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Webinar on

IEC 62304 For Medical Device Software

Learning Objectives

- *Why is having an IEC62304 Compliant Software Quality System important to both developing your software for 510K approval and how you can be putting your company at risk post-approval if you do not have a compliant system in place*
- *What is IEC62304 and how does it differ from other Compliance Standards such as ISO13485*
- *What are the elements that constitute an IEC62304 Compliant System?*
- *Benefits of developing to an IEC62304 standard, What are the components of the Software Lifecycle*
- *What are the major Software Work Products developed to the standard?*
- *How it fits in with a Company's Standard Quality Process*

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- *What are the legal consequences for the company with the submittal if the company does not adhere to the Guidance*
- *One of the most common reasons that a Software Enabled Medical Device is denied a 510K is because the Guidance has not been followed*
- *What are the potential audit consequences if the Company does not have an IEC62304 Compliance Quality System in place*
- *Understand the regulatory need for IEC 62304 Guidance as it relates to submitting a 510K for Software Enabled Medical Devices*
- *What constitutes compliance with the Standard? What areas does the Guidance Address*
- *What are the legal consequences for the company with the submittal if the company does not adhere to the Guidance*

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This Webinar will ensure that Device companies will know exactly what documentation needs to be prepared.

PRESENTED BY:

José Mora is a Principal Consultant specializing in Manufacturing Engineering and Quality Systems. For over 30 years he has worked in the medical device and life sciences industry specializing in manufacturing, process development, tooling, and quality systems. José worked for 10 years at Cordis Corporation, now a Cardinal Health company.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

This course is essential for Medical Device companies interested in submitting software enabled medical Devices or Software as a Medical Device to the FDA for 510K approval. One of the biggest risks most company's face when submitting their device for approval is finding out after seven or more months of waiting that the 510K has been denied because the software portion of the submittal is inadequate and not compliant. They also face potential audit risk which might prevent them from selling their approved product if they have been found to not have an IEC62304 Compliant Software Quality System.

This course will ensure that Device companies will know exactly what documentation needs to be prepared. They will also know how to ensure the documentation is prepared correctly so the software portion of the submittal will be in compliance preventing delays of the 510K approval. Companies can also face potential audit risks and serious findings post submittal that can block their ability to ultimately sell their product successfully. This course will ensure that you know what is expected to have in place for compliance for your company during the preparation of a 510K to prevent this risk.

Who Should Attend ?

Managers, Supervisors, Directors, and Vice-Presidents in the areas of:

Regulatory, Quality

Vice President of Compliance and Regulatory

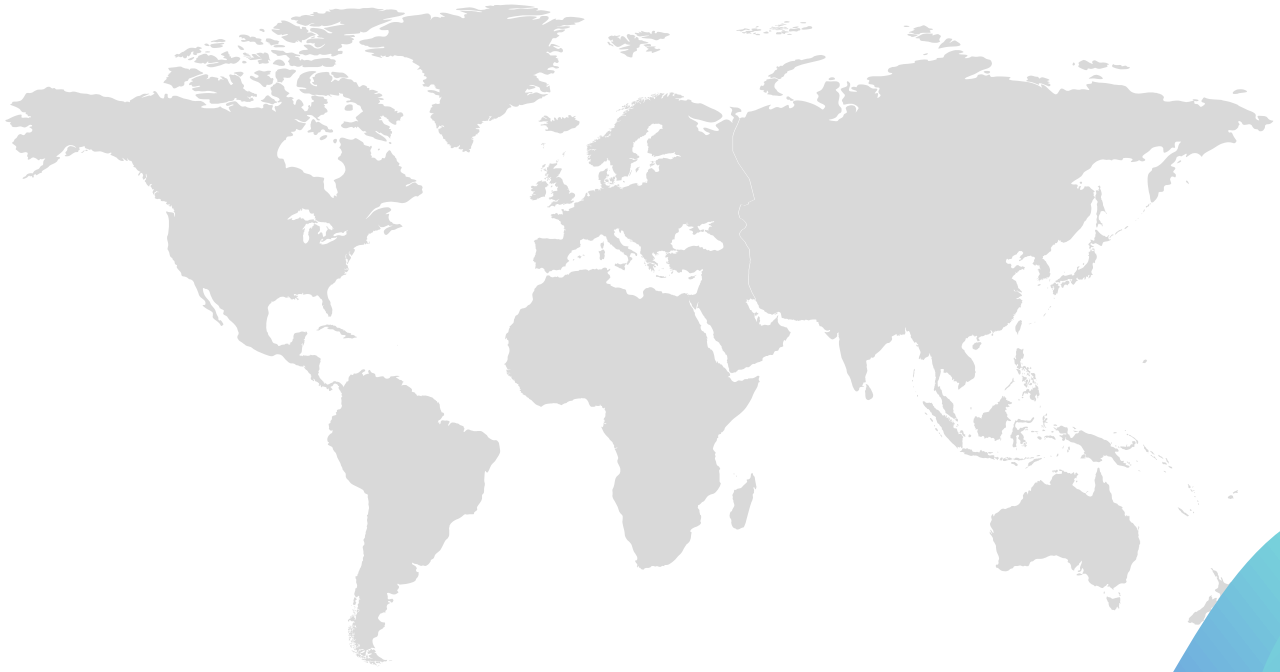
Compliance Expert

Software Engineer, Software Engineering Manager, Software Compliance Engineer

Medical Device Software Engineer

Quality Assurance

Design Assurance, Design Engineers



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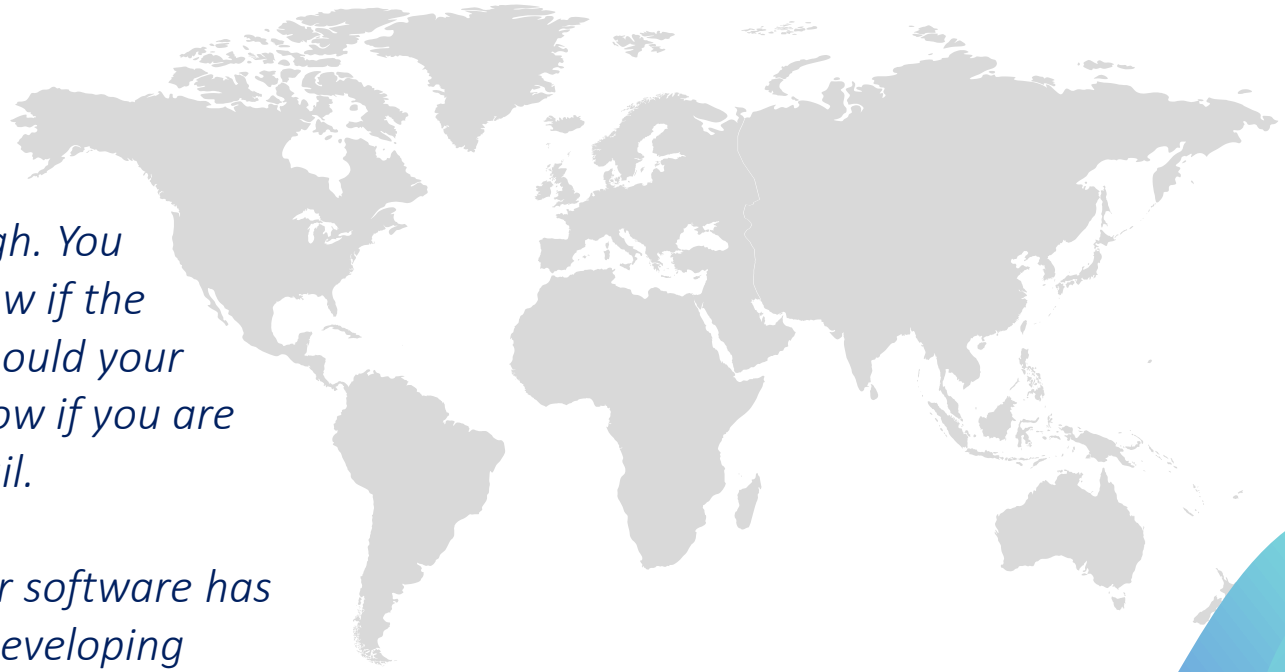
Why Should Attend ?



Developing software for medical devices can be a challenge especially if the device is complicated. You do not know if it is safe enough. You do not know if it tested enough. You do not know if the FDA will consider it for suitability for a 510K. Should your software cause harm to someone you don't know if you are protected from liability should your software fail.

Compliance with IEC62304 is key to ensure your software has been developed to the highest level of safety. Developing software based on the standard shows one way to indicate an intent to ensure the safety of your product. Gives you a framework to ensure you are developing and testing to consistent and stringent standard. Demonstrating compliance with the standard will be apparent in your submission and will be one way to ensure acceptance by the FDA.

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