Medical Device Software

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Overview

- Medical devices and software
- Oversight principles and Current approach
- Trends, Challenges and opportunities
- Addressing challenges
Definition of Device

SEC. 201. [321] For the purposes of this Act –

(h) The term "device" … means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

• recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

• intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

• intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
Medical Device

The Section 201(h) of the Food, Drugs and Cosmetics Act defines a medical device as any healthcare product that does not achieve its principal intended purposes by chemical action or by being metabolized.

- As simple as a tongue depressor or a thermometer
- As complex robotic surgery devices

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A risk based approach ...since 1976

Increasing Risk
Classification determines extent of regulatory control (Risk Based)

Class I
• General Controls

Class II
• General controls
• Special controls

Class III
• General controls
• Premarket approval (PMA)

General Controls
• Electronic Establishment Registration
• Electronic Device Listing
• Quality Systems
• Labeling
• Medical Device Reporting (MDR)
• Premarket Notification [510(k)] (unless exempt)

Special Controls (addressing Risk)
• Guidelines (e.g., Glove Manual)
• Mandatory Performance Standard
• Recommendations or Other Actions
• Special Labeling (e.g., 882.5970, Cranial Orthosis)
Increasing use of software

1. The accelerating pace of change...

   - Agricultural Revolution: 8,000 years
   - Industrial Revolution: 120 years
   - Light bulb: 90 years
   - Moon landing: 22 years
   - World Wide Web: 9 years
   - Human genome sequenced

   - 2045: Brainpower equivalent to that of all human brains combined
   - Surpasses brainpower of human in 2023
   - Surpasses brainpower of mouse in 2015

2. ...and exponential growth in computing power...

   Computer technology, shown here climbing dramatically by powers of 10, is now progressing more each hour than it did in its entire first 90 years.

   - **UNIVAC I**: The first commercially marketed computer, used to tabulate the U.S. Census, occupied 944 cu ft.
   - **Apple II**: At a price of $1,298, the compact machine was one of the first mass-market popular personal computers.

3. ...will lead to the Singularity

   - **Power Mac G4**: The first personal computer to deliver more than 1 billion floating-point operations per second.

**COMPUTER RANKINGS**

- By calculations per second per $1,000

   - 1960s: Holleth, National, IBM
   - 1970s: IMP, DEC, IBM
   - 1980s: DEC, IBM, Apple
   - 1990s: Intel, DEC, IBM
   - 2000s: Intel, IBM, Apple
   - 2010s: Intel, IBM, Apple
   - 2020s: Intel, IBM, Apple
   - 2045: Intel, IBM, Apple

**ELECTROMECHANICAL**

- 1900: Vacuum tubes, transistors, integrated circuits

**RELAYS**

- 1910: Vacuum tubes, transistors, integrated circuits

**VACUUM TUBES**

- 1920: Vacuum tubes, transistors, integrated circuits

**TRANSISTORS**

- 1930: Vacuum tubes, transistors, integrated circuits

**INTEGRATED CIRCUITS**

- 1940: Vacuum tubes, transistors, integrated circuits
Types of Medical Device Software

Software in a device

- Software that is Used in the manufacturing process of a device

Software as a device

- Software in a device
- Software in a device
Oversight primarily to assure quality of product (focus more important for class III devices)

- Premarket oversight on higher risk products (class II and Class III)
- Post market surveillance
Classifications depend on...

What does it do? (engineering view)
- Calculates doses
- Displays medical images
- Controls treatment timing
- Collects user input

How can it be used? (clinical view)
- to formulate treatment plans
- to recommend additional tests
- to diagnose the presence of tumors
- to calculate insulin dose
Principles of oversight control

- Regulations relies on each manufacturer to
  - Understand the role of software in their products
  - Understand the risk of software in their products
  - Follow development processes that are best suited for their organization and their product
  - Maintain vigilance over their product once in the market
A “Life cycle” approach

Does not recommend any specific life cycle model or any specific technique or method, it does recommend that software validation and verification activities be conducted throughout the entire software life cycle. [GPSV]
Quality systems + standards

Major subsystems

- Design Controls
- Corrective & Preventive Actions
- Production & Process Controls
- Management
- Material Controls
- Records, Documents, & Change Controls
- Equipment & Facility Controls

Leveraging standards

ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators
March 27 - 28, 2014; San Francisco, California
Control for software focuses on..

- Design process
  - Systematic risk assessment is expected as an integral part of design and development
  - Products implement with principles of good design and development practices

- Adequately validating the solution
Software Validation

- Part of the design validation for a finished device
- FDA considers software validation to be "confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled."
- In practice, software validation activities may occur both during, as well as at the end of the software development life cycle to ensure that all requirements have been fulfilled.
A conclusion that software is validated is highly dependent upon comprehensive software testing, inspections, analyses, and other verification tasks performed at each stage of the software development life cycle.

FDA software guidance

- General Principals of Software Validation-
  - What to *do*

- Off-The-Shelf Guidance

- Pre Market Guidance (this one from 2005)
  - What to *submit*
Contents of premarket review

- Level of Concern
- Software Description
- Device Hazard Analysis
- Software Requirements Specification
- Architecture Design Chart
- Software Design Specification
- Traceability Analysis
- Software Development
- Environment Description
- Verification and Validation Documentation
- Revision Level History
- Unresolved Anomalies (Bugs or Defects)
Trends and next steps

- Computing platforms
- Computing power
- User tolerance...
- Software location
Software has become increasingly important

**Software is important to medical device functionality**

Percent (N=88)

- Cosmetic
- Supportive
- Critical

**Software-related problems have become the most cited cause of medical device recalls**

Total recalls (cumulative over FY10 – FY12)

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<th>Number</th>
<th>Percent</th>
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<td>Device Design</td>
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<td>Nonconf. Material / Component</td>
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Rapidly Evolving Landscape

- Most medical devices rely heavily on software
- Software development practices are evolving
- Changes to software are easy and more frequent
- Connectivity of devices have lead to new risks
- Diagnostics and analytics rely heavily on software
Current concepts challenged

- **Establishments** - as we know for traditional device do not translate clearly to a virtual software world

- **Finished goods** - devices are finished by the consumer - by relying on consumer to provide portions of the device.

- **Distribution** - distribution of physical product no longer valid (for e.g., internet cloud based)
Adapting oversight by

- Clarifying focus of regulatory oversight

- Considering technology, and current practices
Smart Regulatory Approach

- Platform independent
- Promote innovation
- Protect patient safety
- Promote patient engagement

Functionality focused

Narrowly tailored

Risk based
Functionality focused (EKG machine)
Addressing challenges

interoperability

Device security
US-FDA software documents

- 1989 Draft software policy (withdrawn in 2005)
- 1991 Pre-market software guidance
- 1999 Off-the-Shelf Software Guidance
- 2002 General Principles of Software Validation
- 2005 Cybersecurity Software Guidance -- OTS

- 2011 Medical Device Data System Rule
- 2013 RF wireless devices – Final guidance
- 2013 Draft: Cybersecurity premarket guidance
- 2013 Recognized Interoperability and cyber security standards
- 2013 Mobile medical apps – Final guidance
Mobile medical apps (MMA)

- Patient self-management apps
- Tools to organize and track their health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple health care providers tasks

Enforcement Discretion

Mobile apps that meet "device" definition that are either intended
- To be used as an accessory to already regulated medical device,
  or
- To transform a mobile platform into a regulated medical device.

Lower risk mobile apps that meet "device" definition but not considered "MMA"

No regulatory requirements

Mobile apps not considered "medical devices"
Questions/Discussion

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