

Tailored Education & Training Services

Industry and FDA Recognized Expert Instructors

Training provided to FDA and Health Canada

Awareness and Skills Training

Tailored to your specific needs

IEC 62304 and related software standards

Medical Device and Software Risk Analysis

Medical Device Software Validation

FDA and EU Quality System compliance

Design Control

Computer System Validation

Blood Establishment Computer Systems

Training also available in Spanish or Chinese

...Turn for details



Training Services

- **Tailored to your needs**
- **Subject matter and regulatory and standards experts as instructors**

Instructor for internal FDA software validation training and lead instructor for public AAMI/FDA Software Validation Training courses, Alan Kusnitz, SoftwareCPR[®]'s Managing Partner, develops and coordinates SoftwareCPR[®] training courses. He has provided in-house training for FDA and Health Canada. Our other instructors teach public AAMI/FDA training courses with FDA co-instructors on the Quality System Regulation, Design Control, and Software Validation, have authored key standards on which specific courses are based, or are former FDA staffers.

Our instructors understand regulatory agency expectations and can train your staff accordingly and coach them on how best to articulate and defend your approaches in FDA terms.

Our instructors have been involved in software standards development including IEC 62304, AAMI SW68, AAMI TIR32, IEC 60601-1 PEMS, UL 1998, IEC 80001, and IEC 80002 and can train your staff in pragmatic and efficient methods of conformance to standards.

Our training is tailored to your needs, your products, your regulatory perspective, and your business objectives.

Our training includes FDA enforcement examples, key FDA guidance, electronic, checklists, and other educational aides

We offer both awareness and skills training. Awareness training courses provide short overviews of key concepts and requirements ranging from 2 hour executive overviews to one day introductory courses. Skills training courses are generally multi-day and are highly interactive using short exercises, formal workshops, and free form and structured instructional Q&A.

Fully customized courses integrating customer policies and procedures are prepared on request and can be integrated into internal company training programs or produced as self-study computer-based training modules.

Course topics available include:

- **Medical Device Risk Management**
- **Software Risk Management**
- **FDA Software Regulation & Validation**
- **IEC 62304, TIR32, 60601-1 PEMS**
- **Quality System Regulation**
- **Design Control**
- **FDA Software Submissions**
- **Computer System Validation**
- **Design Tool Validation**
- **21 CFR Part 11**
- **Software Lifecycles**
- **Policies and procedures**
- **Articulating your approach to FDA**
- **Software CAPA**
- **Production Software Issues and Approaches**
- **Computer System Validation Auditing**
- **Software Technical Reviews**
- **Software Testing**

These and other topics can be combined as part of course tailoring to meet your needs.