

Presafe Course - Post Market Surveillance

Background	During the last years the request and requirements on PMS has increased and more is in the ISO 13485:2016 and the new Medical Device Regulation. This half day course will give an introduction to the regulations and guidance on PMS (plan and report) as well as the process interfaces..
Goal	To give an understanding of the PMS process, which is a life cycle approach for your medical device(s).
Who benefits	Management, clinical affairs, design & development engineers, QA/RA specialists, risk managers, customer support/service and marketing.
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	05 October 2017. 13:30 - 17:00 Tuborg Parkvej 8, 2900 Hellerup (Copenhagen, DK).
Price	DKK 3,000 + VAT.
Course material	Powerpoint handouts and certificate of participation.

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