Learning Goal

The learning goal of the course is that participants be able to complete a medical device risk management file.

The course has a strong focus on how to work with risk management as opposed to only covering principles and requirements from the risk management standard.

Program

Day 1 08:45-12:00 12:40-16:45	Day 2 08:45-12:00 12:40-16:45
Introduction Why risk management? The regulatory framework Introduction and the general requirements of risk management Risk management tools incl. FMEA, P-FMEA and FTA Annex Z Risk analysis	Risk evaluation Risk control Overall residual risk evaluation Risk management report Production and post-production information The most common mistakes and how to avoid them Using spreadsheets to document risk management

Risk Management for Medical Devices and ISO 14971

Peter Sebelius, Founder & CEO Gantus AB

Peter Sebelius (PMP) has a vast experience as manager in the medical device industry and is an esteemed trainer.
He is an expert member of standard committees ISO/TC 210/JWG 1 Application of risk management to medical devices, ISO/TC 210/JWG 3 Medical device usability and ISO/TC 210/WG 1 Application of quality systems to medical devices.

Among the many awards that he has received is the Great Design Award and the title “This year’s specialist 2009” by Veckans affärer.

Format

The course consists of:

- Lectures
- Workshops, and
- interactive check-points.

The instructor will follow up on learning objectives throughout the course, meaning that participants continuously will have to answer questions on the topics covered to ensure that the objectives are met.

Templates for key documents relating to risk management is included in the course.

The course will be conducted in English.

The current course receives on average grade of 4.8 of 5.

Free 30 minute introductory course to RM is available at http://gantus.com/iso14971