

Webinar on

Human Factors Validation Testing Following ISO 62366 And New FDA Guidance

Areas Covered

- A required number of participants*
- Qualitative success criteria*
- Choice of tasks to validate*
- Post-test participant inquiry*
- Use scenarios*
- Step by step human factors program development*
- Validation*



This webinar will explain the procedure described in ISO62366 and the 2016 FDA Guidance for a compliant human factors/usability validation.

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. His QS experience includes design control, risk analysis, CAPA, software validation, supplier qualification/control and manufacturing/non-conforming product programs

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

Following the implementation of the results of a Human Factors/ Usability study, a validation of the safety and effectiveness of the use of the device must be conducted. We will explain the FDA required the number of validation participants from each "distinct user population". We will explain how to choose the tests to be conducted and the studies that must be completed prior to the actual validation test. The post-test participant inquiry is critical to validation success. We will describe how to do this.

This webinar will explain the procedure described in ISO62366 and the 2016 FDA Guidance for a compliant human factors/usability validation. HF/U validation is very different from device validation. For example, success criteria are qualitative rather than quantitative as is in device validation. Claiming success because eg. 95% of test participants did not commit a user error is not valid. Nor is 100% positive test results sufficient.



Who Should Attend ?

QA/QC Personnel

Manufacturing

Development Engineers

Production Management

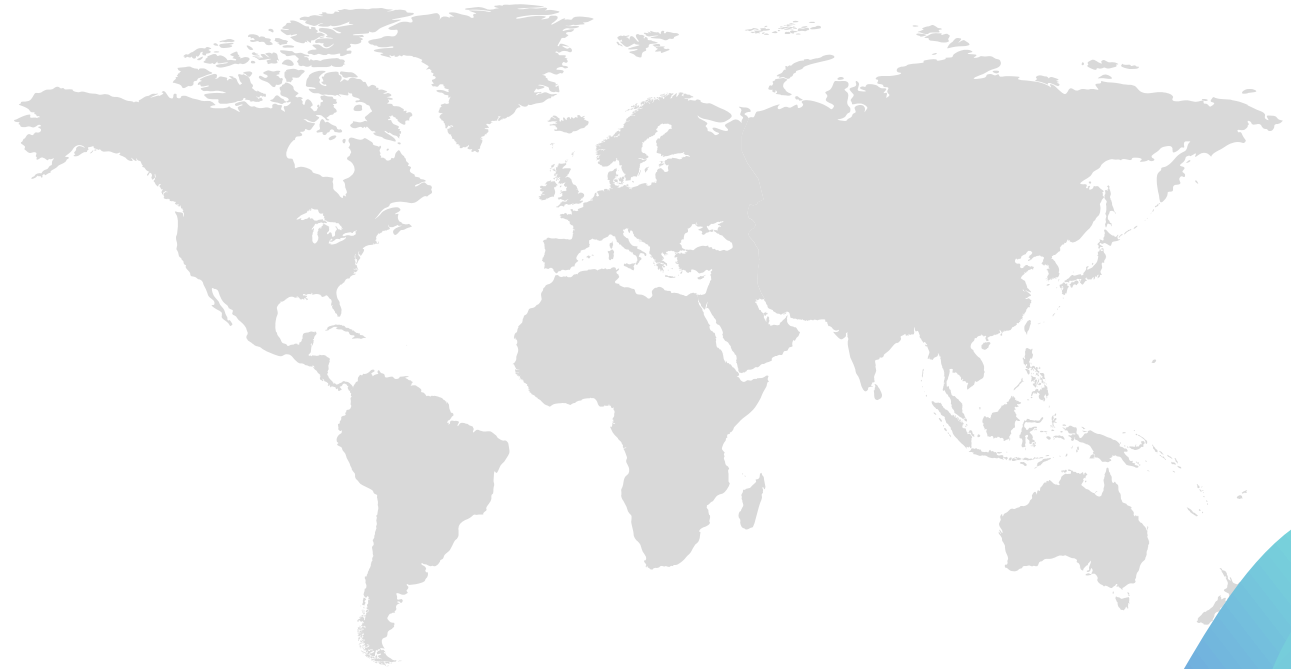
Software developers

Engineering management



Why Should Attend ?

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