BERGO
CONSULTING · RESEARCH · TRAINING

Certificate of Participation

This is to certify that

Dr Annalisa Delnevo

completed a two-day online course on

Medical Device Usability

16 – 17 March 2021

Dr Nick Bradley
Business Manager, BERGO

Learning Outcomes

This delegate received an understanding on how to:

- Achieve compliance with IEC 62366-1: 2015 and the FDA's guidance on human factors
- Use design guidance in ANSI/AAMI HE75: 2009
- Conduct techniques including Hierarchical Task Analysis (HTA), Use Risk Analysis, Cognitive Walkthrough and Heuristic Evaluation
- Manage the risk of use error
- Develop testable requirements and objectives for usability and human factors
- Design and run formative evaluations and a summative evaluation (human factors validation test)
- Develop a usability engineering process
- Document usability activities in a Usability Engineering File and HFE/UE report for the FDA

Programme

1. Introduction to Usability Engineering

- What is Meant by Usability?
- Legal Framework for Manufacturers
- Overview of Usability Engineering Process

Discussion: Experiences and Challenges

2. Usability Techniques

- Design Guidance in ANSI/AAMI HE75
- User Research Techniques
- User Interface Design Techniques

Workshop: Hierarchical Task Analysis

3. Managing the Risk of Use Error

- Why do Use Errors occur?
- Case Studies Involving Use Error
- Techniques to Manage Use Error

Workshop: Use Error Risk Analysis

4. Usability Evaluation

- Formative Evaluation
- Summative Evaluation

Workshop: Cognitive Walkthrough

5. Usability Documentation & Integration

- The Usability Engineering File and HFE Report
- Developing a Usability Engineering Process

Discussion: Next steps and Challenges