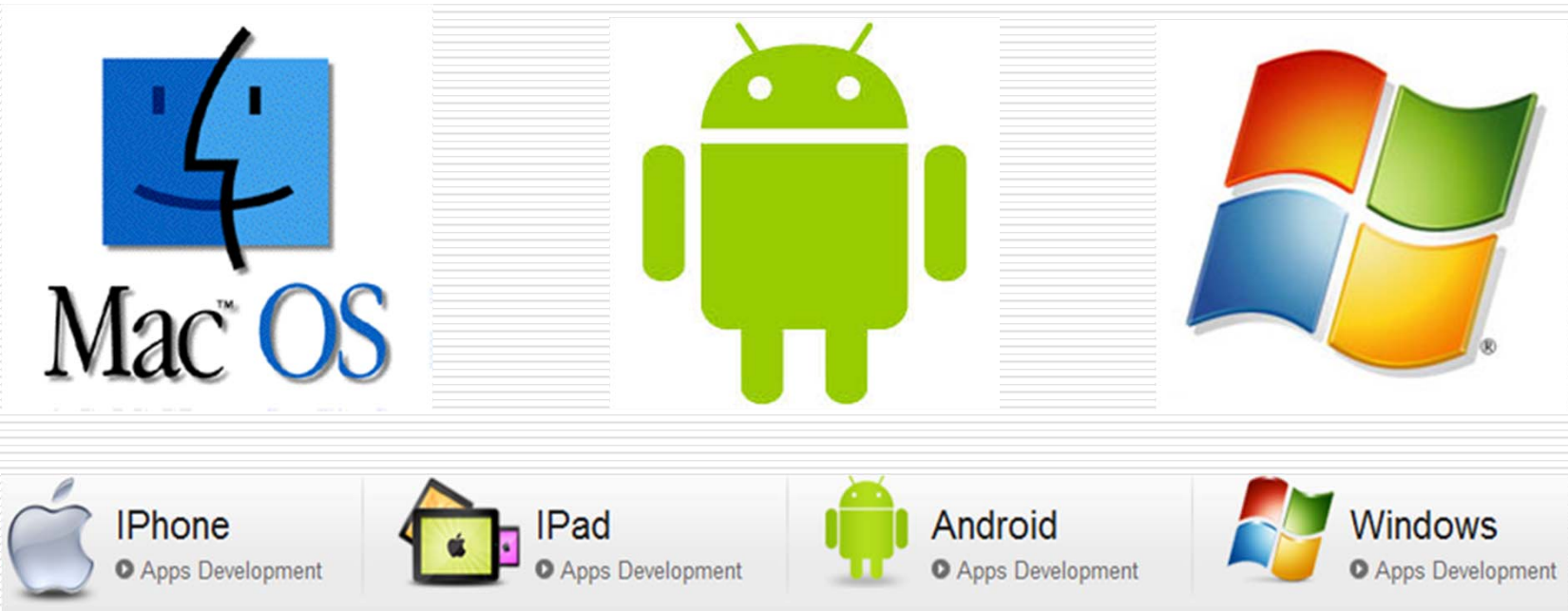
Mobile Medical Application Development: FDA Regulation



Mobile Medical Applications: Current Environment

- Currently over 100,000 mobile health related applications are available for download; there is an increasing sophistication of apps.
- FDA recognizes that the unique characteristics of mobile platforms may pose new and complicated risks.
- In the last 10 years, FDA has cleared approximately 100 mobile medical apps – 40 in the last 2 years.
- There is an increasing need for clarity regarding the limits of regulation and interpretation of what defines a "medical device" as it relates to mobile applications.

FDA
Regulation and Guideline

- **Mobile Medical Applications; Guidance for Industry and FDA Staff (Issued September, 2013) – Template for Compliance**

The FDA issued this guidance document to inform manufacturers and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms.

Even with this guidance document, navigating the regulation is not easy.

FDA
Regulation and Guideline

- **Who is the medical device "manufacturer" that is subject to compliance?**
  - Creates, designs, develops or labels.
  - Initiates specifications or requirements.
  - Procures product development services.
  - App "owner".
  - Excludes app distributors and mobile platform manufacturers.

FDA
Regulation and Guideline

- **What does the guideline include?**
  - Primary focus is on apps that present a risk to patients.
  - Provides guidance plus examples for regulated and *non*-regulated or *maybe* regulated apps.
    - Not medical devices and *not* FDA regulated.
    - May meet the definition of a medical device but present a low risk; subject to FDA "*enforcement discretion*".
    - Are medical devices, present risk and *will* be FDA regulated.

FDA
Regulation and Guideline

- **Examples of apps that are *not* medical devices and *not* subject to FDA compliance:**
  - Intended to provide electronic “copies” of medical textbooks or reference materials with generic text search capabilities.
  - Intended to be used by HCPs to use as educational tools for training. Or by patients for general education.
  - Automate general office operations in a healthcare setting.

FDA
Regulation and Guideline

- **Examples of apps that are subject to FDA *enforcement discretion:***
  - Provides patients with simple tools to organize and track their health information and/or helps patients manage healthcare in their daily environment. Facilitates supplemental clinical care.
  - Performs simple calculations routinely used in clinical practice.
  - Helps patients document, show or communicate medical conditions to HCPs .

FDA
Regulation and Guideline

- **Examples of apps that are subject to FDA *regulations and compliance:***
  - Becomes an extension of a medical device by connecting to such device for purposes of controlling the device or displaying, storing, analyzing or transmitting patient-specific data.
  - Transforms a mobile platform into a regulated medical device by using attachments, displays, sensors or by including functionality similar to those of currently regulated medical devices.
  - Performs patient-specific analysis, diagnosis or treatment recommendations.

FDA Criteria: Determining If An App is a Medical Device

- **Is the app a component of a medical device?**
  - Serves as an extension of the medical device and controls or updates the device.
- **Is the app an accessory to a medical device?**
  - Interfaces with the device to display, store, manipulate, modify and/or trend patient specific medical device data.
- **Is the app intended for use in the diagnosis, treatment, mitigation or prevention of a disease?**
  - Based on patient-specific data, outputs patient-specific results or diagnostics using formulae or processing algorithms.

Does Your App Do Any of the Following?

Analyzes	**Assesses**	**Alarms**
Alerts	**Calculates**	**Controls**
Converts	**Detects**	**Diagnoses**
Downloads (to Device)	**Interprets**	**Manipulates**
Monitors	**Programs**	**Trends**

- **If YES, then it's likely a device.**
  - But manufacturers should take into account other criteria, such as intended use and labeling, when determining if their app qualifies as a medical device.

Medical Mobile Apps

FDA Categories

- Apps for displaying, storing or transmitting patient-specific data in its original format (Medical Device Data System).
- Apps that control intended use, function or energy sources of medical devices to which they connect.
- Apps that transform mobile platforms into medical devices.
- Apps that analyze medical device data to create alarms, recommendations or new information.

Medical Mobile Apps
Medical Device Data Systems

- **The FDA's Medical Device Data Systems (MDDS) category of devices covers products used to transfer, store, convert or display medical device data.**
  - Devices falling under this category are exempt from FDA premarket notification requirements (exempt from 510K).
  - Some mobile apps fall under this category.

Medical Mobile Apps
Does Your App Qualify as MDDS?

- **Devices that provide one or more of the following functions without controlling/ altering how connected devices operate or adding additional information/data manipulation.**
  - Electronic transfer of medical device data.
  - Electronic storage of medical device data.
  - Electronic display of medical device data.
- **MDDS manufacturers must meet FDA Class I medical device requirements.**

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Medical Mobile Apps
App Does *Not* Qualify as MDDS?

- **The app is either a Class I, II or III level device (same regulatory requirements as other medical devices).**
- **The manufacturer must determine the FDA Class and follow the regulatory pathway for that Class.**
  - The Class level depends on the level of risk it poses to users, as well as whether “substantial equivalence” exists for the app.
  - Searching the FDA database for similar apps is the first place to start in the classification process.

Medical Mobile Apps
FDA Clearance or Approval

Class I	Class II	Class III
No FDA review needed (typical scenario).	FDA *clearance* required via 510(k) Premarket Notification. Predicate; "me too" devices.	FDA *approval* required via Premarket Approval (PMA)process. Novel, no predicates.

- **Mobile medical apps can fall into any of these three Classes.**
- **Apps defined as an "accessory" to the device take on the same Class as the parent device.**

Medical Mobile Apps
FDA Clearance / Approval Timelines

Class I	Class II	Class III
Processing typically takes a week. Self register device and pay FDA fee.	Most 510(k) applications reviewed within 90 days but entire process can take up to 10 months. Average is 132 days from submission to clearance.	Process takes 36 months or more depending on FDA request for additional information and/or clinical trial requirements.

Medical Mobile Apps
Steps in FDA's Compliance Process

General Steps Manufacturers of Class I, II and III Medical Devices Must Typically Go Through For Approval
1 - Determine device classification.
2 - Prepare and file 510(k) submission, if required.
3 - Comply with the FDA QSR – 21 CFR Part 820.
4 - If outside of the US, appoint US Agent.
5 - Register with the FDA; pay fee.

Medical Mobile Apps
Quick Notes on QSR

- **Select Class I and all Class II and III medical device manufacturers must implement quality management compliance with FDA Quality System Regulations (QSR) found in 21 CFR Part 820.**
  - FDA does not recognize ISO 13485 or ISO 9001 certification, only QSR compliance is accepted.
  - FDA does not certify quality systems; they conduct random inspections to determine QSR compliance.
  - If a manufacturer outsources production of the device or app, that firm must still comply with quality system requirements.

Medical Mobile Apps
Where To Next, Emerging Issues

- **FDA has reserved the right to issue additional guidance.**
  - Will the FDA's existing regulatory framework for conventional medical devices work for oversight of mobile medical apps? TBD.
  - There is an industry unease that additional guidance is needed to differentiate "medical" (regulated) from "healthcare" (not regulated) apps.
  - Recent HHS/FDA draft report proposes updating strategy to a more risk-based regulatory framework that will better promote innovation, protect patents and avoid regulatory duplication.
- **Patient data security, encryption and HIPAA regulations are a concern.**

Conclusion

- **In the dynamic world of mobile apps, the FDA guidance on regulation indicates that the existing US medical device regulatory structures apply to medical apps.**
  - First: Determine if your app is a Class I or MDDS.
  - If not a Class I or MDDS, most apps currently registered with the FDA have gone through the 510(k) review/ premarket notification – Class II. However, based on the uniqueness of the app, it could be Class III.
  - App manufacturers new to the FDA regulatory environment should thoroughly familiarize themselves with MDDS, 510(k) clearance and assure QSR compliance.

Thank you

The information presented in this summary represents the interpretation of FDA regulations by Ashvins Group and does not represent RA consultation or regulatory binding information.

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