



PRESAFE COURSE - USABILITY EN IEC 62366-1:2015

Background	Usability engineering was requested when the MDD (93/42/EEC) was released. Over the years there have been updates and changes in the standard as well as in the interpretation and industry practice. This course will give the overview of the standard, the process and the tools. Expectations from Notified Bodies will also be discussed as well as authorities' expectations. The process interface and the resource needs will be part of the course. A workshop will give guidance on user risk analysis. The guidance TR62366-2:2016 will also be covered.
Goal	To give a basic understanding and provide some tools on how to run the usability engineering process
Who benefits	Design and development engineers, QA/RA specialists, risk managers, customer support/service, clinical support, marketing, contract manufacturer and component manufacturer as applicable.
Course leader	Anette Sjögren, PREVENTIA AB Anette is a member of the Swedish (TK355 – ISO 13485, ISO 14971 and IEC 62366) and the international technical (TC210) committee and was also part of the international PMS task force.
Language	Course material is in English. Presentation in English or Swedish (depending on the participants).
Time & place	03 October 2017. Registration at 08:45 and program from 09:00 – 16:30. Tuborg Parkvej 8, 2900 Hellerup (Copenhagen, DK).
Price	DKK 5,900 + VAT.
Course material	Powerpoint handouts and certificate of participation.
Program	
Day 1	<p>Introduction to IEC 62366-1</p> <ul style="list-style-type: none"> • Background and regulatory requests • The usability engineering process • Process interfaces and organization requirements <p>User risk analysis and evaluation plan</p> <ul style="list-style-type: none"> • Risk analysis from user view • Output – risk analysis gives input to the usability studies • Presentation work shop <p>Discussion and questions</p>

Presafe Denmark A/S, Tuborg Parkvej 8, 2900 Hellerup, Denmark
 Telephone: +45 39 45 49 99
 Website: www.presafe.dk
 E-mail: presafedk@presafe.com
 CVR no.: 34080771