SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

Medical Device Software Code Inspection Services

Independent design and code reviews

Risk based approach and focus

Engineers experienced in device and software risk management

Proactive prior to product release

Retrospective field event root cause analysis

Reports for legal and regulatory purposes

Facilitation and training for internal reviews

…Turn for details

For more information contact us at info@softwarecpr.com, www.softwarecpr.com, or by phone at 781-721-2921

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Medical Device Software Design and Code Inspection Services

We work cooperatively with your technical, quality, and regulatory staff, legal counsel, contractors, and vendors. We focus on important substantive issue not minor style and format.

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.

Brian Pate, member of the AAMI/FDA working group that developed AAMI TIR32 *Software Risk Management*. Experience as an expert witness and industry expert in safety incident litigation. 21 years of medical device development focused on high quality, robust design, and active risk control measures. Experienced with embedded systems as well as Windows based CIS and clinical productivity tools.

Shawn Yang, 30 years experience medical device development and quality assurance. Programmer for the software for the first artificial heart and other devices including interventional cardiology, heart surgery, electro-physiology, endosurgery, dialysis, imaging, and clinical diagnostics.

Independent Reviews and Inspections

- Help reduce assumptions and bias
- Support due diligence and increase credibility to regulators and in litigation
- Broaden experience of engineers involved in challenging design and coding assumptions

Tailored approaches

- We work with you to define the focus and approach
- Completely independent, participating as independent reviews in your reviews and inspections or something in between.
- Training and facilitation of your internal review process
- Use of relevant sections of AAMI TIR32.
- Design, code, risk analysis or combined reviews.

Possible Outputs

- Potential issues
- Reports as evidence of the review with overall conclusions of design and code quality as well as specific issues
- Suggestions for additional risk control measures
- Suggestions for process improvements

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