Integrating Human Factors into Medical Device Design Control and Beyond

Medical Alley Association | 4150 Olson Memorial Highway | Golden Valley, MN
June 6-7, 2017

Tuesday, June 6, 2017

8:30 – 9:00 am Registration and Continental Breakfast

9:00 – 9:15 am Welcome and Introductions

Day 1 Presenters:
Michael Wiklund, PE, CHFP, General Manager, Human Factors Engineering, UL
Erin Davis, CHFP, Managing Human Factors Specialist, Human Factors Engineering, UL

9:15 – 9:45 am Introduction to Human Factors Engineering (HFE)
- Overview of human factors and design control process
- The history of human factors engineering
- Why is design control necessary?
- What are the business benefits to design control?
- What is the importance of this application to the broader society?
- Exercise: Memory Test

9:45 – 10:00 am Consequences of poor HFE and the regulatory imperative to apply HFE; driving toward improved patient safety and improved healthcare

10:00 – 10:30 am The regulatory imperative to apply HFE
- FDA requirements to apply FDA and relationship to design controls
- Presumption of conformity to IEC 62366-1
- Relationship of HFE to ISO 14971 and IEC 13485

10:30 – 10:45 am Break

10:45 – 11:00 am Group Discussion of Regulatory Challenges & Questions

11:00 – 12:00 pm The Commercial Imperative to Apply HFE
- Ensuring usability and user satisfaction
- Bringing innovative solutions to market

Overview of the HFE Process, Scaling, and Key End-Products

HFE Costs and Benefits

Important Notice
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12:00 – 12:45 pm  
Lunch

12:45 – 3:00 pm  
Models for HFE Practice  
• Who should perform HFE Activities

Value of HFE Procedures  
• Ensuring timely execution of essential and beneficial HFE activities

Defining Potential Use Errors Through Various Means  
• Exercise: Critique sample user interface (patient monitor)

Use-Related Risk  
• Use-related risk analysis  
  o Exercise: Analyze risk associated with sample use error  
• Use-related risk mitigation (design, guarding, instructions, warnings, training)  
  o Resources for designers  
  o Exemplars (case examples)

User Interface  
• Verifying the user interface  
• Introduction to user interface evaluation

3:00 – 3:15 pm  
Break

3:15 – 4:50 pm  
Formative and Summative Usability Testing  
• Exercise: Determine glucose meter use scenarios including critical tasks

Root Cause Analysis of User Interaction Problems  
• Exercise: Determine root cause of specific use errors

Determining Residual Risk

Writing an HFE Report and Completing HFE/Usability Engineering File

Keys to HFE Program Success

4:50 – 5:00 pm  
Wrap-Up/Q&A

5:00 – 6:00 pm  
Reception

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Wednesday, June 7, 2017

8:00 – 8:30 am  Continental Breakfast

Day 2 Presenters:
Elizabeth Roche, Director, Research and Strategy, Ximedica
Savannah Kyle, Human Factors Engineer, Ximedica

8:30 – 10:30 am  Integrating Human Factors Engineering into Medical Product Development - hands on interactive session
Most medical device companies know they need to make their product as usable as possible, and they probably know they need to run some usability studies on it when it’s done. But many struggle with how to design their product with usability in mind from the ground up. How should Human Factors be incorporated outside of usability studies? What tools should be used and when? How does Human Factors inform risk documentation? This workshop addresses the steps necessary to develop a truly usable product – one that fulfills regulatory expectations around safety and efficacy, and that simplifies life for end users. Without a human factors process, companies find themselves trying to evaluate the product on its usability without having designed usability into it from the beginning.

In this session participants will learn to:
• Identify the usability gaps in their HF process today
• Address the steps prior to and between usability studies
• Integrate Human Factors learnings into risk documentation
• Learn specific Human Factors methods that infuse usability into the design
• Understand the value of each method

10:30-10:45 am  Break

10:45 – 12:30 pm  Integrating Human Factors Engineering into Medical Product Development - hands on interactive session (continued)

12:30 pm  Adjournment

A special thanks to our supporters:

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