SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

Mobile Medical Apps
Compliance & V&V
Services and Credentials

Regulatory Classification Analysis

Vendor Qualification & Management

Development Planning

Test Planning

Traceability Analysis

Automated unit and functional testing

Simulator Based Verification

Mobile Device Based Verification and Validation

Configuration Management

Production Controls

FDA Premarket Submissions

Quality Systems Compliance

…Turn for credentials

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

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www.softwarecpr.com

Selected Partner Credentials

- **Mobile App technical expertise as well as efficient V&V and FDA compliance approaches**
- **Instructors for AAMI/FDA Public courses on Quality Systems, Design Control & Software Regulation**

Brian Pate – is our lead expert in Mobile Medical Apps and manages our hands-on V&V services. He is a member of the AAMI/FDA working group that developed the AAMI *Medical Device Software Risk Management TIR32* as well as AAMI SW TIR1 *Guidance on the use of agile practices in the development of medical device software.* Brian has served as an expert witness in safety litigation and performed software development, risk management and validation for a wide range of medical devices. Brian specializes in helping organizations using agile type methods to achieve FDA compliance and IEC 62304 conformance.

Molly Ray - a former FDA staff member has been involved on both sides (industry and FDA) of determination of regulatory classification, enforcement actions, quality systems compliance, and pre-market deficiency issues. Molly performed reviews of approximately twenty 510(k) submissions while at FDA and was involved in development of FDA guidance documents related to computerized systems validation. Molly was a member of the AAMI/FDA working group that developed a guidance for **Medical Device Data Systems**.

Sherman Eagles - a medical device software standards expert. Sherman was chair and/or convener for IEC 62304, 60601-1 PEMS, IEC 80002-1, IEC 80001-1, is the co-chair with FDA of the AAMI medical device software standards committee, and participates in the GHTF as well as many other software related standards including for Health IT. He is also lead instructor for the AAMI/FDA Safety Assurance Case course.

Alan Kusinitz - SoftwareCPR® Managing Partner provided internal training at FDA and Health Canada and is a trainer for public AAMI/FDA Software Validation, Assurance Cases, Design Controls, and Quality System Regulation training. Alan has been involved with a wide range of crisis recovery activities including extensive direct interaction with FDA for device and drug actions – not restricted to software issues – and as an expert witness in safety litigation. He is actively involved in medical device software standards development.

Shawn Yang – an expert in software development and validation for medical devices and a native Chinese speaker . Shawn developed software for the first artificial heart as well as for other cardiac devices as well as IVDs. Shawn performs risk based software design and code inspections.

Sandy Hedberg - developed the first 510(k) that was cleared by FDA for blood establishment computer software and has developed numerous successful 510(k)s for a wide range of medical devices since then. Sandy has performed software validation for medical devices requiring a 510(k), has constructed FDA compliant quality systems and has been involved in FDA enforcement actions and recalls. Sandy is was a member of the AAMI/FDA working group that developed the guidance for Medical Device Data Systems.

Our locations include Boston, Washington D.C. Florida, California, Tennessee, Minneapolis, and Milan Italy. Some of us are fluent in languages other than in English including Chinese, Spanish, Italian, and Vietnamese.

Detailed credentials sheets are available on our website.