SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

ALAN KUSINITZ

EXPERIENCE

- Regulatory and safety crisis management, expert testimony, and FDA negotiations; recovery from import detentions, injunctions, consent decrees, consultant certifications, premarket submission deficiency letters, etc.
- FDA inspection preparation, on-site inspection support, and 483 and warning letter response preparation.
- MDR reporting and corrections and removals.
- 510(k), IDE, and PMA submissions for all classes of devices with special expertise for software information.
- Regulatory compliance and standards conformance auditing and best practice assessments.
- Software validation for medical device, blood establishment, pharmaceutical, & medical gas manufacturers including Part 11 compliance
- Experience with software based devices including Mobile Apps, MDDS, implantable defibrillators, IVDs, PACS, bedside monitors, blood bank systems, clinical information systems, infusion pumps, hemodialysis monitors, insufflators, surgical devices, MRIs, home use devices, CADx, and others.
- Extensive experience with validation of Production and Quality System Software and 21 CFR Part 11 Electronic records; Electronic signatures including pharmaceutical and medical gas computer system validation.
- Risk management including conformance to standards
- Implementation of efficient, effective, compliant quality systems and product and software development processes for large and small companies.
- 38 years of regulatory, quality and development experience.

CREDENTIALS

- Provided training for FDA and Health Canada on software validation and risk management.
- Co-chair with Paul Jones of FDA of the AAMI TIR32 Medical Device Software Risk Management working group and contributor to IEC 80002-1.
- Member AAMI board member nominating committee.
- Represented the Medical Device Manufacturer's Association on the executive board of the AAMI/FDA Medical Device Software Standard Committee for development of SW68 Medical device software — Software life cycle processes and contributor to its successor IEC 62304.
- Reviewer for the AAMI TIR36 Validation of software for regulated processes and AAMI TIR 45 Agile Methods Guidance
- Developer and Lead Instructor of the AAMI/FDA Software Regulation Course and co-developer and instructor for the AAMI Safety Assurance Case Course. Instructor for the AAMI/FDA Quality System, Design Control, and Compliant Use of Agile Methods courses
- Author of the Software Validation chapter in the 1997 AAMI book "Current Issues in Medical Device Quality Systems" referenced in FDA Part 11 and software validation guidance documents and author of the 21 CFR Part 11 Chapter of an AABB Book on Information Technology
- Author of Biomedical Instrumentation Journal Articles on Software Test Coverage, Software CAPA, Risk Management, Translation risk management and the 21 CFR Part 11 Chapter of an AABB Book on Information Technology
- Member of UL 1998 Software in Programmable Components Standards Technical Panel
- Extended developer ISO SPICE 15504
- B.A., M.S. and Valedictorian Union College, Schenectady, N.Y. 1976