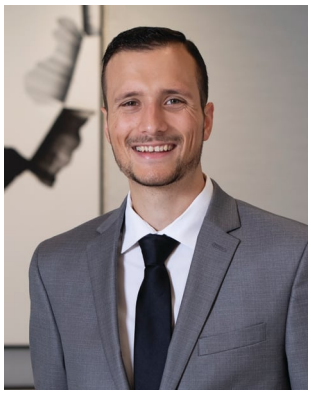
ALSTON & BIRD



Anthony Fanucci, PharmD

Associate

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Related Services

Health Care ▪ FDA/Food, Drug & Device ▪ Life Sciences ▪ FDA Compliance & Enforcement ▪ Corporate Compliance Programs

Anthony, a licensed pharmacist, relies on his pharmacy background and experience as a pharmaceutical licensing consultant to guide FDA-regulated clients through regulatory and enforcement actions.

Anthony Fanucci is an associate in Alston & Bird's Health Care FDA Group and a member of the Food, Drug & Device/FDA Team. Anthony advises pharmaceutical and medical device companies on complex FDA rules and regulations. His clients value his experience in pharmaceutical analytical chemistry, biopharmaceutics, and pharmaceutical dosage forms and drug delivery systems.

Before joining the firm, Anthony served as pharmacist and a pharmaceutical licensing consultant. During his years as a consultant, Anthony co-managed nationwide licensure efforts for six pharmaceutical companies and provided compliance strategies based on company structure, intended market, and products.

Representative Experience

- Advised foreign and domestic drug and drug substance manufacturers regarding FDA facility inspections, warning letters, untitled letters, requests for information, and regulatory meetings, including on-site work in India.
- Advised drug and drug substance manufacturers on developing concerns regarding nitrosamines, benzene, and other genotoxic impurities. This work has included the analysis of de-risking plans for sites making manufacturing changes related to impurities.
- Guided clients with their development of corporate-wide control strategies for nitrosamines and other genotoxic impurities, including the mitigation of nitrosamine drug substance-related impurities (NDSRIs).
- Assisted a national dermatology practice to assess the requirements under a REMS program and advocate on behalf of prescribers facing penalties for alleged non-compliance with such requirements.
- Conducted a holistic review of drug, food, waste, and chemical permits for multiple clients and detailed CHOW requirements for all permits in advance of equity sales.
- Assisted clients on multiple DEA matters, including navigating DEA's controlled substance quotas and telehealth flexibilities.
- Helped guide a medical device startup with the importation and distribution of FDA-authorized COVID-19 antigen tests under COVID-19-modified state licensing requirements to fulfill critical needs.
- Helped a prescription medical device manufacturer and distributor navigate state requirements in states with jurisdiction over medical devices vs. states that do not regulate or license medical device establishments.

- Assisted a product delivery company by analyzing state regulatory requirements for the delivery of cannabis-derived products and recommending an operational strategy that minimized enforcement risks.
- Drafted a legal opinion emphasizing the inapplicability of a state's medical device distribution regulations, which enabled the client to continue its activities in the state in question.

Publications & Presentations

Publications

- "Industry Needs to Better Prepare for Drug Supply Chain Compliance," *Bloomberg Law*, January 10, 2023.

Presentations

- "When FDA Comes Knocking: What to Expect in Inspections," Food and Drug Law Institute (FDLI), webinar, May 25, 2023., May 25, 2023.

Professional & Community Engagement

- Food and Drug Law Institute, New to Food and Drug Law Planning Committee
- American Society for Pharmacy Law, Communications, Member Relations, and Marketing Committee, co-chair
- Wilkes University, board of trustees

Education

- Pennsylvania State University (J.D., 2021)
- Wilkes University (B.S., Pharm.D., 2018)

Admitted to Practice

- District of Columbia
- Vermont (Inactive)