QMS wrapper™

eQMS VALIDATION

With the assistance of software validation, you know you're using a reliable and secure software.

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eQMS Validation

Validation of software is an important and obligatory part of process when you are using eQMS. It is a process of evaluating software
product, to ensure that the software meets customers' demands and expectations.

People mainly think of it as a regulatory requirement only, and it is. Both require it - FDA 's 21 CFR part 820.70(i) states that if computers or automated data processing systems are used as part of the quality system, the manufacturer shall validate computer software for its intended use. Same is the requirement from ISO 13485:2016.

But, Validation for intended use documentation is useful for several reasons: ensures accuracy, reliability, consistent intended performance, the ability to discern invalid or altered records, resulting in fewer errors and less risk to process and data integrity.

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When the user purchases the software for its quality management, it should obtain documentation from supplier to build the basis of its validation.

qmsWrapper is validated according to ISO/TR 80002-2 Medical device software — Part 2: Validation of software for medical device quality systems.
The outcome of validation process is the Validation Documentation Set that will help clients to validate our software for its intended use.

ISO

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This set is consisted of System Requirements, Use requirements, Validation Report and Intended Use documents.

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- System requirements document provides information about configuration that a system must meet in order to qmsWrapper software run smoothly and efficiently.
- Use requirements document gives a detailed description of the use requirements for the qmsWrapper software. It includes a set of use cases that describe user interactions that the software provides. All Use requirements are tested (tests and performing steps are stated) and validation results are shown.
- Validation report explains the various activities performed as part of the testing of qmsWrapper web application. Also provides the test results and the proof of the tests.
- ERES Rationale explains compliance with FDA's 21 CFR part 11 Electronic Records and Electronic Signatures.
- Intended Use document contains all use cases that describe users' interactions that the software provides and it is aimed to be used by customers and their own validation of the software.

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There are no shortcuts in this process. However, qmsWrapper provides means for smooth validation saving clients time, nerves and resources, but demonstrating compliance to regulations and standard.

Considering the benefit, it becomes essential to conduct the process of software validation, so that the software product is readily accepted and satisfies your requirements. In short, with the assistance of software validation, you know you're using a reliable and secure software.