

ALAN KUSINITZ

EXPERIENCE

- **Software & Quality Systems regulatory crisis management and FDA negotiations including recovery from import detentions, injunctions, consent decree negotiation, requests for consultant certifications, warning letter responses, and others.**
- **FDA inspection preparation and on-site inspection support.**
- **Recalls and field safety analysis and corrective action.**
- **510(k), IDE, and PMA software submissions for all classes of devices**
- **Software validation for medical device, blood establishment, pharmaceutical, & medical gas manufacturers including Part 11 compliance**
- **Experience with software based devices including 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.**
- **Regulatory compliance and standards conformance auditing and best practice assessments.**
- **Software hazard analysis and risk management including conformance to standards**
- **Software technical reviews, metrics, and process improvement**
- **Implementation of effective, compliant quality systems, design control, and software development standards, for large and small companies and groups**
- **33 years of high reliability software project management, development, quality assurance, and regulatory affairs**

CREDENTIALS

- **Provide training internally for FDA and Health Canada on software risk management and validation.**
- **Co-chair with Paul Jones of FDA of the AAMI Software Risk Management working Group that developed TIR32 *Medical Device Software Risk Management* and contributor to the IEC group developing 80002 to replace TIR32.**
- **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* precursor to IEC 62304.**
- **Reviewer for IEC 62304 *Medical device software — Software life cycle processes***
- **Reviewer for the AAMI TIR36 *Validation of software for regulated processes***
- **Developer and Lead Instructor of the AAMI/FDA Software Validation and Part 11 Course**
- **Author of the 21 CFR Part 11 Chapter of an AABB Book on Information Technology**
- **Trainer for the AAMI/FDA Quality System Regulation and Design Control courses**
- **Frequent speaker at U.S. and European conferences on Software Regulation, Safety, Development, and Validation**
- **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**
- **Author of Biomedical Instrumentation Journal Articles on Software Test Coverage , Software Corrective and Preventive Action, Risk Management, and others.**
- **Member of UL 1998 *Software in Programmable Components Standards* Technical Panel**
- **Extended developer ISO SPICE 15504 Standard**
- **B.A., M.S. and Valedictorian Union College, Schenectady, N.Y. 1976**