ALSTON & BIRD

Devaki Patel, PharmD

Associate

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Related Services

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

Leveraging her pharmacist background, FDA-regulated companies trust Devaki's sound regulatory guidance.

Devaki Patel is an associate on Alston & Bird's FDA Team. Devaki concentrates her practice on assisting clients navigate novel and complex FDA regulatory matters involving food, drugs, biologics, devices, dietary supplements, and cosmetics. She also advises health care and life sciences companies in corporate transactions and post-transaction licensing matters.

As a licensed pharmacist, Devaki has experience assisting clients with matters related to DEA regulation, pharmacy practice, and telemedicine. She also has experience assisting drug and device manufacturers, distributors, and third-party logistic clients navigate federal and state licensing issues.

While in law school, Devaki served as an intern at the FDA's Office of Generic Drugs Policy at the Center for Drug Evaluation, where she worked on legal and regulatory issues related to generic drugs. She also interned for the FDA's Office of Policy at the Center for Devices and Radiological Health.

Devaki earned her J.D., cum laude, from the University of Maryland, where she served as the senior staff editor and symposium chair for the *Journal of Health Care Law and Policy*.

Representative Experience

- Advised foreign drug substance manufacturer regarding FDA facility inspections and untitled letters, and subsequent site remediations.
- Advised drug and drug substance manufacturers on regulatory considerations concerning cleaning validation procedures.
- Conducted FDA and health care due diligence of pharmaceutical and medical device companies, including for a global investment firm in its successful $1.1 billion acquisition of a Wisconsin-based device manufacturer and distributor.
- Reviewed promotional materials and regulatory disclosures in securities filings for life sciences companies, including investor presentations, press releases, white papers, and exhibit booth panels.
- Assessed appropriate regulatory pathways for novel medical devices and digital health products.
- Negotiated clinical trial agreements, master clinical trial agreements, and material transfer agreements.
- Counseled nonprescription drug (OTC) and dietary supplement manufacturers on regulatory compliance, claim substantiation, ingredient review, and litigation risk with respect to labeling of products.

- Provided strategic advice to cosmetic companies in developing marketing claims as to minimize regulatory and litigation risk.
- Counseled health care clients on state and federal controlled substance prescribing requirements, state medical and controlled substance licensing requirements, and federal DEA controlled substance registration requirements.
- Advised life sciences and health care companies on complex state licensing issues including for software as a medical device (SaMD), biologics, and durable medical equipment.

Professional & Community Engagement

- Food and Drug Law Institute (FDLI), Advertising and Promotion Conference Planning Committee

Education

- University of Maryland (J.D., 2020)
- Philadelphia College of Pharmacy (Pharm.D., 2016)
- University of The Sciences (B.S., 2014)

Languages

- Gujarati

Admitted to Practice

- U.S. Patent and Trademark Office
- Maryland
- District of Columbia