Greenleaf Health

Dawn Wydner

Senior Vice President, Regulatory Compliance

BACKGROUND	• 10-year career in the FDA's Office of Regulatory Affairs • Global quality and compliance direction for pharmaceutical, medical device, and consumer R&D functions
SPECIALTY	• GCP, GLP, GMP processes, including postmarket surveillance • Audits and compliance, safety, and quality monitoring • Operational strategy and risk management across all GxPs
EXPERIENCE	• Led and conducted FDA bioresearch monitoring inspections under medical device and drug compliance programs • Managed complex global compliance issues for industry R&D portfolios across therapeutic areas

Dawn Wydner joined Greenleaf Health as Senior Vice President, Regulatory Compliance, after working closely with Greenleaf's Quality, Manufacturing, and Compliance Team as an independent consultant. Dawn has extensive FDA regulatory compliance expertise as well as quality and compliance experience within industry. During her ten years at the U.S. Food and Drug Administration (FDA), she was a Commissioned Public Health Service Medical Officer, conducting complex, thorough bioresearch monitoring (BIMO) inspections to assess good clinical practices (GCPs), good laboratory practices (GLPs), and good manufacturing practices (GMPs) under medical device and drug compliance programs domestically and internationally. She has also worked in bioresearch quality and compliance and clinical quality assurance roles for Janssen Research & Development, where she managed company-wide, global compliance activities and provided expert strategic direction and advice to senior leadership.

Dawn offers Greenleaf clients a deep understanding of all aspects of operational strategy, coordination, and conduct to ensure quality, safety, and compliance across the global pharmaceutical R&D, medical device, and consumer products industries. Her expertise covers the end-to-end lifecycle of a product and processes from GLP to GCP to GMP, including postmarketing surveillance; audits and compliance, safety, and quality monitoring; and operational risk management across all GxPs. She is frequently sought as a subject matter expert based on her proven track record of consistently establishing proactive compliance and application of quality oversight. Dawn is adept at utilizing her broad skillset to enable easy collaboration, big-picture strategic thinking, and compliance mindsets.

Prior to her career at the FDA, Dawn worked as a Registered Nurse in the hospital setting, caring for patients within transitional trauma, pediatrics, infectious diseases, and oncology. She has obtained her Ph.D. in Health Psychology and RQAP-GCP certification.