Food and Drug Law Institute (2022-Present)
    - Patient Organization Engagement Committee (2023)
- Consumer Health Products Association
- Maryland Tech Council