SOFTWARECPR®

CRISIS PREVENTION AND RECOVERY, LLC

JOHN F. MURRAY, JR.

CREDENTIALS

- 25 years of experience at the US Food & Drug Administration
- Active member in the creation of the following FDA Guidance Documents:
  - General Principles of Software Validation
  - Premarket Software Submission
  - Off the Shelf Software
  - Cybersecurity (pre and post market)
  - Part 11 Guidance
  - Medical Device Data Systems (MDDS) Rule
  - MDDS Guidance
  - Mobile Medical Applications
  - General Wellness
  - 21st Century Cures Act
- Many years of experience for the following regulatory activities:
  - Software Device Classification Determination
  - Software 510(k) and PMA review
  - Software based inspections
  - Compliance review of software based 483 and industry responses
  - FDA enforcement actions

EXPERIENCE

- Internationally Recognized Internal FDA Software Expert and Frequent Conference Speaker
- Software Compliance Expert, Office of Compliance FDA CDRH
- FDA Software Expert Regulatory Review Scientist
- Member of the Digital Health Team at CDRH including the precertification Pilot program.
- Team lead Intelligent Medical Devices, Office of Science and Technology CDRH
- Co-Chair AAMI Software and Information Technology Committee (SWIT)
- Co-Chair AAMI Software Committee
- Instructor 15 years AAMI Regulatory Requirements for Software Validation Course
- Standards Committees Member or Chair in the creation of:
  - IEC 62304 Software Lifecycle Processes
  - AAMI TIR 32 Software Risk Management
  - IEC 80002-1 Application of IEC 14971 to Software
  - AAMI TIR 45 Agile Practices
  - AAMI TIR36 Validation of SW for Regulated Processes
  - AAMI SW 68 Software Lifecycle Processes