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Webinar on

BEST SELLER - Mobile Medical Apps (Is It A FDA Regulated Device) And Cybersecurity

Learning Objectives

- *When does your mobile app become a medical device?*
- *When does FDA consider your mobile app a consumer product which it will not regulate?*
- *How does FDA determine not to regulate one app versus another?*
- *How does the new guidance impact industry?*
- *What is FDA's position on the cyber security and mobile medical applications?*

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Areas Covered

- *What mobile apps are medical devices*
- *What mobile apps will be regulated by FDA*
- *FDA Guidance: "Mobile Medical Applications“*
- *Review of quality system requirements from the FDA (QSRs) and the EU (ISO 13485)*
- *Review of software development standards: ISO 62304 and FDA guidance documents*
- *How to get a mobile app approved by FDA Cybersecurity for mobile apps explained*

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This webinar will explain how to determine if your app is a medical device and if it will be subject to FDA requirements.

PRESENTED BY:

Edwin Waldbusser retired from the industry after 30 years in management of the development of medical device products and development of company Quality Systems. He was involved in the development of products such as IVD devices, kidney dialysis systems and inhalation devices. His QS experience includes design control, risk analysis, CAPA, software validation, supplier qualification/ control and manufacturing/non-conforming product programs.

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Best Seller

Duration : 60 Minutes

Price: $150

Webinar Description

The FDA has released a Guidance explaining how they intend to apply their regulatory authority to software applications intended for use on mobile platforms. They have defined what types of apps they consider a medical device. Apps that are medical devices must meet all FDA device requirements, however, FDA will not enforce their requirements on Mobile apps that meet the FDA's definition of a medical device but pose a low health risk.

This webinar will explain how to determine if your app is a medical device and if it will be subject to FDA requirements. The FDA approval process for a new app will be explained including FDA software validation requirements which are more extensive than just testing performance. Cybersecurity is very important for mobile apps. The FDA requirements for cybersecurity in the app design will be explained.

Who Should Attend ?

Development Engineers

Production Management

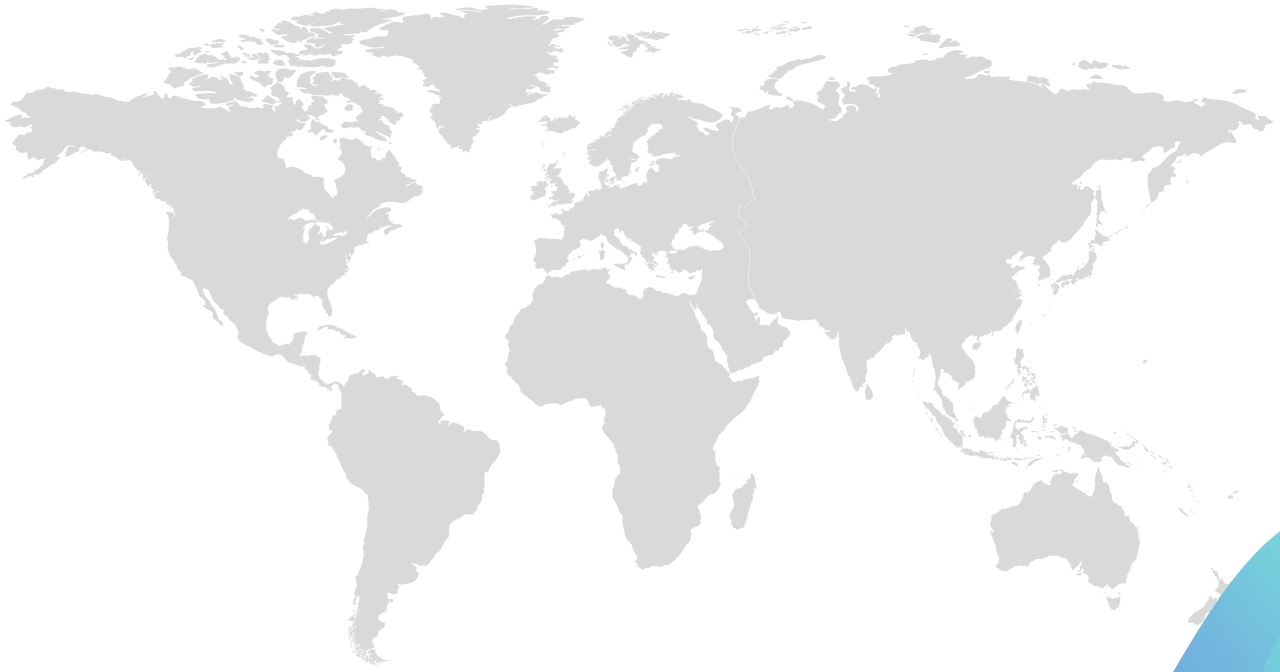
QA/ QC personnel

Software developers

IT personnel

Legal dept

Regulatory Personnel



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Why Should Attend ?

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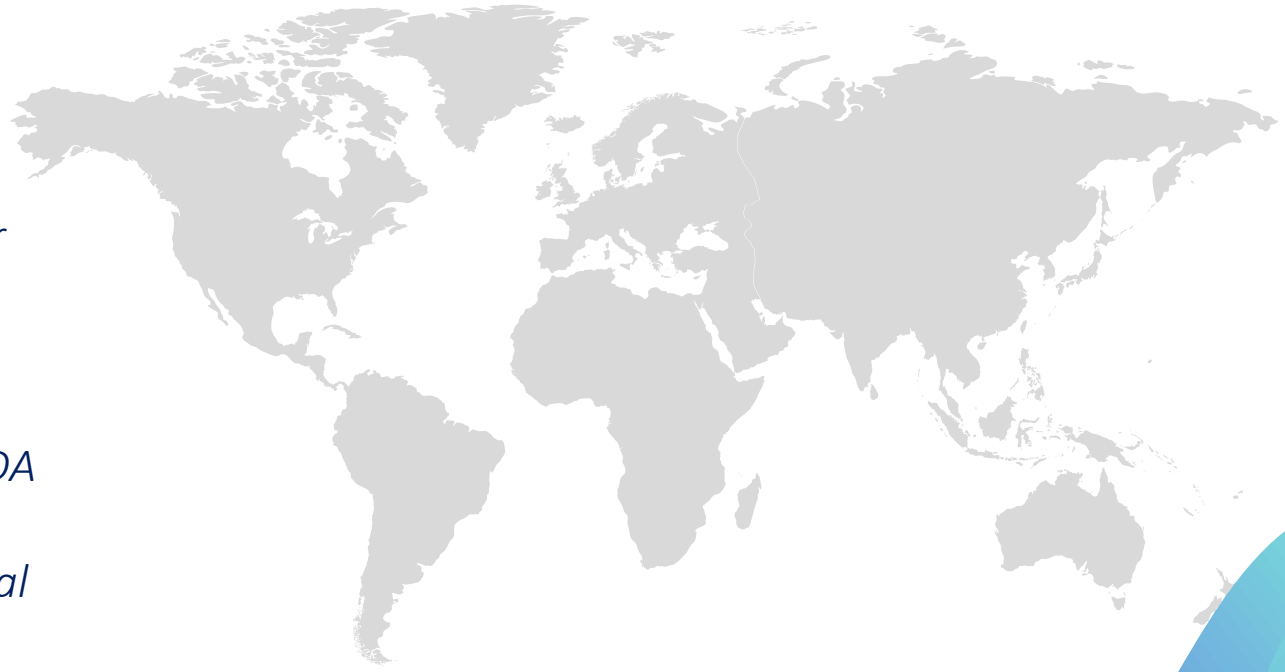

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