ALSTON & BIRD

Benjamin K. Wolf

Senior Associate

+1 202 239 3035 | ben.wolf@alston.com
Washington, D.C. | The Atlantic Building, 950 F Street, NW | Washington, DC 20004-1404

Related Services

Health Care ▪ FDA/Food, Drug & Device ▪ Life Sciences ▪ Food, Beverage & Agribusiness ▪ FDA Compliance & Enforcement

Ben's training as a biomedical engineer at a cardiac device company and as regulatory counsel at the FDA helps him advise drug, device, food, and tobacco manufacturers.

Benjamin Wolf is a senior associate in the Health Care Group and a member of the Food, Drug & Device/FDA Team. Ben counsels clients in many industries regulated by the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA). He has particular interest and experience in medical devices, agency compliance actions, and inspection-related issues, as well as the regulation of food, beverages, animal feed, dietary supplements, cannabis, and tobacco products.

In his role in industry, Ben developed medical devices, assisted with regulatory applications, and worked to address regulators' questions. At the FDA, Ben reviewed product applications, conducted inspections, and developed policies for submission review, inspections, recalls, and other post-market issues with focuses on medical devices, combination products, and tobacco (including e-cigarettes). In private practice, Ben has worked extensively in prominent FDA regulatory firms on matters involving medical devices, current good manufacturing practices (CGMP), pharmaceuticals, stem cells and human cell & tissue products (HCT/P), tobacco, food, animal feed, dietary supplements, cannabis, and cannabidiol (CBD) products. He is recognized by *The Best Lawyers in America©* in "Ones to Watch" for Health Care Law.

Representative Experience

- Assisted a global life sciences company in reclassifying a domestic manufacturing site back into acceptable compliance status following a Form-483.
- Advised a domestic generic drug manufacturer with on-site inspection support and related regulatory meetings with FDA.
- Advised multiple India-based generic drug manufacturers with on-site inspections and Form-483 responses.
- Advised a domestic food manufacturing facility with a microbiological contamination issue.
- Assisted with the submission of an Investigational New Drug (IND) application on behalf of the developer of a SARS-CoV-2 vaccine. Alston & Bird's work included a protocol review, as well as advice regarding the delivery system for the vaccine and assistance addressing FDA questions regarding the application.
- Designed, directed manufacturing procedures, and ensured regulatory compliance of medical devices.
- Developed policies and standards for post-market regulation of laboratory-developed tests (LDTs), the manufacture of medical devices, submission review, inspection, and FDA enforcement.

- Assisted makers and importers of medical devices, pharmaceuticals, food, raw pet food, baby formula, and tobacco products in conducting recalls.
- Aided pharmaceutical and medical device companies during FDA inspections and in responding to FDA inspectional observations and subsequent compliance and enforcement actions including warning letters and regulatory meetings.
- Advised clients marketing cannabidiol (CBD) and cannabis products on the legality of those products on a federal level and in label review, marketing, and business risk.
- Audited e-vapor clients for adherence to CGMP (also known as tobacco product manufacturing practices (TPMP)) and related regulatory requirements.
- Reviewed medical device, pharmaceutical, food, animal feed, dietary supplement, and tobacco labeling for regulatory compliance, claim substantiation, and litigation risk.
- Performed regulatory due diligence of medical device and pharmaceutical companies, including compounding pharmacies.
- Assessed appropriate regulatory pathways for medical devices and tobacco products.
- Reviewed compounded drugs formulations for permissibility to manufacture at a compounding pharmacy.
- Developed and submitted regulatory submissions for tobacco products which resulted in permitted marketing.
- Advised hearing aid manufacturers and distributors on matters related to hearing aid marketing, including OTC hearing aid requirements.

Publications & Presentations

Publications

- "Overlapping Jurisdiction with Other Agencies and Law Enforcement Entities," chapter in *Medical Devices Law and Regulation Answer Book*, Practising Law Institute, September 2022.
- "Practical Considerations for Draft Transition Plans for Devices Under EUAs or COVID Enforcement Policies," *Medical Device and Diagnostic Industry*, January 14, 2022.
- "Top Regulatory Issues for Food & Beverage Companies to Watch for in 2022," *Food Manufacturing, December 23, 2021.*
- "Food Ingredient GRAS Conclusions: What You Should Know," *Food Manufacturing,* February 15, 2021.
- "Pending Regulatory Developments for Food Innovators: Microorganisms, Cell Cultures and COVID's Impact," *Food Manufacturing,* December 10, 2020.
- "The Top 5 Regulatory Issues for US Food Launches in 2021," *New Food Magazine,* December 8, 2020.
- "Regulation of Drugs, Biologics, Controlled Substances, Cannabis, and Compounded Drugs," in A Practical Guide to FDA's Food and Drug Law and Regulation, 7th ed., Food and Drug Law Institute, 2020.

Presentations

- "Introduction to Tobacco and Nicotine Products Law and Regulation," Food and Drug Law Institute (FDLI), webinar, October 26, 2021.
- "COVID -19: Introduction to FDA's Legal Authorities and Emerging Issues," Food and Drug Law Institute (FDLI), webinar, August 18-19, 2020.

- "Introduction to Medical Device Law and Regulation," Food and Drug Law Institute (FDLI), webinar, April 7-8, 2020.

Professional & Community Engagement

- American Bar Association
- Food and Drug Law Institute (FDLI)
- Olney Theatre Center, board of directors

Education

- The George Washington University (J.D., 2013)
- Columbia University (B.S., 2003)

Admitted to Practice

- Virginia
- District of Columbia