Quality From a Regulatory Reviewer Perspective

UMSEC Summer Software Symposium
Assuring Confidence in Predictable Quality of Complex Medical Devices

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Who am I?

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SECTION A. GENERAL

I. REQUIREMENTS

§ 820.30(a) General.

Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a) (2) of this section, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

The following class I devices are subject to design controls: (i) Devices automated with computer software; and ...
How Do Design Controls Work?

- Via mechanisms to provide visibility (i.e., means to measure the controlled variable) throughout the development process.
- Via documented procedures to exercise continuous (or at least frequent) control of resources (i.e., feedback mechanisms).
- Via a semantic structure (language, taxonomy) to facilitate communications.

What Are The Limitations?

- Design controls do not assure the quality of products and services (but they provide a framework for assessing and documenting quality).
- Design controls do not completely eliminate design errors (but they prevent many errors and facilitate finding and correcting errors earlier in the development process).
- Management still needs the right people and the right tools to do the design work and review the results for adequacy.
QSR versus Pre-market submissions

- Device manufacturers may use the same procedures and records for compliance with quality system and design control requirements, as well as for pre-market submissions to FDA.
- Specific safety or effectiveness issues related to software validation
Guidance Documents

- General Principles of Software Validation
- Guidance for Off-the-Shelf Software Use in Medical Devices
- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Websites

- [http://www.fda.gov/cdrh/humanfactors](http://www.fda.gov/cdrh/humanfactors) for human factors information
Level of Concern

♦ Choose the appropriate level of concern
  ♦ Minor, Moderate, Major
  ♦ Key Questions
  ♦ Assess the Level of Concern before mitigating any hazard; that is, you should assess your software device against these questions as though you have not implemented hazard mitigations

Level of Concern

♦ FDA reviewers examine:
  ♦ Device Description from pre-market submission
  ♦ Software Description
  ♦ Hazard Analysis
  ♦ Software Requirements
  ♦ Opinion of Domain and Software Experts
  ♦ Precedent
Level of Concern

- Drives the documents that you submit to FDA in a pre-market submission.
- Ideally documentation should be artifacts from your design control activities.
- If the FDA reviewer disagrees with your assessment of level of concern, it should be a simple photocopy exercise to provide the additional documentation requested.

Interlude
Challenges

- Challenges
  - Number of submissions
  - Timelines
  - Variety of devices
  - Experience and training of reviewers
  - The Law
    - Precedent
    - Changes
  - Standards
    - Declaration of Conformity

Challenges

- Lack of clear definition of evidence and how to evaluate it.
  - Guidance Documents
  - Checklist
    - Presence versus quality
  - Domain Experts
Challenges

♦ Poor documentation of requirements and environmental assumptions.
  ♦ Hazards
  ♦ System of systems
  ♦ Human Factors

♦ Infusion Pump
  ♦ Right Drug, Right Person, Right Rate

So, Convince Me

♦ Convince me that your medical device is safe and effective.
♦ Convince me that your medical device is substantially equivalent to a predicate medical device.
♦ Convince me that, following a recall, your post-market corrective actions are adequate.
Assurance Cases

♦ The goal of the assurance case approach is no different than the goal of the current system – Safe and Effective Medical Devices. But, is it a better way?

We must develop the argument and provide the evidence. 😊

Fruitful Areas

♦ COTS Software
♦ Open Source Software
♦ Assurance Case Fragments (SEI)
♦ Post-market Recalls
  ♦ The assurance case should help in identifying what went wrong
COTS Software

♦ COTS

♦ Industry might ask vendors to provide the safety case for the component. Examples of this could be operating systems, database systems, etc.

♦ Many of these vendors may have already generated a safety case for use by other industries (e.g. defense) or by other regulators (e.g., those in the European Union).

Open Source Software

♦ Open Source Software

♦ You may peer into the source code using, for example, static analysis tools.

♦ The assurance case developed for the open source software should show an adequate grasp of the technical and clinical risks associated with the use of the software.

♦ A good assurance case should be adequate for premarket submissions.
Challenges

♦ Challenges for adoption
  ♦ Buy-in by all the stake-holders
    ♦ FDA
      • Reviewers
      • Management
      • Counsel
    ♦ Industry
  ♦ Training
  ♦ Tools

Training

♦ Currently the effort is to educate reviewers and management on what an assurance case is.
  ♦ Claim
  ♦ Evidence
  ♦ Argument
    ♦ Assumptions
  ♦ Path for Adoption