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Webinar on

Medical Device Software Validation That Meets FDA Requirements

Learning Objectives

- *Software validation is more than testing*
- *Requirements traceability*
- *Risk analysis*
- *Unit, integration and system testing*
- *Algorithm validation*
- *Challenges to the software*
- *Configuration management*

This course will teach how to conduct a software validation program for medical devices containing software that will satisfy FDA requirements and produce a safe product.

PRESENTED BY:

Edwin 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.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

This course will teach how to conduct a software validation program for medical devices containing software that will satisfy FDA requirements and produce a safe product. We will explain the role of risk analysis in validation. How software requirements are developed and used in validation will be described.

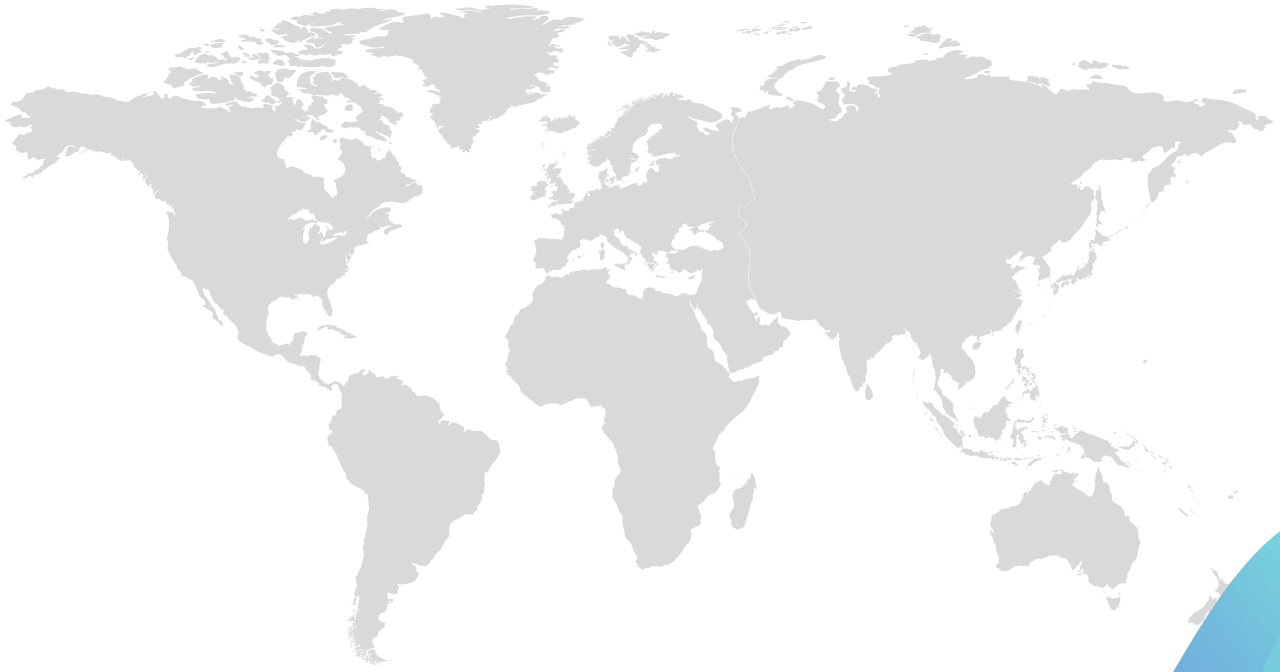
Who Should Attend ?

Engineering personnel

Software developers

QA

Management



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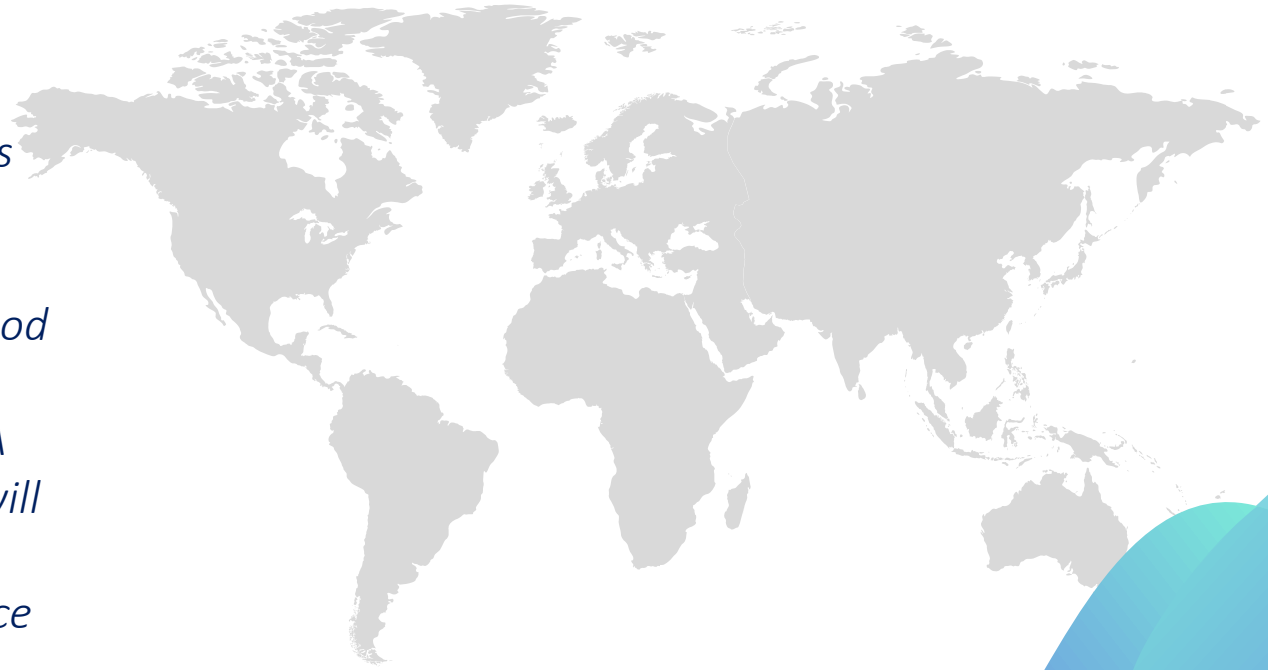
Why Should You Attend ?



Testing software to prove that it works and has no bugs is not sufficient to obtain FDA approval. There are additional analyses and tests that FDA feels are necessary to prevent user injuries. Also required are good Design control and Configuration Management. These requirements were developed after analysis by the FDA of many recalled medical devices In this webinar, you will learn how to meet FDA requirements and the analysis that is required in addition to functional tests to produce a validated software product.

Handouts are software traceability matrix form, validation plan template, and validation report form.

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