Medical Device Risk Management Seminar

Syllabus, Rev.3

Course Overview:

One-day seminar, 09:30-15:30 | 8 academic hours

The aim of this seminar is to provide concise but complete knowledge and skills required for medical device risk management, according to ISO14971:2019

Risk Management Training	**Session Kick-Off**	• Welcome & introductions
	Risk Management per ISO 14971:2019 Introduction	• ISO 14971:2019 Introduction: Overview, Terms and Process • General Requirements for Risk Management • Risk Management Process overview
	Risk Management Process	• Management Responsibilities and competence of personal • Risk management plan • Risk Analysis, Risk Evaluation, Risk Control • Evaluation of overall residual risk acceptability • Risk management review • Production and post-production activities
	Risk Management in Medical Device - Case Studies	• Case Studies and Exercise • Identify the links between ISO 14971:2019 and MDR 2017/745
	Risk Management in Medical Device Software	• Software Risk Management • Software risk control vs Risk controls implemented by software
	Risk Management Tools	• Techniques that support risk analysis Risk Analysis Tools Examples: Appendix B • dFMEA, pFMEA etc.; Risk Management vs FMEA • FTA – Fault Tree Analysis • ISO 14971:2019 - Medical devices — Application of risk management to medical devices 3rd edition – changes from ISO 14971:2007 (2012) • Overview of ISO 14971 :2019 Changes • Risk History and legal requirements reference between QMS risk Management, EU MDR, and ISO 14971 • V&V tests as risk control measures
	Session Wrap-Up	• Course review & questions • Reflection & feedback