Melissa Roy

Associate

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Melissa Roy is an associate in Frier Levitt's Life Sciences practice group, where she counsels pharmacies, pharmaceutical manufacturers, and other healthcare industry clients on complex FDA regulatory, compliance, and enforcement matters. Her dual credentials as a PharmD and JD give her particular depth in pharmacy practice, including compounding pharmacy (503A/503B) compliance, cGMP, and REMS requirements.

Melissa brings more than a decade of experience within the U.S. Food and Drug Administration, with roles in the Office of Regulatory Affairs (now the Office of Inspections and Investigations) and the Center for Biologics Evaluation and Research (CBER). Most recently, as Regulatory Counsel in the Office of Inspections and Investigations, she advised on statutory interpretation and regulatory compliance for FDA-regulated drugs, biologics, and medical devices, and led development of federal guidance documents and rulemaking that shaped national enforcement and inspection standards. At CBER, Melissa served as the Center's primary liaison to Congress, developing policy positions and drafting sensitive public comment letters, technical talking points, and Congressional responses. She began her FDA career as a Consumer Safety Officer with the Office of Regulatory Affairs, inspecting pharmaceutical manufacturers and compounding pharmacies for compliance with cGMP, REMS, and 503A/503B regulatory requirements.

Before joining Frier Levitt, Melissa served as Executive Director of Legal and Compliance for a specialty pharmacy company, directing the implementation of regulatory, quality, and compliance frameworks and advised executive leadership on federal and state regulatory strategy. She previously founded and managed her own law practice in Texas.

Education

Georgetown University Law Center, J.D.

St. John's University, Doctor of Pharmacy

Admissions

- New Jersey
- Texas