

FDA & EU Consulting & Training Services and Credentials

Tailored training courses

Training provided to FDA

FDA Interaction & negotiation

Crisis Management

Independent Audits

Software Validation

Risk Management

Design Control

Quality Systems

Premarket Submissions

Project Management

...Turn for credentials

Selected Partner Credentials

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

Alan Kusinitz - SoftwareCPR[®] Managing Partner provides internal training at FDA and is a trainer for public AAMI/FDA Software Validation, 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 and as an expert witness in safety litigation. He is actively involved in medical device software standards development.

Stan Hamilton - member of the AAMI/FDA working group that developed the AAMI *Medical Device Software Risk Management TIR32*. Stan has provided risk management and validation 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 been involved in consent decree and import detention crisis recovery including root cause analysis and recovery from significant field safety events.

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, and has been involved in responses to FDA enforcement actions.

Brian Pate - a member of the AAMI/FDA working group that developed the AAMI *Medical Device Software Risk Management TIR32*. 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.

Mary Decareau – an instructor for the public AAMI/FDA Software Validation course with extensive software validation experience including clinical trials computer systems and medical devices.

Bob West – a PMI certified project manager with extensive medical device design control and project management experience.

Molly Ray - a former FDA staff member has been involved on both sides (industry and FDA) of enforcement actions 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.

Sherman Eagles - a medical device software standards expert. Sherman was chair and convener for IEC 62304, 60601-1 PEMS, AAMI SW68, 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.

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 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

Jeff Wallace - has extensive experience in software testing, design tool automation, and medical device and quality system software validation. Jeff runs the SoftwareCPR[®] test lab in North Carolina and its development tool services offerings.

Raffaele Caliri - has extensive experience in software development and validation for in vitro diagnostic devices and performs compliance assessments and validation planning for a wide range of medical devices.

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.

Our locations include Boston, Washington D.C. Florida, California, Tennessee, Minneapolis, North Carolina, Panama, and Milan Italy.

Some of us are fluent in languages other than in English including Chinese, Spanish, Italian, Vietnamese, and Japanese.

Detailed credentials sheets are available online at:
<http://www.softwarecpr.com/companyinfoframepage.HTM>