Speaker Bio

• **Steven R. Rakitin** has over 35 years experience as a software engineer and 25 years in the medical device industry. He has written extensively on the subject of software quality and published a book titled *Software Verification & Validation for Practitioners and Managers, 2nd ed.* He has also published the following papers on medical device software safety risk management:


• He is a member of the AAMI HIMSS CE-IT Collaboration team and has worked on several IEEE Software Engineering standards committees. As a member of an AAMI/FDA committee, he helped write the Recommended Practice for the Application of quality management system concepts to medical device data systems, AAMI SW87:2012.

• He received a BSEE from Northeastern University and an MSCS from Rensselaer Polytechnic Institute. He has earned certifications from the ASQ as a Software Quality Engineer and Quality Auditor. He is a member of the IEEE Computer Society, ASQ Software Division, ASQ Biomedical Division, AAMI, and MassMEDIC. He is on the Editorial Review Board for the ASQ Journal Software Quality Professional. He has presented invited papers and tutorials at conferences worldwide for HIMA, AAMI, ASQ, and IEEE.

• As president of Software Quality Consulting Inc., he has worked with over 75 medical device manufacturers from startups to Fortune 500 companies. He helps medical device manufacturers develop software in a manner that is safe, compliant and cost-effective. He. He can be reached at steve@swqual.com.
Agenda

• Mobile Medical App Definitions...
• How is FDA regulating MMAs?
• How many MMAs are out there?
• Q&A
Definitions

• 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 official National Formulary, or United States Pharmacopoeia, or any supplement to them,
  – intended for use in 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 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 achievement of any of its primary intended purposes.

§201(h) of the Federal Food Drug & Cosmetic (FD&C) Act
Definitions

- **Mobile Platform**
  - Commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature.
  - Examples include smart phones, tablet computers, and other portable computers.

- **Mobile Application (Mobile App)**
  - A software application run on a mobile platform with or without wireless connectivity, or a web-based software application tailored to a mobile platform but executed on a server.

- **Mobile Medical Application (MMA)**
  - A mobile app that meets definition of a medical device and either is intended:
    - to be used as an accessory to a regulated medical device; or
    - to transform a mobile platform into a regulated medical device.

- **Mobile Medical App Manufacturer**
  - May include anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components.
Definitions

- **MMA manufacturers include any person or entity that:**
  - Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a MMA software system from multiple components.
    - Could be a person or entity that creates a mobile medical app by using COTS software components and markets product to perform as a MMA.
  - Initiates specifications or requirements for MMAs or procures product development/manufacturing services from other individuals or entities (second party) for subsequent commercial distribution.
    - When a “developer” creates a mobile medical app from the specifications that were initiated by the “author,” the “author” who initiated and developed specifications is considered a “manufacturer” of the MMA under 21 CFR 803.3.
    - Manufacturers of a MMA would include persons or entities who create the original idea (initial specifications) for a mobile medical app unless another entity assumes all responsibility for manufacturing and distribution, in which case, that entity would be considered the manufacturer.

Mobile Medical Applications, Guidance for Industry and FDA Staff, Sept 25, 2013
Definitions

- The following are NOT considered MMA manufacturers:
  
  - Makers of smart phones and tablets who do not intend their platforms to be used for medical device functions
  
  - Entities that distribute MMAs, such as iTunes App Store, Google Play, etc.
  
  - Providers of tools, services, or infrastructure used to develop, distribute or use an MMA – such as ISPs, web/cloud hosting providers, etc.
  
  - Licensed practitioners who develop an MMA for use in their own practice or within their own group
  
  - People who develop MMAs solely for use in teaching or research
When does an app become regulated?

• **Intended use** of an app determines whether it meets FDA definition of a medical device.

• **Intended use is** defined through labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives.

• If **intended use** includes diagnosis of disease or other conditions, or cure, mitigation, treatment, or prevention of disease, or is intended to affect structure or any function of the body, mobile app is a medical device.
Regulatory Approach

- **MMAs subject to regulatory oversight**
  - FDA is using a risk-based approach that focuses on subset of MMAs that **meet regulatory definition of “device”** and that:
    - Are intended to be used as an accessory to a regulated medical device, or
    - Transform a mobile platform into a regulated medical device
    - Could pose a risk to patient safety if the MMA were to malfunction or not function as intended
  
  - For these MMAs, FDA requires compliance with all appropriate regulations and guidance documents – including requirements for pre-market notification (510k), pre-market approval (PMA), QSR requirements, and other device specific regulations, guidance documents and standards - examples listed in App. D
Regulatory Approach

• **MMAs subject to enforcement discretion**
  
  – Many mobile apps may meet regulatory definition of a device but pose minimal risk to patients and consumers
  
  – FDA will exercise enforcement discretion and will not expect manufacturers to submit premarket review applications or to register and list their mobile apps with FDA...
  
  – For these mobile apps, FDA recommends (but does not require) manufacturers comply with QSR...
Examples of Regulated MMAs

- **Mobile apps that transform a mobile platform into a regulated medical device**
  - These MMAs use a mobile platform’s built-in features such as light, vibrations, camera, or other similar sources to perform medical device functions.

- **Some Examples:**
  - Mobile apps that use an attachment to the mobile platform to measure blood glucose levels.
  - Mobile apps that use an attachment to the mobile platform to measure blood oxygen saturation for diagnosis of specific disease or condition.
  - Mobile apps that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (ECG).
Examples of Regulated MMAs

- **MMAs that connect to existing device for purposes of controlling its operation, function, or energy**
  - These MMAs control operation or function (e.g., change settings) of an implantable or body-worn medical device.

- **Some Examples:**
  - MMAs that control inflation or deflation of a blood-pressure cuff.
  - MMAs that alter function or settings of an infusion pump.
  - MMAs that act as wireless remote controls or synchronization devices for CT or X-Ray machines.
Examples of Regulated MMAs

• **MMAs that display, transfer, store, or convert patient-specific medical device data from a connected medical device**

• **Some Examples:**
  – Mobile apps that connect to a nursing central station and display medical device data to a physician’s mobile platform for review. (i.e., a medical device data system or MDDS).
  
  – Mobile apps that connect to bedside (or cardiac) monitors and transfer data to a central viewing station for display and active patient monitoring.
Enforcement Discretion

• While these mobile apps MAY meet definition of medical device, FDA intends to exercise enforcement discretion because they pose lower risk.

• Some Examples:
  – Mobile apps that use video games to motivate patients to do their physical therapy exercises at home
  – Mobile apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities
  – Mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness...
How Many MMAs Are Out There?

• FDA has cleared nearly 100 mobile medical apps.
  – These include blood pressure monitors, apps that send real-time readings of electrocardiographs to your doctor, and apps that access vital signs for use in emergency cardiac care.

Source: Keeping Up with Progress in Mobile Medical Apps, FDA CDRH website, Sept 2013

“Apple app store still leads Android in total number of medical apps”, Jul 12, 2013 by Timothy Aungst, PharmD
Thank you...

... for taking time to attend this presentation.

If you have questions, please call or e-mail...

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