SOFTWARECPR®

CRISIS PREVENTION AND RECOVERY, LLC

WINDI HARY

EXPERIENCE

- 21 years including C-Level, regulatory, quality, and clinical roles in medical device industry.
- Former Chief Quality and Regulatory Officer for HeartFlow (Mountain View, CA).
- Management Representative under ISO 13485.
- Person Responsible for Regulatory Compliance under EU MDR.
- Lead auditor for ISO 13485 (MDR, MHLW Ordinance No. 169).
- Lead US regulatory submissions for:
  - Seven 510(k) clearances
  - One De Novo approval (DEN130045)
- Solid understanding of compliance activities and quality management system processes to achieve MDSAP and FDA inspection readiness.
- Expert with regulatory compliance of cloud-based Software as a Medical Device (SaMD) spanning US, UK, European, and Japan markets, including Post-Market surveillance activities.
- Integration and alignment of the quality system following acquisition.
- Former Manager, Quality and Regulatory at Philips Healthcare.
- Assisted Massachusetts General Brigham's Digital CRO activities related to FDA.

CREDENTIALS

- ASME V&V40 Subcommittee Verification and Validation of Computational Modeling of Medical Devices – FDA Consensus Standard
- MITA Working Group for Artificial Intelligence (AI)
- ADVAMED
  - Artificial Intelligence (AI) and Machine Learning (ML)
  - Clinical Decision Support Software
  - Pre-Certification Program
  - SaMD
- De Novo clearance for first ever AI-enabled cardiology diagnostic software.
- M.A., Stanford University
- B.A., Magna Cum Laude, Vanderbilt University