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Darshan Kulkarni

Consultant

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Areas of Focus

Practice
Health Care

Darshan has more than two decades of experience helping companies regulated by the Food and Drug Administration to develop, protect and distribute their products and innovations. Having been a pharmacist for more than 10 years, he has substantive technical experience that makes him uniquely equipped to assist clients across all stages of the product development process, including regulatory strategy, clinical trial, genericization, manufacturing and FDA reviews and compliance benchmarks. Additionally, Darshan advises on advertising requirements for FDA regulated products including drugs, cosmetics, foods and medical devices.

As a thought leader in his field, Darshan has authored chapters on federal regulatory laws surrounding drug advertising, medical devices, pharmacy compounding and reimbursement for several publications by the American Bar Association. He has taught courses on regulatory documents, bioethics and the promotion of biomedical products for medical writers at Philadelphia's University of the Sciences and he is currently a Visiting Professor at the Children's Hospital of Colorado where he lectures on clinical research issues.

Darshan has served as global corporate counsel for an international pharmaceutical holding company where he spearheaded engagements with the FDA. He was also a Vice President of Regulatory Strategy & Policy for a global venture-backed consulting company and General Counsel/Chief Compliance Officer for a venture -backed health technology company.

Darshan clerked for the Hon. Clifford Scott Green in the Eastern District of Pennsylvania.

Affiliations

- American Bar Association, Health Law Section
 - Life Science Interest Group, Former Chair
- American Bar Foundation, Fellow
- PA Early Learning Investment Commission, Commissioner
- Pharma Marketing Network, Advisory Board Member

Education

- Temple University School of Law, J.D.
- University of the Sciences (Philadelphia), Pharm.D.
- Temple University, Pharmaceutical Quality Assurance Regulatory Affairs, QA/RA, M.S.
- Interprofessional Geriatric Care, Fellowship

Bar Admissions

- Pennsylvania
- New Jersey