GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

Medical Device Software Validation that Meets FDA Regulations

Date : August 17, 2021

Areas Covered

How to validate medical device software in compliance with FDA 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 Waldbusser
- retired from the industry after 27 years in management of development of medical device products and development of company Quality Systems. He has been a consultant for the last10 years, working with companies from startups to Fortune 100 in the US, Germany, United Kingdom, Netherlands, Canada, Poland, and Saudi Arabia.

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

Date : August 17, 2021

Time : 01 : 00 PM EST

Duration : 60 Minutes

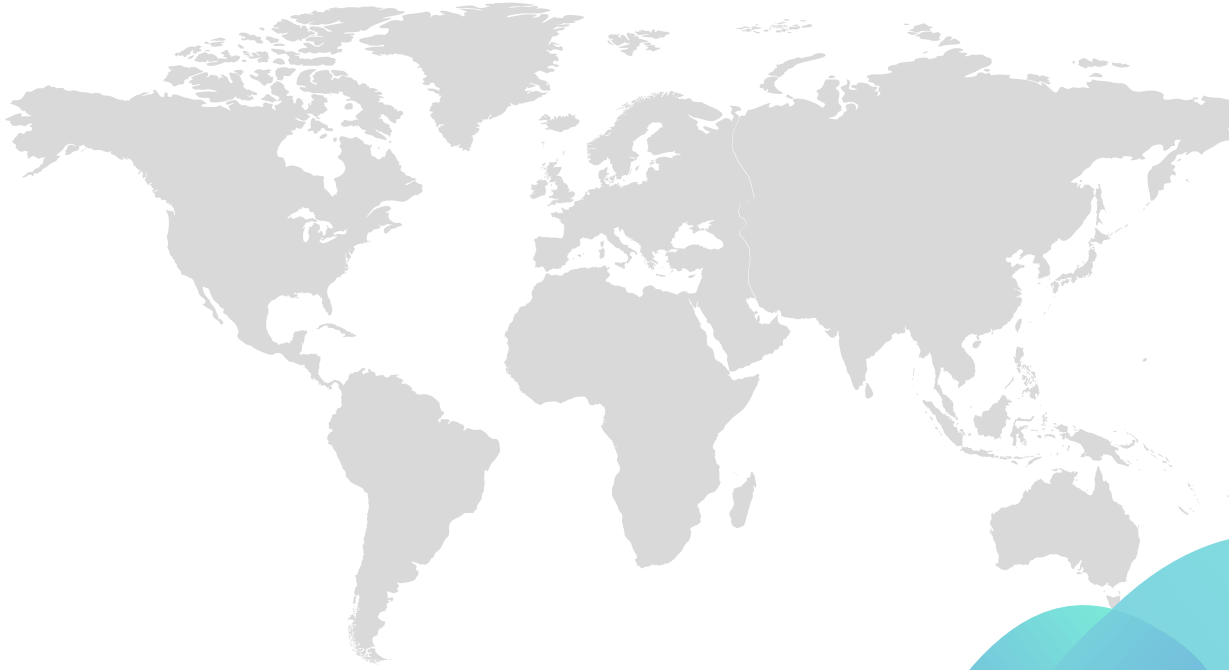
Price: $179

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 invalidation. How software requirements are developed and used in validation will be described.

Who Should Attend ?

- *Engineering personnel*
- *Software developers*
- *QA*
- *Management*



GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

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.

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321