FiHTA
Healthtech Finland

USBIMED
Usability and safety for medical devices

FiHTA & USBIMED COURSE:

Ensure Competitiveness & Safety of Your Medical Device

Medical Device Usability and Relevant Standards

TRAINER:

Edmond W. Israelski PhD, CHFP,
Director – Human Factors, AbbVie

Tuesday 26.8.2014 | Teollisuuskeskus, Auditorium (2nd floor) |
Eteläranta 10, 00130 Helsinki
NOTE: Participation partly through webinar also possible.

Designed to meet the collected expectations and needs of medical device companies:

To reach the competitive advantage in design and development efficiency, we'll discuss e.g.
How to exceed the expectations and gain competitive advantage through usability engineering? What are the major challenges companies have faced in relation to usability and meeting the requirements? Useful usability engineering methodologies ? Key deviations in requirements in different markets/countries? How usability engineering file is inspected by notified body or FDA ?

To tackle the concrete questions on relevant standards, we'll discuss e.g.
IEC 60601-1-6, IEC 62366, AAMI/HE75 and FDA updates – what is changing, what is not? Understanding the role and relevance of the variety of different standards and guidelines? FDA requirements vs. IEC 62366 standard? Usability Engineering File -User centered design process and how to implement it in practice so that requirements are fulfilled? Defining the scope and right balance of usability engineering process to a certain project? Risk analysis, verification and validation in usability engineering? Tips & best practices?

Bio of Ed Israelski in Nutshell
· CURRENT · director of human factors (HF) at AbbVie since 2001 · leads a cross-company team to imbed best-practice Human Factors Engineering (HFE) design methods to ensure safety and usability · does this through hands-on design and evaluation, management, resourcing, training, policies, and guidelines · convener for IEC and ISO ergonomic groups in developing international HF medical devices standards · certified HF professional CHFP · has authored fifteen book chapters and numerous articles in the area of HF · holds thirty patents · fellow of the Human Factors and Ergonomics Society · selected by MDDI magazine as one of the 100 Notable People in the Medical Device industry in 2008 · on the editorial board for the journal Human Factors and a regular reviewer for several other scientific journals · chief technology officer at Human Factors International, a user interface design and consulting firm in information technology · adjunct instructor at Northwestern Univ and Virginia Tech · PAST · co-chair of the AAMI HFE committee for medical devices · member of the National Academy of Sciences Committee on Human-System Design Support for Changing Technology · juror for the MDEA Medical Design Excellence Awards · has worked as a systems engineer, product manager, market researcher, industrial/organizational psychologist as well as a HF engineer · technical manager of the HF systems group at Lucent Technologies - Bell Labs, formerly AT&T · director of HF for telecommunications products at SBC/Ameritech · adjunct instructor at New Jersey Institute of Technology.
· EDUCATION · B.S. in electrical engineering from NJIT · M.S. in operations research from Columbia University · Ph.D. in industrial and engineering psychology from Stevens Institute of Technology.

COURSE PROGRAM

09:00	**Registration & Coffee**
09:30 Webinar starts	**Welcoming words**, *Tom Ståhlberg, FiHTA - Healthtech Finland*
09:45	**Designing usable medical devices (60 min)** • Why to invest in usability - business, clinical and safety implications • Usability engineering definitions • Common methods and procedures overview o Contextual Inquiry o Risk Analysis o User Interface Specification o Iterative Design o Formative Evaluations o Summative Usability Testing • Medical device applications and examples
10:45	**IEC 60601-1-6 and IEC 62366 - Part I (60 min)** • IEC 60601-1-6 and IEC 62366 - What do they say? • Key Clauses - Primary operating functions o Usability Specifications o Usability Verification o Usability Validation Plan o Relation to ISO 14971
11:45	**Lunch break (75 min)**
13:15	**IEC 60601-1-6 and IEC 62366 - Part II (30 min)**
13:45	**Other HFE/Usability Standards (90 min)** • AAMI HE-75, AAMI TIR 50, AAMI TIR 59 • Symbols, Alarms and Home Device Standards • FDA guidance from CDRH and CDER
15:15 Webinar ends	**Coffee break**
15:45	**Workshop / practical examples:** Illustrate conformance to specific testable usability requirements in IEC 62366 (60 min) • Primary operating functions • Usability specifications • Usability validation
16:45	**Wrap up and future perspective**
17:15	**Discussion and concluding remarks**, *Tom Ståhlberg, FiHTA*
17:30	**Adjourn**

Course fee: Members of FiHTA, Swedish Medtech, Medicoindustrien & LFH: 450€. For non-members: 540€. VAT 24% shall be added to the fee. Ask for group discounts. **Webinar fee:** Members 310€ & Non-members 420€. VAT 24% shall be added. Non-refundable payment required in advance, latest by Aug 24th. **Cancellation policy:** Cancellation of registration prior to the commencement of the event: 14 days or less, 50 %. If no cancellation, full fee. **To register latest by Aug 12th and for more information visit:** www.fihta.fi.