Thursday, Oct. 3, 2013 • 10:00 a.m. - 4:00 p.m. EDT

Agenda

10:00 a.m. – 10:15 a.m. **Introduction to the Virtual Conference**

Tim Gee, Chairperson

10:15 a.m. – 11:00 a.m. **What Does the FDA Consider a Regulated App? Understanding the FDA's Final Guidance, Enforcement Discretion and Definition of Accessories**

On Sept. 25 the FDA will release its final guidance regulating medical device mobile apps. Some of industry's concerns will be addressed and some will not. What can developers do now to understand if their product falls under the FDA regulatory radar? Plus, how is the FDA using "enforcement discretion" for products that might be considered a medical device under FDA regulations. Brad Thompson — one of the industry's leading attorneys and strategists for medical device apps — leads you step-by-step through what the FDA expects from you. You can't miss this presentation!

Attendees will learn:

- How to decipher the scope of the FDA's regulation of mobile medical apps
- What the FDA means when it says "health" versus "wellness"
- The FDA's concept of intended use — is clarification needed?
- What accessories are and which ones FDA regulates?
- When FDA regulates decision-support software found in mobile apps

Brad Thompson, Member, Epstein Becker & Green; General Counsel, mHealth Regulatory Coalition

11:00 a.m. – 11:45 a.m. **FDA's Use of Enforcement Discretion**

Industry estimates that 500 million smartphone users worldwide will be using a healthcare application by 2015. The FDA has jurisdiction over mobile apps that meet the definition of "device" in section 201(h) of the FD&C Act. In this presentation, FDA staff will detail how the FDA intends to use this discretion and give examples of

what does and does not constitute a device.

Attendees will learn:

- Implications of the Biosense letter and the FDA's thinking going forward
- What's on the FDA's checklist for a successful approval — what are best practices and red flags that every firm should know

Bakul Patel, Senior Policy Advisor to the Center Director, CDRH, FDA (invited)

11:45 a.m. – 12:30 p.m. Break

12:30 p.m. – 1:15 p.m. **Successful FDA Clearance: A Case Study on Designing, Developing and Commercializing a Mobile Medical Application**

On March 14, Calgary Scientific received clearance from the FDA to market its medical imaging application, ResolutionMD™ Mobile, as a mobile diagnostic application on Android smartphones and tablets. This new FDA clearance extended the previous clearance to versions of the solution running on Apple® iPhone® and iPad® devices granted in 2011. The company also obtained ISO 13485/9001 and CE Mark certifications and four FDA 510(k) clearances. This presentation will detail the who, what, where, when and how of securing FDA approval.

Attendees will learn:

- Obtaining FDA clearance — identifying and addressing the safety and effectiveness criteria; establishing a repeatable process for future clearances
- Understanding the issues that impact design, usability and end-user implementation
- Different factors that went into creating and designing Calgary Scientific's mobile device user interface
- How to become a strategic supplier — using an app to leverage your company strategy

Kyle Peterson, Director, Regulatory & Corporate Affairs, Calgary Scientific

1:15 p.m. – 2:15 p.m. Lunch

2:15 p.m. – 3:00 p.m. **Beyond FDA: Emerging Regulations, Risks and Rewards from FTC, FCC and States**

A growing network of federal and state authorities — such as the FDA, FTC, FCC and California — are regulating and taking

enforcement action in the mobile health arena. This presentation provide insights into the complex web of regulations, guidance and enforcement that is shaping mobile health, and provide recommendations for moving forward in this rapidly changing environment.

Attendees will learn:

- Various FDASIA-driven regulations are finally coming on-line — how do these effect medical devices?
- To be or not to be: Examples of mobile apps that are not mobile medical device apps
- How FTC guidances affect your marketing and privacy disclosures
- Roundup of state-level actions that are effecting medical device app development

Marian Lee, Partner, King and Spalding

3:00 p.m. – 3:45 p.m. **Driving Adoption of Mobile Apps for Medical Device Connectivity and Remote Healthcare: Top Trends**

The market is flooded with medical device and health-related apps — many of them harmless, but some of them potentially dangerous and in need of regulation. App developers always tend towards developing cool software but they must understand the risks and the intentions of the devices they create. This presentation will focus on the top trends influencing the development of apps and provide a regulatory and strategic pathway for potential app developers.

Attendees will learn:

- Uncovering what constitutes a medical mobile app and the role of apps in medical device systems
- Reviewing the evolution of hardware platforms and exploring market segmentation
- Evaluating the key drivers for growth in mobile apps in medical applications
- Addressing the challenges and barriers to market entry for a medical device manufacturer

Tim Gee, Principal, Medical Connectivity Consulting

3:45 p.m. – 4:00 p.m. **Closing Comments and Adjournment**

Tim Gee, Chairperson