Tales from the Field:

Agile in the Regulatory Context

Agenda

Background

Regulations, Standards, and Guidance

Experiences – What Works Well?

- Pre-Market
- Post-Market
- Auditor / Inspector Comments

Quick Background

About Me

About CMD MedTech

Regulatory Overview

- FDA is focus of this presentation
- Software-centric topics, but also cover systems-level agile practices
- FDA generally indicates “whats” not “hows”
- FDA participated in and recognizes TIR45:2012

Regulation

Most all sections of 21 CFR 820.30 (Design Controls) are touched by agile development:

- Design and Development Planning
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Design Changes
- Design History File

Review the Quality System Regulation preamble! States FDA's intent on QSR development and subsequent enforcement

- The word "flexibility" is used 56 times.

Key Guidance

FDA Software:

- Guidance for the Content of Software in Premarket Submissions
- General Principles of Software Validation
- Mobile Medical Applications
- Cybersecurity in Premarket Submissions
- Off-the-Shelf Software
- Human Factors
- General Wellness: Policy for Low Risk Devices

Other FDA:

- When to re-submit a 510(k)

AAMI

- AAMI TIR45:2012 Guidance on the use of agile practices in the development of medical device software

Key Standards

EN / IEC 62304: Medical Device Software – Software Lifecycle Process

- The primary standard for medical device software development

EN / IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- References IEC 62304, and contains additional requirements

EN / ISO 14971: Medical devices -- Application of risk management to medical devices

EN / IEC 62366: Medical devices -- Application of usability engineering to medical devices

Regulations, Standards, Guidance

Following regulation and applicable guidance and standards is the easiest and most predictable path to market.

Guidance = FDA and Notified Body expectation (usually! We'll dive into this later)

99% of the time, conformance = faster overall time to market

Experiences from the Field - Overview

Systems Engineering Background

Regulatory and Quality Role

- Design Assurance (“Systems Engineering Lite”)
- Remediated QMS and Business Processes
- Led FDA Inspections and Audit Prep (Front and Back Room)

Pre-Market – Case Study 1

Major international medical device manufacturer

Acquired a “software shop” with non-medical and (surprise to them) medical software

No QMS to start

Acquired company very adverse to anything outside of “pure agile”

Acquiring company was not knowledgeable on agile practices

510(k) deadline already set in stone!

Solutions:

- Training
- Managed Expectations
- Skirting the Grey Areas

510(k) went through with minimal AIs, but deficiencies in DHF/DMR remained.

Pre-Market – Case Study 2

Major Med Device Manufacturer / Distributor

Innovation “spin off” – desired faster time to market

95% of hires have no medical device experience

Parent company had no medical device software experience

“I don’t want to document, I got hired on to code.”

Many standards and guidance that needed integrated to development already underway

Solutions:

- Quality plan to address lack of control
- Regulatory debt / regulatory stakeholders
- SE and SwE leadership with eventual transition to team
- Suggestion of new hires

Post-Market – Case Study 1

Market leader in Class II in vivo blood handling products

Recently adopted agile (<2 years)

Under warning letters

Major DHF / DMR deficiencies, including software

Front Room Inspection Summary:

- Inspector – long career with military, transition to FDA
- “I don’t understand software at all”
- Looked towards FDA guidance on content of software in premarket submissions
- Was subject to the mercy of the inspected company WRT software

Post-Market – Case Study 2

Same company as “pre-market – case study 1”

Product cleared a year earlier had its DHF & DMR inspected by FDA

Inspector competent in software and complex hardware systems

Front Room Inspection Summary:

- Items ignored during design (to get 510(k) cleared earlier) resulted in 483s
- One 483 was related to the use of unvalidated tools to manage agile processes (JIRA)
  - Verification referenced items in JIRA which should have been considered uncontrolled
- Inspector was familiar with scrum/agile, but only focused on outputs described in FDA guidance
- Inspector did not dive into control required for 2-week sprint configuration management

The new Six Sigma?

The original authors of the Agile Manifesto have had much to say about the recent explosion of agile methodologies.

- Dave Thomas: *The word "agile" has been subverted to the point where it is effectively meaningless, and what passes for an agile community seems to be largely an arena for consultants and vendors to hawk services and products.*
- Andrew Hunt: *[Agile] has become sloganized; meaningless at best, jingoist at worst. We have large swaths of people doing 'flaccid agile,' a half-hearted attempt at following a few select software development practices, poorly*

Dave Thomas: ***I think it is time to retire the word "Agile." […] Let's develop with Agility.***

Our Strategy (as a Hawking Vendor)

Avoid the dogma of tools and practices

Understand the plight of engineers moving from unregulated to regulated environments

Help our clients be as agile as possible:

- within the constraints of regulatory bodies
- with the safety of the patients and clinicians as the cornerstone.

Illustrate the “pay me now vs. pay me later” option:

- Engineer job security and specialization
- Cost of audits, inspections, 483s, etc.
- Unvalidated tools = adulterated product
- Can’t avoid documentation – even if someone else writes it

Summary

Auditors are like snowflakes

Higher level problems invite subsequent levels of scrutiny

Consider pushing down agile practices into lower level QMS elements or guidance

510(k) clearance does not = compliant QMS, DHF, or DMR!