ALSTON & BIRD

Cathy L. Burgess

Partner

+1 202 239 3648 | cathy.burgess@alston.com
Washington, D.C. | The Atlantic Building, 950 F Street, NW | Washington, DC 20004-1404

Related Services

FDA/Food, Drug & Device ▪ FDA Enforcement & Litigation ▪ Life Sciences ▪ Health Care ▪ Legislative & Public Policy ▪ Chemical & Product Regulation ▪ Health Care Litigation ▪ Corporate Compliance Programs ▪ Toxic Substances Control Act (TSCA) ▪ Biotechnology, Pharmaceutical & Life Sciences Patent Litigation ▪ Food, Beverage & Agribusiness ▪ FDA Compliance & Enforcement

FDA-regulated entities benefit from Cathy's common-sense advice for achieving business objectives that avoid compliance and enforcement risks. With more than 30 years of extensive experience in the areas of CGMP regulation and product risk management, she provides strategic counseling and works with clients to identify and address potential risks throughout the product life cycle.

Cathy Burgess leads the firm's FDA Compliance and Enforcement Team and FDA practice.

Cathy advises clients on a range of matters affecting prescription and OTC drugs, biologics, medical devices, foods, and cosmetics, and has extensive experience regarding current good manufacturing practice (CGMP) regulation and supply chain management. For products regulated under the Federal Food, Drug, and Cosmetic Act (FDCA), Cathy conducts liability risk assessments and works with clients to identify and analyze potential legal risks associated with their products. She advises clients on quality system remediation, inspection management, recalls, and responses to Form FDA 483s and warning letters. Cathy also conducts whistleblower investigations, special audits, and due diligence reviews related to FDA compliance. She assists clients in designing compliance programs, internal audit programs, and other risk mitigation strategies. She is recognized as a leading practitioner for life sciences in *Who's Who Legal*, ranked in *The Best Lawyers in America*® in FDA and Food and Beverage Law, and ranked Band 2 in *Chambers USA* in Pharmaceutical/Medical Products Regulatory. Cathy is a recipient of the FDLI 2023 Distinguished Service and Leadership Award.

Before joining Alston & Bird, Cathy served as associate general counsel for the American Red Cross, where she was responsible for regulatory matters, and served as the Red Cross Office of General Counsel's representative in negotiations related to the Red Cross amended consent decree.

Representative Experience

Compliance

- Counsel to foreign and domestic manufacturing facilities regarding FDA inspections, regulatory meetings, warning letters, import alerts, and consent decrees. This work has included extended on-site support in India, Central Europe, and China.
- Counsel to multinational clients on risk assessment and control strategies for nitrosamine and other genotoxic impurities. This work has included preparing submissions to regulatory authorities, working with experts in analytical chemistry, cleaning validation, and toxicology, on long term remediations, and preparing executive managers for meetings with regulatory authorities focused on nitrosamine impurities.
- Advising and counseling domestic and foreign pharmaceutical manufacturers on issues related to data integrity.

- Advising foreign and domestic pharmaceutical manufacturers on the implications of FDA inspection delays.
- Counsel to blood banks and other clients regarding blood product regulatory compliance matters.
- Counseled on pharmacy compounding and outsourcing facility issues.
- Counseled on new drug applications for marketed unapproved products.

Enforcement

- Negotiated the successful resolution of import alerts and warning letters related to CGMPs, data integrity, and inspection refusal.
- Negotiated an FDA consent decree in a case involving the mass seizure of a generic drug company's inventory.
- Served as the defense team's first chair for expert testimony on CGMPs and analytical method validation in *United States v. Barr Laboratories*, widely recognized as the leading case on CGMPs.
- Defended a targeted medical device executive in a criminal referral which resulted in a declination letter.
- Developed medical device company compliance plans and remediation strategies in response to recidivist warning letters.
- Provided legal assistance and strategic advice to Red Cross senior management and the board of governors' Audit Committee on matters related to the Red Cross amended consent decree.
- Assisted a medical device client in responding to FDA import holds and detentions.
- Counseled the principal investigator of an investigational device whose research was suspended pending resolution of a warning letter.
- Drafting testimony and responses to questions for the Committee on Energy and Commerce Subcommittee on Oversight and Investigations.

Pandemic Related Counseling

- 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.
- Counseled clients regarding FDA Emergency Use Authorizations.
- Advising commercial manufacturers seeking to develop diagnostic test kits and personal protective equipment for health care workers.
- Provided advice and counsel on drug and medical device regulation, as well as development of preparedness strategies and crisis communications, related to the SARS and H1N1 influenza pandemics.

Regulatory Due Diligence

- Regulatory due diligence reviews in the prescription and OTC drug, pharmacy compounding, and medical device areas.

Food and Cosmetic Counseling

- Advising dietary supplement and food companies on product safety issues, including on product recalls and contamination incidents.
- Counsel to a major food client in connection with regulatory advice, development of a legislative strategy, and compliance audits.

- Assisting cosmetics companies on developing marketing claims to minimize regulatory and litigation risk and advising on the regulatory status of ingredients.
- Advising clients on compliance obligations surrounding the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

Publications & Presentations

Publications

- *Topics in Food and Drug Law: How to Comply with Drug CGMPs*, 3rd ed., Food and Drug Law Institute, June 2023.
- "Overlapping Jurisdiction with Other Agencies and Law Enforcement Entities," chapter in *Medical Devices Law and Regulation Answer Book*, Practising Law Institute, September 2022.
- "Data Integrity Guidance Revisions by FDA and PIC/S Deepen Industry's DI Resource Pool," *International Pharmaceutical Quality*, April 23, 2019.
- "CGMP Enforcement Alternatives in the United States," "FDA Inspection Process," and "FDA Pre-approval Inspections," in *Good Manufacturing Practices for Pharmaceuticals,* 7th ed., CRC Press, 2019.
- "Overlapping Jurisdiction with Other Agencies and Law Enforcement Entities," in *Medical Devices Law and Regulation Answer Book*, 2019 ed., Practising Law Institute, 2018.
- *How to Comply with Drug CGMPs,* 2nd ed., Food and Drug Law Institute, April 2017.
- "3D Printed Medical Devices: More Lawsuits and More Questions," *Bloomberg BNA Medical Devices Law & Industry Report*, February 4, 2015.
- "A Social Experiment: 2015 Outlook for FDA's Social Media Policy," *Bloomberg BNA Social Media Law & Policy Report*, January 20, 2015.
- "Agency Action," *Top 20 Food and Drug Cases, 2014 and Cases to Watch*, FDLI, 2015.
- "Understanding, Anticipating, and Preventing Pharmaceutical Recalls," *Bringing Your Pharmaceutical Drug to Market*, FDLI, 2015.
- "Alameda County's Drug Take-Back Ordinance," *Industry Today*, October 22, 2014.
- "A Roadmap to Meaningful Use: FDA Releases More Social Media Guidance," *Bloomberg BNA*, September 19, 2014.

Presentations

- "Understanding the Legal Aspects of Information Provided to Regulators as Part of a Remediation Process | If You Said You Did It–Show It!" and "An Examination of CAPAs Commitments and Remediation Plans," PDA Annual Meeting 2024: Maintaining Quality & Compliance in Pharmaceutical Drug Manufacturing and Regulatory Expectations, Hyderabad, March 11–15, 2024.
- "Responding to the Latest FDA Inspection and Enforcement Activity," Advanced Legal, Regulatory and Compliance Forum on OTC Drugs, American Conference Institute, New York, NY, January 23–24, 2024.
- "Trends and Developments as FDA Ramps Up Domestic and Foreign Inspections," Enforcement, Litigation, and Compliance Conference For the Drug, Device, Food, and Tobacco Industries, FDLI, Washington, District of Columbia, December 6-7, 2023.
- "Do This, Not That," 18th Annual FDA Inspections vSummit, FDANews, webinar, November 8–9, 2023.

- "Nuts & Bolts of Regulation and Licensure Strategy," 2023 National Vaccine Law Conference, Washington, D.C., September 14-15, 2023.
- "When FDA Comes Knocking: What to Expect in Inspections," Food and Drug Law Institute (FDLI), May 25, 2023.
- "Regulating and Mitigating Nitrosamines and Other Impurities in Drug Products." 2023 FDLI Annual Conference, Washington, D.C., May 17-18, 2023.
- "Califf's FDA, 2023, and Beyond: Key Developments, Insights, and Analysis," FDANews, April 27, 2023.
- "Califf's FDA, 2023, and Beyond: Key Developments, Insights, and Analysis," FDANews, April 27, 2023.
- "cGMPs: Discovering the Unique Role of Current Good Manufacturing Practices (cGMPs) in the Post Approval Process," American Conference Institute 40th FDA Boot Camp, March 23, 2023., March 23, 2023.
- Moderator for "Compliance Central with FDA Center Compliance Directors," Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food, and Tobacco Industries,", December 7, 2022.
- "Compliance Central with FDA Center Compliance Directors," Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food, and Tobacco Industries, Food and Drug Law Institute (FDLI), Washington, D.C., December 7-8, 2022.
- "The 10 Best — and 10 Worst — Things to Do When FDA Staff Are on Site," FDANews 17th Annual FDA Inspections Summit, November 16-18, 2022., Washington, D.C., November 16-18, 2022.
- "Continuing Impact of FDA's Inspection Approach on Industry and What Happens Next," Food and Drug Law Institute Enforcement, Litigation, and Compliance Conference, December 9–10, 2021.
- "Communicating with the FDA: How to Expedite an Inspection and Escape the Queue," 16th Annual FDA Inspections vSummit, November 16–17, 2021.
- "How Does FDA's Recent Guidance on Remote Interactive Evaluations Change the Inspections Landscape?" Food and Drug Law Institute Annual Conference, webinar, May 26, 2021.

Professional & Community Engagement

- Food and Drug Law Institute, board of directors (2018-2022)
- Food and Drug Law Institute, Audit Committee, immediate past chair
- Food and Drug Law Institute, FDLI curriculum advisor for COVID-19 course
- FDLI Enforcement Conference, Planning Committee (2017, 2023), chair (2017)
- American Health Lawyers Association
- Food and Drug Law Institute, in-house training team to FDA
- Food and Drug Law Institute, Drugs and Biologics Committee, co-chair (2012–2015, 2015–2018)
- Regulatory Affairs Professionals Society
- American Red Cross, Tiffany Circle
- *The Best Lawyers in America*®, "Lawyer of the Year" in Food & Beverage Law for 2020
- *The National Law Journal*, "Life Science Trailblazer"
- *Food and Drug Law Journal*, editorial board

Court Admissions

- U.S. Supreme Court
- The United States District Court for the District of Columbia

Education

- The Catholic University of America (J.D., 1988)
- Georgetown University (B.S.F.S., 1982)

Admitted to Practice

- District of Columbia