Tuesday, June 6, 2017

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

9:00 am  Welcome and Introductions

9:00 – 10:30 am  The Importance of Applying Human Factors to Design Control
Michael Wiklund, General Manager, Human Factors Engineering, Life & Health, UL
- 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?
- Regulatory and commercial imperatives to perform human factors engineering within medtech comprehensively and correctly
- Who should be involved in design and development planning?
- Design review: when and why

10:30 – 11:00 am  Break

11:00 – 12:00 pm  Design Inputs & Outputs and Verification vs. Validation
Michael Wiklund, General Manager, Human Factors Engineering, Life & Health, UL
- Definitions & what else to include
- Design verification vs. design validation
- How to perform design verification
- How to conduct effective design validation and validation usability testing
- Using root cause analysis in the design process

12:00 – 12:45 pm  Lunch

12:45 – 1:45 pm  User-Related Risk Analysis
Michael Wiklund, General Manager, Human Factors Engineering, Life & Health, UL
- Overview of ISO 14971
- Use of product and process standards in risk management
- Documentation of risk management activities
- User interface research and user interface design

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1:45 – 3:00 pm  Human Factors Engineering: How integration propels development and innovation  
*Michael Wiklund, General Manager, Human Factors Engineering, Life & Health, UL*
  - Best practices and demonstrated case studies that support the value of a truly integrated approach, covering:
    - What successful integration looks like and what it accomplishes
    - How an integrated approach improves: time to market, cost of development, regulatory approval and market adoption
  - Design of innovative and advanced devices and medical technology

3:00 – 3:15 pm  Break

3:15 – 4:00 pm  Human Factors Benefits Beyond End Users
  - Impact on clinical trials outcomes
  - Better data speed the product development
  - Competitive advantage
  - Market acceptance
  - Patient safety

4:00 – 5:00 pm  Effectively Managing Change During Development
  - User needs that dictate required functionality
  - Design issues that impact other system components

5:00 – 6:00 pm  Reception

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Wednesday, June 7, 2017

8:00 – 8:30 am    Continental Breakfast

8:30 – 10:30 am    Integrating Human Factors Engineering into Medical Product Development - hands on interactive session
Elizabeth Roche, Director, Research and Strategy, Ximedica
Savannah Kyle, Human Factors Engineer, Ximedica
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)
Elizabeth Roche, Director, Research and Strategy, Ximedica
Savannah Kyle, Human Factors Engineer, Ximedica
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:
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- 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
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12:30 pm    Adjournment

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