LexVid Services, Inc., Presents:

Regulatory Due Diligence for FDA Regulated Companies

Total: **58 Minutes**

Speakers:
Darshan Kulkarni

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Join this Continuing Legal Education (CLE) session to get the latest insights and updates on how to effectively conduct due diligence for acquisitions in the life sciences sector, considering the dynamic legal, regulatory, and compliance environment. Key Topics:

- DOJ, OIG, and ORI investigations impact: Discover how recent actions and advisories from the Department of Justice (DOJ), Office of Inspector General (OIG), and Office of Research Integrity (ORI) influence due diligence efforts. We'll cover crucial aspects such as adherence to the False Claims Act, the integrity of clinical trial data, and handling of research misconduct. (24 min.)

- Updates on FDA regulations: Dive into the most recent changes and enforcement actions by the Food and Drug Administration (FDA) and understand how they alter the risk landscape for potential acquisitions. (22 min.)

-New legal and regulatory developments: Unpack the latest trends in the life sciences sector, including CRAACO, decentralized studies, and others, and how to evaluate the compliance risks they present. (12 min.)

Total: 58 minutes

Presenters:

Darshan Kulkarni 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.

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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.

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