SQUIRE PATTON BOGGS

# Delia A. Deschaine

**Partner**

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## About Delia

Delia Deschaine is a partner in the firm's Global Corporate Practice, where she advises clients on the US Food and Drug Administration (FDA)'s laws, the US Drug Enforcement Administration (DEA)'s laws, and US state-controlled substance and pharmacy laws. Her practice focuses on providing comprehensive counsel to pharmaceutical and biotechnology manufacturers on a diverse array of issues, such as:

- New product development and approval, regulatory submissions, regulatory exclusivity, formal dispute resolution, controlled substances scheduling, advisory committee review, and citizen petition drafting and commentary
- Compliance with the FDA's Current Good Manufacturing Practices (CGMPs), Risk Evaluation and Mitigation Strategies (REMS), the Drug Supply Chain Security Act, and the requirements surrounding registration and listing; field alert reporting; import and export; recalls; and labeling, advertising and promotional activities

Delia possesses a deep understanding of the FDA's requirements concerning CGMPs and the FDA's Quality System Regulations (QSR). She routinely advises clients on their obligations in this regard, encompassing quality systems, data integrity, supply chain management, aseptic processing, validation and sterilization protocols. Delia utilizes her expertise to assist manufacturers and suppliers in responding effectively to FDA Form 483s, warning letters and import alerts.

Additionally, Delia concentrates her practice on the intricate federal and state regulation of controlled substances. She defends pharmaceutical and biotechnology companies, distributors, pharmacies, hospitals, physician groups, academic medical centers, and researchers in controlled substances' related government investigations and litigation. Her advisory services in this realm include:

- Assisting clients in navigating controlled substances scheduling matters
- Ensuring compliance with stringent DEA and state law regulatory frameworks
- Conducting thorough internal investigations to address potential compliance issues

Delia further utilizes her subject matter expertise to deftly advise clients in corporate transactions, conduct regulatory diligence, and draft and negotiate commercial agreements, including manufacturing services agreements, research agreements and quality agreements.

Delia has been named in *DC Super Lawyers* Rising Stars (2018-2020) and *The Best Lawyers in America* (2023-2024).

## Experience

- Represented a pharmaceutical company in an appeal of a complete response letter, leading to a favorable FDA Advisory Committee Meeting and approval of the drug.*
- Drafted citizen petitions for pharmaceutical and biotechnology clients on novel issues of drug approval.*
- Assisted a biotechnology client nearing launch on development of an FDA compliance program, including contract manufacturing arrangements, pharmacovigilance, drug registration and listing, National Drug Code (NDC)/labeler code requirements and state licensing matters.*
- Drafted and negotiated contract manufacturing agreements, and related quality agreements, on behalf of gene therapy companies and other pharmaceutical and biotechnology clients.*
- Revised supply and distribution agreements for a pharmaceutical manufacturer of controlled substances.*
- Defended a client in a high-profile government investigation and litigation regarding the client's compliance with the DEA's suspicious-order monitoring requirements, leading to a court enjoining the DEA's immediate suspension order and a favorable outcome of an administrative proceeding.*
- Defended a pharmaceutical manufacturer in a government investigation, leading to a *nolle prosequi* of allegations of criminal federal Food, Drug, and Cosmetic Act violations.*
- Represented several manufacturers in responding to FDA Form 483s and warning letters, in every case resulting in no (or no further) enforcement action from the FDA.*
- Supported a private equity company's acquisition of a global manufacturer of cardiovascular devices, including conducting due diligence on various health regulatory matters involving FDA quality and regulatory compliance; sales and marketing practices; health regulatory corporate compliance; health information privacy and security; and state device manufacturing and distribution licensure, and assessing global health regulatory transition issues related to the transaction.*
- Counseled a national telehealth company on compliance with the Ryan Haight Online Pharmacy Consumer Protection Act and related COVID-19 waivers.*
- Drafted and submitted a citizen petition to the FDA on behalf of a client, raising safety concerns about a first-in-class drug and asking the FDA to take a closer look at those issues before approval.*
- Represented an academic institution in negotiating various agreements related to biological research, including preclinical and clinical material transfer agreements, a clinical manufacturing services agreement and a related quality agreement.*
- Represented a US pharmaceutical manufacturer in obtaining a state's withdrawal of an opiate product registration fee request.*
- Represented an academic research institution in negotiating a manufacturing services agreement and related quality agreement.*
- Drafted a letter to the DEA on behalf of an academic institution regarding the DEA's fee-waiver rule.*

- Represented a pharmaceutical opioid manufacturer in a civil settlement regarding alleged violations of the Federal Controlled Substances Act.*
- Provided legal regulatory guidance to a pharmaceutical company on the commercial launch of a new medication that is a controlled substance subject to DEA regulation.*
- Conducted regulatory due diligence of a drug manufacturing business for a private equity transaction, including assessing regulatory matters falling under the FDA, the DEA, and US state-controlled substance and drug distribution laws.*
- Supported a private equity sponsor in its sale of a pharmaceutical company, including aiding the company in addressing health regulatory matters involving the FDA, the DEA and state-controlled substances laws, and the Consumer Product Safety Commission.*

*Indicates work completed while at a prior firm.

## Credentials

### Education

- University of Maryland Francis King Carey School of Law, J.D., *cum laude*, 2010
- Manhattanville College, B.A., 2000

### Admissions

- District of Columbia, 2012
- Maryland, 2010

### Memberships & Affiliations

- Member, Food and Drug Law Institute, Medical Products Committee, 2022
- Legal chair, board of directors, Epping Forest Inc.

## Recognitions

- *DC Super Lawyers* Rising Stars, 2018-2020
- *The Best Lawyers in America*, 2023-2024

## Expertise

### Services

- Litigation
- Corporate

### Industries

- Healthcare
- Life Sciences

## Publications & Speaking Engagements

- Presenter, "IND Manufacturing in the AMC Setting: cGMP, Contracting, Liability, Commercial Partnerships, COI, and Other Challenges," American Health Law Association's Advising Providers: Legal Strategies for AMCs, Physicians, and Hospitals Conference, February 7, 2024.
- Presenter, "Appreciating the Nuances of the Approval Process for Controlled Substances," American Conference Institute's 41st FDA Boot Camp, September 20, 2023.

- Presenter, "Appreciating the Nuances of the Approval Process for Controlled Substances," American Conference Institute's 40th FDA Boot Camp, March 22, 2023.
- Presenter, "CSA Compliance Think Tank: The Critical Components of an Effective Controlled Substances Compliance Program," American Conference Institute's 6th Annual Summit on Controlled Substances, March 13, 2023.
- Co-presenter, "The Dobbs Decision: What's New and What's Brewing," Northeast Business Group on Health, February 13, 2023.
- Co-presenter, "From Roe to Dobbs: The Impact of State Abortion Laws on Employers," Lawline On-Demand Webinar, November 18, 2022.
- Co-presenter, "The Impact of Roe v. Wade's Reversal on Pharmacies and Pharmacists," American Society for Pharmacy Law Roundtable, September 9, 2022.
- Co-presenter, "Dobbs Impact on Privacy Laws and Labor & Employment," Pharmaceutical Care Management Association Webinar, July 13, 2022.
- Co-presenter, "CSA Compliance Think Tank – Building an Effective Controlled Substances Compliance Program," American Conference Institute's 5th Annual Summit on Controlled Substances – Regulation, Litigation, and Enforcement, July 11, 2022.
- Co-presenter, "Controlled Substances Bootcamp: An Introduction to Key Agencies, Regulation, and Scheduling," American Conference Institute's 3rd Annual Summit on Controlled Substances – Regulation, Litigation, and Enforcement, July 20, 2020.

## About our firm

One of the world's strongest integrated law firms, providing insight at the point where law, business and government meet. We deliver commercially focused business solutions by combining our legal, lobbying and political capabilities and invaluable connections on the ground to a diverse mix of clients, from long-established leading corporations to emerging businesses, startup visionaries and sovereign nations. More than 1,500 lawyers in over 40 offices across four continents provide unrivaled access to expertise.