

# Device Software Safety Risks

Standards Lead to Closer FDA Scrutiny

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- B. 21 CFR Part 820 – Quality System Regulation
- C. 21 CFR Part 11 – Electronic Records; Electronic Signatures
- D. MethodSense’s “IEC 62304 Action List: Preparing Your Device for Market”

- E. FDA's Guidance on Part 11, Electronic Records; Electronic Signatures – Scope and Application

**The International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO) standards mentioned in this report can be purchased at [www.iec.ch](http://www.iec.ch) or [www.ansi.org](http://www.ansi.org).**