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Webinar on

How to Conduct a Human Factors/Usability Validation

Learning Objectives

- *Required number of participants*
- *Qualitative success criteria*
- *Choice of tasks to validate*
- *Post-test participant inquiry. Forms: Usability Validation Tracking Matrix*
- *Validation Protocol*
- *Validation Test Results Report will be given as Ha*

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

PRESENTED BY:

Jose Ignacio 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. Prior to working full time as a consulting partner for Atzari Consulting.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

This webinar will explain the procedure described in ISO62366 and the 2016 FDA Guidance for 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 ?

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 a 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. handouts are usability validation tracking form, protocol form, and test results report form.

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