Medical Device Risk Management Training Seminar

Syllabus, Rev.2

To promote your professional development, you'll also receive Gstudy Training certificate

Risk Management Training	
Module	Topics
Risk Management per ISO 14971:2019 Introduction	• Risk History and legal requirements reference between QMS risk Management, EU MDR, and ISO 14971 • 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 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 • TR 24971:2019
Risk Management in Medical Device - Case Studies	• Case Studies and Exercise • Identify the links between ISO 14971:2019 and MDR 2017/745
Session Wrap-Up	• Feedback

** Total of 8 academic hours.*