PRESS KIT BIOGRAPHY

darshantalks
regulatory guy. irregular podcast.

Darshan Kulkarni is an FDA regulatory lawyer, author, professor, and speaker, who takes a holistic approach to the healthcare and life sciences industries. Through the lens of patient centricity, including the underlying concepts of privacy, transparency, innovation, and access, Darshan looks at the broader implementation of programs by life sciences companies and healthcare professionals. With a background in creating companies, developing products, and helping guide finished products through the approval process where he has sold products as a pharmacist, Darshan has a unique perspective on how the pharmaceutical, regulatory, and life sciences industries intersect and function.

BACKGROUND

Most recently, Darshan serves as the General Counsel and Chief Compliance Officer to a highly reputable VC backed healthcare startup based out of the University of Pennsylvania. Previously, he led a prominent biopharmaceutical company in developing a global program that would foster clinical trial transparency and enhance public health. Darshan has also advised companies and individuals on implementing various strategies including creating a 505(b)(2) based strategy for a generic pharmaceutical company, suggesting promotional compliance strategies for a medical device company, and providing legal consultations for an anti-aging health hacker. He has also served as Vice President of Regulatory Strategy and Policy at a VC backed global consulting company. Darshan is currently the Principal Attorney of the Kulkarni Law Firm and focuses his practice on providing healthcare companies with comprehensive legal, compliance, and regulatory advice. He also serves as Visiting Professor at multiple universities.

Darshan has over 15 years of experience as a pharmacist. He contributes to the Darshantalks podcast to open up new discussions about the regulatory and pharmaceutical world. The topics he covers on his podcast range from cannabis law to emerging FDA actions and help individuals navigate laws and regulations specific to their industry. Through discussing a variety of life sciences topics, Darshan hopes to bring together regulatory, legal, strategic, and operational professionals in healthcare and the life sciences to address important issues such as patient centricity and data transparency.

Darshan has also written several book chapters on federal regulatory law including for the Research Compliance Professional's Handbook and various publications on behalf of the American Bar Association.

Darshan speaks at national conferences regularly and discusses a broad range of healthcare, regulatory, and pharmaceutical matters at events held by Venture Cafe, ExL, CBI, DIA, and BIO. Most recently, he spoke at JLABS about security and privacy for AI—discussing the privacy nuances around patient data.

PROFESSIONAL ASSOCIATIONS

In addition to speaking across the country, Darshan also has experience serving on regulatory boards and community groups in the greater Philadelphia area. He is a commissioner for the PA Early Learning Investment Commission, an organization dedicated to fostering investment in early learning programs for children in Pennsylvania. He is also involved in different legal boards, serving as Chair for the American Bar Association Health Law Section and is a Fellow of the American Bar Foundation. These boards promote discussion between legal professionals and advance understanding about the challenges facing the U.S. legal system.

He currently serves on the advisory board for Applied Clinical Trials at Advanstar Communications—serving as a legal consultant on the clinical trial industry and giving editorial direction to the publication. Darshan was previously on the editorial board of cosmetics and personal products for FDAnews, and provided the publication with his clinical trial and pharmaceutical expertise.

Darshan's unique insight into the healthcare and life sciences industries have allowed him to help his clients not only comply with regulations, but also reach broader goals of patient centricity, data transparency, and privacy.

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