How to conduct a human factors validation test following ISO62366 and the FDA Guidance

Description: Validation testing aims to show that a device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions. This webinar will explain the procedure described in ISO62366 and the 2016 FDA Guidance for a compliant human factors/usability validation test. 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.

Objectives of the Presentation:

- Required number of participants
- Qualitative success criteria
- Choice of tasks to validate
- Post test participant inquiry
- Validation
- Step by step human factors validation test development

Why Should you 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 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.

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