

13C - How Clinicians and Device Manufacturers Can Collaborate To Reduce Risk

Presenter

Steven R. Rakitin, President, Software Quality Consulting, Inc. - steve@swqual.com

Session Summary

Designing, deploying, and maintaining medical devices that are safe and connected to ever-changing networks creates safety challenges for clinicians and device manufacturers. Reducing risk to ensure patient safety requires a collaborative effort with specific expertise in clinical requirements gathering, system validation, and analysis tools.

Clinicians and device manufacturers need a common language for describing how medical devices should behave when connected to networks. The session includes a discussion of examples of techniques for expressing clinical requirements.

Every hospital network is different, and while device manufacturers do a reasonable job of system validation, they often can't create or simulate the actual network environment that exists at every hospital. This means that to minimize risk, some level of system validation is required at each hospital. Clinical engineers often can't get essential technical information from device manufacturers to do this validation, and others may need training in device validation best practices. This presentation provides recommendations for on-going system validation.

Device manufacturers should use safety cases to support claims their devices are safe. Clinical engineers should use safety cases to ensure a device is safe when used in their unique environment. As networks evolve, clinical engineers can review these safety cases and take additional steps to ensure devices will continue to work safely. This presentation describes how device manufacturer's pre-release and a clinical engineer's post-deployment can use safety cases.

About the Presenter - Steven R. Rakitin

Steven R. Rakitin, President, Software Quality Consulting, Inc. Steven has over 35 years experience as a software engineer and software quality manager. Writing extensively on the subject of software quality, Steven published a book entitled *Software Verification & Validation for Practitioners and Managers*. He helped write the first IEEE Software Engineering Standard (for Software Quality Assurance Plans), is currently serving on two IEEE Software Engineering Standards working groups, and is a member of the AAMI HIMSS CE-IT Collaboration. He received a BSEE from Northeastern University and an MSCS from Rensselaer Polytechnic Institute. He has earned certifications from the American Society for Quality (ASQ) as a Software Quality Engineer (CSQE) and Quality Auditor (CQA).

Steven is a member of the IEEE Computer Society, ASQ Software Division, ASQ Biomedical Division, and the Association for the Advancement of Medical Instrumentation (AAMI). He is on the Editorial Review Board for the ASQ Journal Software Quality Professional, and has presented invited papers and tutorials at conferences worldwide for the Health Industry Manufacturers Association, AAMI, ASQ, and IEEE. As president of Software Quality Consulting Inc. (www.swqual.com), Steven helps medical device manufacturers comply with regulations and software standards.