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IEC 62366-1:2015 USABILITY OF MEDICAL DEVICES

TRAINING FACTSHEET


Date: April 9th & 11th 2024, Online
Duration: 8 hours
2x 7:30 – 11:30 AM US Eastern Standard Time
2x 1:30 - 5:30 PM Central Europe Summer Time

Speakers:
Linda Ahnen & Serge Dubeau

About the speakers:

Linda Ahnen - *PhD, Director, Quality & Regulatory Affairs*
Linda is a physicist by training, specialized in biomedical engineering, with a strong background in research and development. At Veranex, Linda supports customers in achieving regulatory compliance, defining and executing usability and clinical strategies.

Serge Dubeau - *VP Human Factors Engineering*
Serge has 30+ years of industry experience, led design and engineering teams in a variety of projects for Fortune 100 and start-up companies, resulting in various design awards and over a dozen patents. As VP of Human Factors at Veranex, he leads the global HFE teams driving safe, effective products that meet global regulatory requirements.

TRAINING OBJECTIVES:

- Understand the basic concepts of human factors/usability engineering
- Formalize usability activities within the design process
- Perform risk management activities related to usability
- Understand formative and validation activities related to usability
- Formalize the content of the human factors/usability engineering file

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TRAINING CONTENT:

- Usability concept
- Use Specifications (intended use, users, environment, and user interface)
- Communication between users and devices
    - Use cases, task analysis, device functions, use errors
- Human factors/usability engineering process
    - Scope of usability engineering
    - Design process – V-model
    - Risk management
    - HFE/UE file

TRAINING FORMAT:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment (participants will receive a training certificate)

TO WHOM IT IS ADDRESSED:

- Managers and employees working in Quality Assurance or Regulatory Affairs departments of medical device manufacturers
- Managers and employees working in Research and Development departments of medical device manufacturers
- Anyone seeking to understand the regulatory requirements related to usability/human factors of medical devices

PRICE:

EUR 750 incl. course material and certificate

Registration: https://education-veranex.talentlms.com/
Contact: MDD-training@veranex.com