

Presafe Course - ISO 13485:2016

Background	During the last five years work has been ongoing with the revision of the ISO 13485:2003. In March 2016 the new edition was published. Industry must now prepare for the new edition and find out what GAPs there are towards current quality management system. There is ongoing work with a handbook, a guidance document, replacing the TR 14969. The handbook will be covered as well.
Goal	To give an understanding of the full standard. You should be qualified as internal auditor in ISO 13485 after the course.
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	28-29 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.

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

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Day 1	**Introduction and background** **Quality Management System** • General requirements • Documentation requirements • Quality Manual • Medical Device File • Control of documents and records • Handbook guidance **Management Responsibility** • Commitment • Policy and objectives • Planning • Organization • Management review • Handbook guidance **Management of resources** • Provision of resources • Human resources • Work environment • Handbook guidance • Clean room guidance
Day 2	**Product Realization** • Design and development • Risk management • Process validation • Purchasing • Production • Handbook guidance • Process validation example • Risk analysis template **Measurement, analysis and improvement** • Customer feedback • Complaint • Internal audit • Monitoring product and process • Non-conformity • CAPA process • Handbook guidance • CAPA process guidance and then examination