

Medical Device & Software Risk Management Services

Authors of AAMI TIR32 *Medical Device Software Risk Management*, IEC 62304 *Medical device software – Software life cycle processes*, and IEC 60601-1 PEMS section.

Engineers experienced in device and software risk management

Articulation in FDA and ISO 14971 Terminology

Tailored to your process & preferences

On-site Training courses

...Turn for details



Medical Device and Software Risk Management Services

We work cooperatively with your technical, quality, and regulatory staff, legal counsel, contractors, and vendors. We can help bridge the gap between your technical staff and regulatory and quality groups and articulate the validity of your approach to FDA.

Our staff has many years of experience dealing with medical device and software risk and hazard management for FDA compliance, submissions, and safety purposes. Our experience ranges from low to high risk devices as well as risk-based approaches to validating Production and Quality Systems software and Part 11 compliance. We believe that properly performed risk management can improve the efficiency of design control and validation activities as well as ensuring safety and effectiveness. Several members of our senior staff that are recognized experts in risk management include:

Alan Kusinitz, provides internal training at FDA and Health Canada and co-chaired with FDA development of AAMI TIR32 *Medical Device Software Risk Management* and participated in AAMI SW68 and IEC 62304 and 80002 and is a Member of UL 1998 *Software in programmable Components* Standards Technical Panel

Sherman Eagles, convener for development of IEC 62304, IEC 60601-1 PEMS, IEC 80001 *Application of risk management for IT-networks incorporating medical devices* and member of working groups for AAMI TIR32 and IEC 80002 *Guidance for the application of ISO 14971 to medical device software*.

Lucille Ferus, Stan Hamilton, and Brian Pate – Members of the AAMI/FDA working group that developed AAMI TIR32 *Software Risk Management*. They have provided training, developed tailored risk management processes and performed risk management to meet FDA and EU requirements for a wide range of Medical Devices and Production software. Stan has also applied the Hazard Analysis and Critical Control Points (HACCP) approach to Production and Quality System software validation and defended client approaches during major FDA enforcement actions.

Process

- Preparation of plans, procedures, and templates for the entire risk management process
- Approaches to address the unique challenges of analyzing and mitigating software risk and integration into an existing device risk management process
- Identification of risk management activities for each phase of an existing lifecycle
- Definition of risk-based approaches to Production and Quality System software validation

Analysis and Documentation

- Preparation of risk management reports, risk analysis summaries and safety cases for 510(k)s, PMAs, IDEs, and technical files

Reviews and Mentoring

- In-process independent risk analysis reviews by our risk management and technical experts
- Technical review of requirements, design, and code to aide in identification of potential causes for hazards and appropriate risk control measures
- Review of test plans for adequacy in testing for adequate risk control

Training

- On-site training on Medical Device Risk Management, Software Risk Management, and IEC 62304 safety classification, as well as software pre-market submission information
- Skills training can be developed for implementation of your internal procedures