Usability Engineering Under IEC 62366

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PURPLE VERTEX

ANSI/AAMI/IEC 62366 is a Recognized Consensus Standard by the US FDA and a harmonized standard in the EU. This means that compliance to it provides a presumption of conformity to the requirements within those jurisdictions. Compliance with the standard helps both ensure a smooth path to market clearance and drives a safer product.

IEC 62366 is the recognized standard for Usability Engineering for medical devices.

AREAS COVERED IN THIS WEBINAR

The main focus will be on presenting tips and techniques for the practical application of the standard. Each phase in the development lifecycle will be discussed along with how deliverables required can be created, maintained, and evolved to meet regulatory requirements.

WHY SHOULD YOU ATTEND

A practical application of the standard is not always intuitive. There are some nuances that can lead to unnecessary and excessive work. This training session will discuss techniques and methods that have proven successful in better ensuring safe and effective products and compliant regulatory submissions.

INSTRUCTOR PROFILE

DON HURD

Don Hurd has over 35 years of experience in supporting the development of applications of or containing software in regulated industries, the last 17 in medical devices. With his diverse background, Mr. Hurd provides a unique insight into driving product quality and ensuring high productivity of development organizations. Mr. Hurd is currently the Vice President of Quality and Validation Services for The Realtime Group, a contract R&D firm specialized in serving the regulated industries, primarily medical devices. In this role, Mr. Hurd led the company to certification in both ISO 9001 and ISO 13485, maintaining certification for nearly 15 years. In his role at Realtime, Mr. Hurd supports clients in efforts ranging from Quality Management System development, deployment, and remediation; product and development quality planning; verification and validation of products, product software, and non-product software; supplier qualification, approval, and management; transitioning product from development to manufacturing; supporting post-market vigilance/surveillance; and interfacing with ISO auditors and FDA inspectors. Mr. Hurd has been an ASQ Certified Quality Auditor since 2009.

THIS WEBINAR IS AVAILABLE IN

LIVE ACCESS | DOWNLOADABLE LINK | PENDRIVE / USB | DVD

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