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FDA & EU
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Training provided to FDA and Health Canada

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Independent Audits

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Risk Management

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Selected Partner Credentials

- **Instructors for AAMI/FDA Public courses on Quality Systems, Design Control & Software Validation**
- **Engineering, validation, quality system and regulatory experts with a focus on efficiency**

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.

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.

Brian Pate - 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 and manages our software validation outsourcing service. Brian specializes in helping organizations using agile type methods to achieve FDA compliance and IEC 62304 conformance He and Stan Hamilton also provide support for conformance with EN 62366.

Mary Decareau – an instructor for the public AAMI/FDA Software Validation course with extensive software validation experience including clinical trials computer systems, production and quality system software, and medical device software and risk analysis.

Stan Hamilton - member of the working group that developed the AAMI *Medical Device Software Risk Management TIR32*. Stan has provided risk management and validation training, performed risk management and validation planning to meet FDA and EU requirements for a wide range of Medical Devices and Production software. Stan has been involved in consent decree and import detention crisis recovery including root cause analysis and recovery from significant field safety events.

Molly Ray - a former FDA staff member has been involved on both sides (industry and FDA) of 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 is a member of the AAMI/FDA working group developing a guidance for Medical Device Data Systems.

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 a member of the AAMI/FDA working group developing a guidance for Medical Device Data Systems.

Lucille Ferus - a member of the AAMI/FDA working group that developed the AAMI *Medical Device Software Risk Management TIR32*. Lucille has extensive experience with quality systems compliance, high and low level of concern software devices, EN 62304 assessments and conformance, and has been involved in responses to FDA enforcement actions.

Raffaele Caliri - has extensive experience in software development and validation for medical devices, and performs software compliance assessments, EN 62304 gap analysis and remediation, validation planning, requirements and design documentation, and software risk analysis.

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

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 by clicking on the credentials link on the home bar.