

# MMA Roadshow: A Workshop on Managing mHealth App Development Under FDA Regulation

Massachusetts Institute of Technology  
March 20, 2014 | Events

FDA recently published its final guidance on mobile medical apps, and while helpful, the guidance leads to more questions. This workshop will focus on answering those questions for app developers in or close to FDA regulated territory.

## Agenda

**Over the course of a four hour program, we will examine topics such as:**

1. How to develop mobile apps that come as close to the FDA line as possible, but don't cross over into regulated territory.
2. For those apps that FDA does regulate, how to figure out the appropriate classification in a system that frankly hasn't been updated in a long time.
3. If your app requires premarket clearance, what predicates are available and more importantly what strategies are there for showing substantial equivalence.
4. Practical steps for developing an FDA quality system that is nuanced to fit mobile apps, and is designed to be as economical as possible.
5. In a global economy, what are the differences between the US regulatory system and the EU system, and how can a company efficiently enter both markets?

## People



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6. From the perspective of seasoned executives, what are the management challenges you can anticipate in mobile app development in a regulated environment?

You will hear directly from regulatory attorneys, regulatory affairs specialists, quality system experts, European law attorneys, experienced mHealth executives and of course, the FDA.

## Who Should Attend

These workshops will focus on mobile medical apps issues that will help both the novice and experienced FDA regulatory professional alike.

**Registration fee: \$100**

### To Register:

#### MMA Roadshow Registration

*For questions regarding the MMA Roadshow, please contact: Lisa Blackburn at [lblackburn@ebglaw.com](mailto:lblackburn@ebglaw.com).*

### Future Dates:

May 6-8, 2014 — mHealth Europe Summit

June 12-13, 2014 — HIMSS Innovation Center

**Epstein Becker Green is pleased to sponsor the MMA Roadshow.**



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