Global CompliancePanel

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Knowledge, a Way Forward...

2-day In-person Seminar:

Software Risk Analysis Tools for Medical Devices and Risk Mitigation

Dev Raheja

October 8th & 9th, 2015

San Diego

9 AM to 6 PM

Course "Software Risk Analysis Tools for Medical Devices and Risk Mitigation" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

SPEAKER

Dev Raheja

Author - Safer Hospital Care (Taylor & Francis), Patient System Safety

Dev Raheja, MS,CSP, author of the books Preventing Medical Device Recalls and Safer Hospital Care, is an international risk management, patient safety and quality assurance consultant for medical device, healthcare and aerospace industry for over 25 years. Prior to becoming a consultant in 1982 he worked at GE Healthcare as Supervisor of Quality Assurance/Manager of Manufacturing Engineering, at Cooper Industries as Chief Engineer, and at Booz-Allen & Hamilton as Risk Management consultant for variety of industries. His clients include Johnson & Johnson, Siemens Medical Systems, Medtronic, Carl Zeiss, Warner-Lambert, Zimmer Holdings, and DuPont.

OVERVIEW

The FDA recalls related to software performance are on the increase for at least five years at the time of this writing. Software failures were behind 24 percent of all the medical device recalls in 2011, according to data from the FDA. Similar to hardware, software also has hazards (any source of harm) and hazardous situations which transform a hazard into harm. We must identify hazards and identify what event can turn them into harm and write software specifications to prevent such combinations. The risk management tools such as FMEA (Failure Mode and Effects Analysis), FTA (Fault Tree Analysis) can help to mitigate software risks.

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AGENDA

DAY ONE

Lecture 1: FDA requirements for software risk analysis

Lecture 2: What constitutes software under FDA requirements

Lecture 3: Software risk management through good design practices

Lecture 4: Principles of efficient risk analysis

Lecture 5: Overview of ISO 14971 for software

Lecture 6: Role of probability in software development

Lecture 7: FDA guidance for software risk assessment for pre-market approval

Lecture 8: Good practices for requirements analysis

Lecture 9: Negative requirements analysis

Lecture 10: Workshop on negative requirements analysis

Lecture 11: Six hat thinking for efficient risk analysis

Lecture 12: Software risk prediction using Preliminary Hazard Analysis

Lecture 13: Assigning the criticality based on the probability of the harm and severity for each hazard

Lecture 14: Mitigating risks using world class practices

Lecture 15: Workshop on PHA

Lecture 16: Risk Analysis using Software Functions FMEA

Lecture 17: Workshop on Software FMEA

Lecture 18: Module level FMEA

Lecture 19: Code level FMEA

DAY TWO

Lecture 1: Workshop on code level FMEA

Lecture 2: Risk Analysis Using the Fault Tree Analysis

Lecture 3: Constructing fault trees

Lecture 4: Workshop on Fault Tree Analysis

Lecture 5: Design improvements through Fault Tree Analysis

Lecture 6: Device alarms requirements to avoid user risks

Lecture 7: Risk analysis for interoperability performance

Lecture 8: Risk management through good design control

Lecture 9: Risk assessment for human factors

Lecture 10: Risk control of unexpected use and misuse

Lecture 11: Risk control through software verification

Lecture 12: Risk control through software validation

Lecture 13: Risk control for software maintenance

Lecture 14: Developing safety assurance cases

Lecture 15: Controlling off-the-shelf software risks

Lecture 16: Selecting software structure for safety

Lecture 17: Selecting software architecture for safety

Lecture 18: Maintaining effectiveness of controls during risk analysis, risk evaluation and risk Control

Lecture 19: Defensive programming

Lecture 20: Management responsibility

Lecture 21: FDA documentation requirements

Lecture 22: Summary

Why should you attend

You have to do risk analysis using the tools in ISO 14971. It is one of the first things FDA will ask for! It is required by law (21 CFR Section 820) and appears on regulatory submission checklists. In addition, it will help define validation that should be done to prove the safety of your actual device use. You can also eliminate costs associated with recalls and lawsuits.

For the medical device industry, there are numerous standards now in play that guide the product development cycle. The internationally recognized IEC 62304 standard prescribes the software development processes, activities, and tasks for effective medical device software development. IEC 62304 specifically calls out that the manufacturer shall apply a risk management process complying with ISO 14971. Both the FDA and IEC 62304 specify the use of ISO 14971.

Pricing List

Price for One Delegate pass Price: $1,295.00

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar Team
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