Medical Device Risk Management

December 12, 2019

Please register via Eventbrite, or see http://www.incose.org/cleveland

12:00 PM – 1:00 PM EST

Webinar (your computer) or two locations
NASA Glenn, Building 162, room 209 (NASA-badged members/guests)
Philips Healthcare/Orange Village (Philips Healthcare-badged members/guests)

Speaker: Jim Richards

Abstract:

Medical devices are globally regulated and safety and effectiveness are mandated to have controlled design processes that consider safety risks throughout the product lifecycle. The talk will present an overview of applicable standards and how product risk management interacts with the design process. Some detailed examples of design guidance from the standards will be presented.

Jim's Bio:

Senior Systems Engineer at Philips Healthcare since 2005 with experience as lead for teams of system engineers, physicists, and system designers to deliver top tier CT products with a focus on problem solving and integration of new technologies. Extensive experience in design controls and quality systems and as a risk management process owner. Support for the business as a lead for compliance audits with TUV, FDA and other international and independent auditors. Experience with product and process CAPA's and development of training for post market risk management and complaints handling. Past experience includes systems design, physics and electrical engineering in the development of advanced technologies and feasibility studies for product development of multiple CT scanner family platforms and imaging systems development for invasive cardiac, cardiovascular and x-ray products. Working in the Medical device industry since 1979.
Member of IEEE and the following societies:
    IEEE Electromagnetic Compatibility Society Membership
    IEEE Product Safety Engineering Society Membership
    IEEE Reliability Society Membership
    IEEE Systems Council
Outside Interests include:
    Father of 2 teen boys
    Outdoor sports - hiking, canoeing and kayaking
    Nature Photography
    Music – Guitar, Fiddle and Mandolin.

We hope that you can join us!