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EVENTS LIST

The Value of a Human Factors Program

Date : Feb 22, 2018 - 09:00 AM - Feb 23, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/the-value-of-a-human-factors-program-feb-2018-1516630543

Organizer : GlobalCompliancePanel

Venue : Four Points by Sheraton Los Angeles International Airport

Location : 9750, Airport Blvd
Los Angeles, CA, USA, ZIP: 90045

This seminar will explain the implementation of ISO 62366 and the regulatory expectations discussed in the 2016 FDA Guidance for a compliant human factors/ usability program.

The ISO 62366 is an "Consensus" Standard, making it a gold standard for regulatory submissions. We will look at other reference points regarding HF, like AAMI/ANSI HE75:2009 and how HF Engineering include consideration of:

1. Device Users
2. Use Environments and User Interfaces
3. Preliminary Analyses
4. Exploratory HF/Usability Evaluations
5. Hazard Mitigation and Control

We will look at the implication of HFE through Design Controls in the QSR:

- Design input -includes "needs of the user and patient"
- Design validation - "... devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis ...." [incl. use- related risks]

Why you should attend:

This year FDA published their priority list for the completion of their Guidance documentation. This FDA activity gives us inspection and enforcement insight into the priorities within the

agency. Human Factors was in the #3.

Following the implementation of the results of a Human Factors/ Usability study, a validation of the safety and effectiveness of the use of the device must be conducted. This Seminar will help to sort through the confusion of the FDA Guidance and ISO standards and help meet regulatory expectations by demystifying the tasks necessary to build a robust Risk based HF program.

Areas Covered in the Session:

- HF Planning
- Scope of Validation
- Use scenarios
- Step by step HF program development

Who will benefit:

- QA/QC Personnel
- Medical Device Manufacturing
- Software Developers
- Engineering Managers

Day 1 Schedule

This session will demystify the regulatory expectations discussed in the 2016 FDA Guidance for a compliant human factors/ usability program and the implementation of ISO 62366 Standard

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Lecture 1:

Definitions, requirements and approaches for Human Factor Engineering using ISO 62366

- Definition of Human Factor Engineering
- The importance of HFE for public health
- Main reasons for non-compliance
- Available HFE resources
- FDA's inspection and enforcement strategy for HFE
- Lessons from FDA Warning Letters and how to avoid them

Lecture 2:

Introduction to FDAs Guidance for Human Factor Engineering

- Regulatory Expectations for HFE
- Requirements for HFE

- Implementation for of HFE from FDAs Guidance
- Developing a gap analysis
- Steps for implementation a Defensible HFE program

Lecture 3:

Strategies to detect and avoid HFE issues

- Recruit, train and retain employees who will be responsible for ensuring HFE
- Preventing issues related to Human Factors
- Changing the quality culture
- Understand high risks in HFE
- Learning from internal audits and FDA inspections

Day 2 Schedule

This session will introduce you to ANSI/AAMI HE75:2009(R)2013 Human Factors Engineering-Design Specifications as they relate to medical devices and medical related software. You will walk away with a better understanding of the impact these requirements have on your product lifecycle and related product release schedule.

Lecture 4:

Definitions, requirements and approaches for Human Factor Engineering using HE-75

- User Capabilities
- Real World Demand
- Managing the Risk of Use Error
- Environmental Considerations

Lecture 5:

HFE Usability Testing

- Overview of the Standard
- User Input
- Design Priorities
- Types of Usability Testing
- Logistics
- Protocol Related Activities

Lecture 6:

HFE Labeling

- Introduction to Labeling, Symbols and Markings
- Design Guidelines

Lecture 7:

HFE Design

- Alarm Design
- Design Elements - Connectors and Connections
- Controls
- Visual Displays
- Use of Automation
- Software User Interface
- Integrated Solutions

Thomas Bento

Sr. Vice President of Regulatory & Quality Assurance , Nihon Kohden America

Thomas is a student of Quality and Regulatory Compliance and has been supporting the design, development and compliance of Medical Device Manufacturing for over 15 years. He started his career training in Software engineering and shortly moved into Commercial Software Quality. After many years of working for companies like Mitek Systems and Hewlett Packard, the decision was made to work in the regulated space of Medical Device Manufacturing, working at Edwards, Pulmonetic Systems and as a regulatory consultant for small, medium and large Medical device manufactures.

He is currently the Sr. Vice President of Quality & Regulatory Assurance at Nihon kohden America, manufacturers of Patient Monitors, Neurological and Cardiovascular devices.

Through his experience he has found that most Medical Device Manufactures feel that more is better to meeting regulatory expectations. He finds that this is the exact opposite and that manufacturers are better off by cultivating a simplified defensible approach to regulatory compliance.

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

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