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Medical Device Software: An Incremental Approach to Risk and Quality Manage...

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Event URL : http://www.sfbayeventslist.com/events/medical-device-software-an-incremental-approach-to-risk-and-quality-manage

Organizer : New York Media Technologies LLC in association with Netzealous LLC

Venue :

Location : DoubleTree by Hilton Hotel San Diego Downtown1646 Front StreetSan Diego, CA 92101United States,
San Diego, CA , US, ZIP: 92101

Description

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Engineers are dedicated to making things work, so a focus on how they might fail and harm someone can seem alien.

Managing risk, however, is essential for all medical products- medical devices, including those involving software, have produced some painful examples of poor risk management with serious consequences. Experience has shown that there is a better way, that it is possible to manage risk in a changing business and technical world.

Regulatory bodies are placing increased emphasis on risk management, and technology shifts are introducing new sources of risk. Newer Lean-Agile methods are recognized by the FDA as a good way to accomplish risk management.

Techniques for risk management are well established, but require specific interpretation when applied to software. In this session, we will show a way of knitting risk management into the development process, so that it is integral to product development, not a ten ton caboose dragging the train back down the mountain.

Why you should attend:

Perhaps your engineering team is beginning its transition to an Agile approach - or perhaps you have a seasoned Agile team and you're just beginning work on FDA-regulated products. You know that risk management is required, but it's not at all clear how you should address it as you go through your backlog grooming, iterations, and end-user demonstrations. The process in ISO 14971 seems "linear" and unsuited to a highly iterative, dynamic lifecycle. How can you fit it into your approach?

Areas Covered in the Session:

- Software has introduced (or been blamed for) some serious safety hazards
- All medical device standards intersect on the topic of risk management
- Risk analysis starts with the intended use statement
- Risk information is available from multipl sources - use them!
- Note that safety is an emergent property
- Changes are often the biggest sources of risk
- Don't ignore the human factors side; understanding your users is crucial to safety
- Applying engineering risk methods to software requires us to translate some concepts
- Though standards draw a roadmap for risk management, WE must figure out the route
- Risks often arise when we add new features - so incremental risk management is the most effective
- Forget the notion that "software can't hurt anyone"
- Never conduct risk analysis by using a checklist from 14971
- Exploding technology brings numerous chances for risk to multiply

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Who will benefit:

- Project managers

- Regulatory specialists
- Quality assurance specialists
- Documentation specialists
- Test managers
- Software team leaders and lead developers

Event Categories :