Medical Device Regulations and Product Innovation

SOFTWARE QUALITY CONSULTING

consulting • training • auditing

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Brief Bio

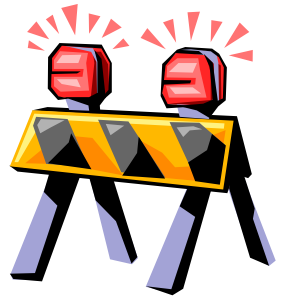
- 40 years experience as a software engineer
- 25 years experience in medical device industry
- Published several papers on medical device software and software quality
- Author of Software Verification & Validation for Practitioners and Managers
- IEEE Software Engineering standards committees and AAMI/FDA Workshops
- Education and Certifications:
  - BS EE Northeastern University
  - MS Computer Science Rensselaer Polytechnic Institute.
  - ASQ Certified Software Quality Engineer (CSQE) and Quality Auditor (CQA).
  - Senior member of IEEE Computer Society
- Frequent presenter at conferences for AAMI, ASQ Biomedical Div. and IEEE

FDA Regulatory Model

Class	Type	Risk to patients	Regulations	Pre-market Notification / Approval
I	General	Low	• General controls (GMPs) • Design Controls for specific devices OR devices that include software	• Generally exempt from pre-market notification unless specifically required
II	Diagnostic, Therapeutic	Moderate	• General controls and Special controls - including GMPs, Design Controls and guidance documents	• Pre-market notification 510(k) clearance, special labeling requirements, mandatory and voluntary performance standards, and post-market surveillance
III	Life supporting, life sustaining	High	• General controls and Special controls - including GMPs, Design Controls and guidance documents.	• Pre-market approval (PMA) • Mandatory inspection • Evidence of safety and effectiveness

Role of Regulation

- **All medical devices have safety risks…**
  - **Regulations are intended to help device manufacturers produce devices that are safe and effective**
  - **Regulations will always lag behind current technology**
  - **Regulations are by no means perfect…**
- **All medical devices need to meet a very high standard…**
  - **Mobile medical apps are regulated – using same regulations used for traditional devices - only if there is meaningful risks to patients**



  - **Most apps exempt – about 100 required FDA approval**

Adverse Events with Infusion Pumps

- **From 2005-2009: 56,000 adverse events associated with use of infusion pumps, including numerous injuries and deaths.**
- **At least 14 deaths attributed to faulty infusion pumps**
- **Many Class I recalls – which means there's a reasonable probability use of recalled device could cause serious adverse health consequences or death.**
- **Adverse event reports and device recalls not isolated to a specific type of infusion pump or use environment…**

FDA White Paper: Infusion Pump Improvement Initiative, April 2010

Adverse Events with AEDs

- **From 2005–2009: Number of adverse events reported with AEDs increased by 85% annually**
  - **Problems included:**
    - unable to power up
    - failing to deliver shocks
  - **Up to 70 kinds of AEDs were recalled, including models from every AED manufacturer.**

  - **17 Class I recalls - where there was reasonable probability that problems would have led to serious injury or death.**

Harris, M., “The Shocking Truth About Defibrillators”, IEEE Spectrum, March 2012

Device Recalls

Common problems in software-related recalls

- **Interfacing errors between devices and information management systems**
- **Use and environment issues resulting from not considering workflows or all states of operation**
- **Maintenance and software update issues – including:**
  - Incorrect software updates, wrong configuration/calibration data, deficient software update procedures, etc.
- **Incorrect algorithms and calculations, such as dose calculations, battery charge calculations, etc.**
- **Image processing errors related to merging, annotating, scaling, etc.**
- **Inadequate error detection and recovery**

Simone, L., "Software-Related Recalls: An Analysis of Records," BI&T Nov-Dec 2013

Device Recalls

Conclusions:

- **“Straightforward design and coding defects continue to be observed as causal factors in recalls.**
- **These are defects that often could be detected using basic tools known to increase software quality.”**

Simone, L., “Software-Related Recalls: An Analysis of Records,” BI&T Nov-Dec 2013

- **Bottom Line:**
- **Innovative medical devices need to be developed using proven engineering practices that have been shown to be effective in producing devices that safe and effective…**