



# CDRH Regulated Software

## An Introduction

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# CDRH Regulates

- **Software in the following areas**
  - **Medical Devices**
  - **Automation of Production Systems**
  - **Automation of Quality Systems**
  - **Computers used in Clinical Investigations**
  - **Electronic Record & Electronic Signatures**
- **The focus of this presentation is on Medical Device Software**



# Purpose of this Presentation

- **A regulatory introduction to Medical Device Software**
- **This presentation is not a complete thesis on medical device software but only serves as an introduction, there is an expectation that more software related presentations will be developed in the future**

# Learning Focus

- The legal definition of Medical Device Software
- Illuminating Examples of Medical Device Software
- The basics of general controls used to regulate Medical Device Software
- Common Software Regulatory Clarifications
  - (a. k. a. mystifications)



# This is Educational Material

- Illuminating/Illustrative
- Not all inclusive
- Not formal policy/ guidance or regulation
- Designed to focus your thinking process
- You will need to go back to study and use the source regulatory documents



# So what is Medical Device Software?

- Any software that meets the legal definition of a device is a device and is known as Medical Device Software

# Legal Definition of a Medical Device?

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, 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 primary 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 primary intended purposes."



# There is no definitive list

- The product spectrum is highly diverse and complex
- Decision requires a detailed review of the information available ( i.e. labeling claims, advertising matter, or oral or written statements by such persons or their representatives)
- Can be confusing very quickly
  - (mixed terms & definitions)





# Medical Device Software can appear in many forms

- Software that is a component of a medical device
- Software that is an accessory to a medical device
- Standalone software a.k.a. “software only devices”
  - Software intended to run on general purpose computers

# Questions that are worth asking?

- Does it meet the legal definition of a device?
  - Does not have to be all inclusive
- Is it simply an electronic version of some existing library source material?
- Does it meet the definition of an existing classification?
- Is it an accessory to an existing medical device?
- Is it intended for use in a patient specific manner?
- What is the risk and the intervention case?



# Initial 3 step regulatory process

- 1. First we must decide if the product is a device?
  - This is based on the intended use?
- 2. Who is the Manufacturer?
- 3. How should the device be classified?
  - What is the risk?



# Initial focus needs to be on the intent

- The legal definition is based on the intent of the product
- The legal definition is not based on the engineering definition of software functionality
- The legal definition does not contain any reference to any specific hardware, software or information technology
- The software does not have to be a complete solution only used in

# How do I know If my software is a device?

- **Answer the following questions:**
  - Is my software a component of a medical device?
  - Is my software an accessory to a medical device?
  - Do I “intend” for my software to be used:
    - In the diagnosis of disease or other conditions
    - In the cure of disease
    - In the mitigation of disease
    - In the treatment of disease
    - In the prevention of disease



# If the Software is a Device

- Then it is still a device regardless of the means by which the software is delivered to the end user
  - factory-installed
  - installed by a third-party vendor
  - field-installed or -upgraded.
  - On a compact disc
  - On a memory stick
  - Downloaded from a website
  - embedded



# illuminating Examples of Software Devices

- Remote Medication Management System software that is 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

# Illuminating Examples of Software Devices

- Clinical Software that is 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
- Several Examples
  - Data management software that is intended for use in EKG analysis
  - Drug dose calculating software
  - Clinical scoring systems software
  - Medical applications software





# Illuminating Examples of Software Devices

- Decision support software that is 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
  
- Several Examples
  - Treatment recommendation software
  - Stent selection software
  - Treatment support software for Oncology
  - Online calculator software that is intended for use in . . .

# Device Classification determines the regulatory requirements

- Device classification is based on device risk
- Medical Devices can be Classified into 1 of 3 classes
  - Class I
  - Class II
  - Class III
- Medical Device Software is also Classified into 1 of 3 classes

## Device classification depends on

- the *intended use* of the device and also upon *indications for use*. For example, the software's intended use is to retrieve and process data from the stethoscope. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for the detection of heart murmurs". Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product.



# Device Class and Regulatory Controls

- **Class I General Controls**
- **Class II General Controls and Special Controls**
- **Class III General Controls and Premarket Approval (PMA)**

# General Controls

- **General Controls are the basic provisions (authorities) of the May 28, 1976 Medical Device Amendments (hereafter referred to as the Amendments) to the Food, Drug and Cosmetic Act, that provide the FDA with the means of regulating devices to ensure their safety and effectiveness. The General Controls in the Amendments apply to all medical devices**
- **The general controls apply to all device software**



## List of General Controls that each Manufacturer is Legally Required to Comply with

- Adulteration;
- Misbranding;
- Device registration and listing;
- Premarket notification;
- Banned devices;
- Notification and repair, replacement, and refund;
- Records and reports;
- Restricted devices; and
- Good Manufacturing Practices.

# Good Manufacturing Practices

- The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices.

# 21 CFR 820 Quality System Regulation

- All parts of the Quality Systems can be applicable to software
  - Not just the parts that specifically mention software
- All software components must be under design control and or purchasing control
  - Design validation shall include software validation and risk analysis 21 CFR 820.30 (g)
  - Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented 21 CFR 820.50 (a) (1)





# Significant Software Controls

- **Sec. 820.30 Design controls**
- **Sec. 820.50 Purchasing controls**
- **Sec. 820.100 Corrective and preventive action**

## Design Control Guidance For Medical Device Manufacturers

- This guidance is intended to assist manufacturers in understanding the intent of the regulation. Design controls are based upon quality assurance and engineering principles. This guidance complements the regulation by describing its intent from a technical perspective using practical terms and examples
- Available on the CDRH website
  - Guidance search words
    - “design controls”



# Software Validation Guidance;

- **Final Guidance for Industry and FDA Staff**
  - General Principles of Software Validation
- **Available on the CDRH website**
  - Guidance search words
    - “software validation”



# Premarket Notification

- A general control (see previous slide)
- Requires review by FDA
- Review to establish a reasonable assurance of safety and effectiveness
- Level of review based on risk, safety, uniqueness and complexity

# Pre Market Notification Software Guidance

- This guidance document is intended to provide information to industry regarding the documentation that we recommend you include in premarket submissions for software devices
- It is not a how to guidance
  - Provides guidance on what to submit
- Available on the CDRH website
  - Guidance search words
    - “software premarket”

# Purpose the Off the Shelf Guidance

- This guidance document was developed to address the many questions asked by medical device manufacturers regarding the use of OTS software. The specific response to these questions depends on the medical device in question and the impact on patient, operator, or bystander safety if the OTS software fails.
- This document lays out in broad terms how the medical device manufacturer can consider what is necessary to document for submission to the agency
- Available on the CDRH website
  - Guidance search words
    - “off the shelf”

# Cybersecurity Guidance

- **Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software**
- **Available on the CDRH website**
  - **Guidance search words**
    - **“cybersecurity”**
- **Outlines general principles that we consider to be applicable to software maintenance actions required to address cybersecurity vulnerabilities for networked medical devices—specifically, those that incorporate off-the-shelf (OTS) software.**



# Software Guidances

- They are not all inclusive
- Intended for use by skilled professionals
- They are not intended to be engineering design specifications
- Appropriate engineering level of detail is created by skilled professionals utilizing the advice provided by guidance and the framework recommended





# Pre Market Software Review Paradigm

- Level of review based on risk, safety, uniqueness and complexity
- Level of review is progressive until the assurance case is established
- At the basic level a review of software design output
- Possibly followed by an expert software engineering review
- On a case by case basis a detailed software code review that may included automated tools

# IEC 62304

- **Medical device software — Software life-cycle processes**
- **This standard provides a framework of life cycle PROCESSES with ACTIVITIES and TASKS necessary for the safe design and maintenance of MEDICAL DEVICE SOFTWARE. This standard provides requirements for each life cycle PROCESS. Each life cycle PROCESS is further divided into a set of ACTIVITIES, with most ACTIVITIES further divided into a set of TASKS.**



# Common Software Regulation Clarifications

- Software by itself can be a device
- The entire Quality System can apply to software
- There is no prohibited software list
- There is no prohibited software method
- You can convert paper copies to electronic form



# More Software Clarifications

- FDA does not have a software certification system
- Risk analysis can not justify doing nothing
- Electronic record keeping systems are automated systems
- Automated generally means contains software



# CDRH Software Questions

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