



PRESAFE COURSE - RISK MANAGEMENT ISO 14971:2012

Background	Risk management 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 risk analysis.
Goal	To give a basic understanding and give some tools on how to run and benefit from the risk management process.
Who benefits	Management, design and development engineers, QA/RA specialists, risk managers, customer support/service, clinical support and 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	04 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.

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Day 1	<p>Introduction to the ISO 14971</p> <ul style="list-style-type: none">• Background and regulatory requests• The risk management process<ul style="list-style-type: none">o Risk Management Plan (RMP)o Acceptance criteriao Risk Analysiso Risk Management Report• Process interfaces and organization requirements <p>Risk analysis</p> <ul style="list-style-type: none">• What kind of risk analysis and technique?• Work shop RMP and risk analysis• Presentation work shop <p>Discussion and questions</p>
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