Greenleaf Health

Kristen C. Grumet

Senior Vice President, Regulatory Compliance

SPECIALTY

- Medical device compliance; Phase II-certified performance auditor in the area of medical devices
- Regulatory strategy for quality and compliance

EXPERIENCE

- Nine years as an FDA Field Investigator specializing in medical devices
- FDA Design Control Inspection Strategy Team member
- 25-plus years of quality systems compliance management and consulting for industry
- Successful management of Third-Party Certifications for companies under Consent Decree

Kristen is an expert in the field of medical device compliance, with 9 years of experience as an FDA Field Investigator specializing in medical devices and more than 25 years of quality systems compliance management and consulting for the industry. As a member of FDA's Design Control Inspection Strategy (DCIS) Team and FDA's Pacific Region Design Control Training Cadre, Kristen contributed to the development and implementation of the DCIS questionnaire for medical device inspections and trained companies in use of the questionnaire. She was a Phase II-certified performance auditor in the area of medical devices at the FDA and has the distinction of being part of the first cadre of certified medical device investigators in FDA history, conducting numerous inspections of European medical device facilities during her six-year tenure with the FDA foreign inspection cadre.

In her work with medical device companies, Kristen has managed successful Third-Party Certifications for companies under Consent Decree. She has led projects across the spectrum of quality assurance and regulatory compliance activities, including: compliance assessments; internal audits and investigations; quality systems program development and implementation; corrective action planning and quality system remediation; combination product training; and QSR and FDA inspection readiness training.

As Senior Vice President of Regulatory Compliance at Greenleaf Health, Kristen continues to provide medical technology clients with customized guidance and support in developing and implementing strong corporate quality systems and regulatory strategies for compliance, as well as focused reviews of quality issues such as management of medical device recalls.

Kristen has presented at FDA design control workshops and a wide range of compliance-related seminars for the medical device industry and provides expert advice through webinars, presentations, and publications in industry forums such as the Food and Drug Law Institute (FDLI) and FDANews.

Kristen has a degree in environmental population and organismal biology from the University of Colorado, Boulder. She also has extensive FDA-sponsored training in areas such as performance and quality audits, design control and process validation requirements, and medical device quality management system requirements.