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# Medical Device Software Standards and FDA Compliance Training Course

**IEC 62304 Software Lifecycles**  
**IEC 80002-1 Software Risk Management**  
**IEC 80001-1 Networked Devices**  
**IEC 60601-1 PEMS**  
**Comparison to FDA Requirements**  
**Efficient approaches to conformance**  
**Software Risk Management**  
**Safety Assurance Cases**  
**Checklists, examples and templates**  
**Articulation for compliance**

**...Turn for details**

## Medical Device Software Standards and Compliance Training

- **Instructors that authored the standards**
- **Focused on efficiency and pragmatic implementation options**
- **Extensive risk management modules including safety cases**

**Our public course** *Efficient Use of Medical Device Software Standards 62304, 60601-1 PEMS, 80001-1, and 80002-1 for Safety and Regulatory Compliance* can be provided at your company.

**IEC 62304 is an EU harmonized standard**, FDA is performing internal training on this standard, and other regulatory authorities are adopting it. This makes it important that software, QA, and RA staff have a thorough understanding of this and related medical device software standards and their relationship to FDA requirements as well.

**This course will provide** in-depth practical coverage of both requirements of these standards and practical efficient and effective implementation approaches including comparison with FDA guidance and expectations. The course has extensive emphasis on software risk management using the recently released **80002-1 Medical Device Software Risk Management** technical report and we are also providing an overview of **assurance/safety cases** which is a new initiative by FDA.

**For Quality Assurance and Regulatory Affairs** professionals this course will provide a clear understanding of requirements versus areas of flexibility and provide checklists and questions to use for gap analysis, auditing, and vendor and OEM qualification and management.

**For software development, risk management, and test engineers** this course provides examples, checklists, and partial templates as well as helping with articulation and defense of your approaches to regulatory bodies and internal quality assurance and regulatory affairs departments.

### Instructors

**Sherman Eagles** was a Medtronics Staff Fellow and convener for 62304, 80001-1 and 60601-1 PEMS and other standards so his perspective is important to fully understand the intent of the standards. He is also co-chair of the AAMI and ADVAMED Software Committees and member of the GHTF software committee.

**Alan Kusnitz** was co-chair for AAMI TIR32 Medical Device Software Risk Management, contributor and reviewer for 80002-1, reviewer for 62304 was on the committee that developed SW68 the pre-cursor to 62304 and has provided internal training at FDA and Health Canada.

Cost is quoted based on location of company. No per student fees.