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Course Unannounced Audits

Course Description	This course is designed to provide participants with an understanding of the risk classification criteria for medical devices of the EU Medical Devices Directives, to prepare medical device organizations to unannounced audits.
Learning Objectives	Gain an understanding of the reclassification of new and/or existing medical devices according to the classification criteria of EU Medical Devices Directives. The course will provide the tools to medical device organizations to undergo unannounced audits
Course Benefits	At the end of the course participants will be able to: • classify their devices • Prepare a plan to implement activities aimed at taking unannounced audits
Intended Audience	• The course is especially designed for medical device manufacturers and all the personnel involved in design and classification of medical devices (QA, DD, RA etc.) • All those that are involved in the unannounced audits (AQ,RA,etc.) • Regulatory, quality, design, development, manufacturing, marketing managers and personnel.
Course Duration	0,5 day
Prerequisites	Participants should have experience with or basic knowledge of quality management systems for the medical device industry. Recommended is a basic awareness of medical devices, quality assurance, and ISO 13485
Further information	• A certificate of attendance will be issued • Each participant will receive a copy of the didactic material • This course can be delivered as in-company training, customized for specific organisations and their circumstances.