

Presafe Course - medical device regulation

Background	The medical device directive (MDD) has been in force since 1996 and it is mandatory to comply with it to CE mark products in the EU. There has been an amendment in 2007 (2007/47/EC) and today there are new regulations on their way to replace the directive – the MDR. The new regulation is based on the MDD, the guidance documents to the MDD (MEDDEV) and also some new and changed parts are coming.
Goal	To give a good introduction of the MDR as preparation of what is coming soon.
Who benefits	Management, 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	26-27 September 2017. Registration at 08:45 and program from 09:00 – 16:30 both days. Tuborg Parkvej 8, 2900 Hellerup (Copenhagen, DK).
Price	DKK 10,900 + VAT.
Course material	Powerpoint handouts and certificate of participation.
Program	
Day 1	**Background and introduction** **Chapter I – Chapter VII**
Day 2	**Chapter VIII – Chapter X** **Annexes I – XVI** **Discussion about the new regulation**

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