Course Title: Introduction to ISO 14971:2019 Risk Management for Medical Devices Training Course

Course Duration: 2 Days (9.30 am - 4.30 pm)

Pricing: € 595.00 per person

Format: Live - virtual.

Queries: info@thelearningreservoir.com

Course Details	
Course Description	This two-day course is designed to provide participants with a comprehensive understanding of ISO 14971:2019, the international standard for risk management of medical devices. The course will cover the essential principles, concepts, and requirements of the standard, and provide practical guidance on how to apply them in real-world situations. ISO 14971:2019, provides the processes for identifying, evaluating, and mitigating hazards associated with the use of medical devices. While not mandatory, it is the most commonly used, industry-recognized standard to demonstrate conformity to when addressing product safety requirements.
Standards used in Course	ISO 14971:2019 Medical devices — Application of risk management to medical devices
Delivery Method	Taught live by an expert tutor via Zoom. You can interact with other delegates and ask questions, just as you would in a traditional classroom.
Instructor	Dr. Fiona Masterson With over 25 years' experience in quality management, operations management, and higher education, Fiona combines technical expertise with highly engaging training. She has worked in fast-paced manufacturing environments including medical device companies, and lectures part-time in universities. She is a lead quality auditor and has extensive experience in auditing risk management systems. She has Bachelor and Master of Science degrees, and a Doctorate in Mechanical Engineering. Fiona has published in peer reviewed journals on topics such as medical device and pharmaceutical regulatory affairs, on-the job training and innovative training technologies and strategies.

Learning Objectives	On completion of this training, participants will be able to: • Understand the purpose and scope of ISO 14971 standard for Risk Management of Medical Devices. • Identify the regulatory requirements for risk management in the medical device industry. • Analyse hazards associated with medical devices and estimate the risks involved in their use. • Evaluate the risks associated with medical devices and determine the acceptability of these risks. • Develop and implement effective risk control measures for medical devices. • Create a comprehensive risk management plan, risk management file, and risk management report. • Review and update risk management documentation as part of a post-market surveillance program. • Apply the principles of risk management to real-life case studies and examples in the medical device industry. • Understand the importance of risk management in ensuring patient safety and compliance with regulatory requirements. • Familiarize themselves with the guidance document, ISO TR 24971:2020, and its relationship to ISO 14971:2019. • Understand the relationship between ISO 14971 and other key regulatory standards and requirements for medical devices, including ISO 13485, 21CFR820, MDSAP, EU MDR and IVDR. • Explain how ISO 14971 fits into the overall regulatory landscape for medical devices, including its role in supporting compliance with other standards and regulations.
Who should take this course	The course is designed for professionals working in the medical device industry, including product managers, engineers, quality assurance personnel, regulatory affairs professionals, and others who are involved in the design, development, and manufacturing of medical devices. The course is also beneficial for individuals who are seeking to enhance their knowledge and understanding of the ISO 14971 standard and its application in the medical device industry.
Course Certificate	A certificate of completion will be issued on successful course completion.
Materials	Each participant will receive course materials in the days prior to the course starting. Please ensure you have access to these on the day.

Course Content Breakdown	
Day 1	• Introduction to ISO 14971:2019: • Definition of Risk Management for Medical Devices • Regulatory Requirements for Risk Management • Overview of the ISO 14971 Standard • Scope of the standard • Terms and definitions • Key Changes in the 2019 Revision • The guidance document, ISO TR 24971:2020, relationship to ISO 14971:2019. • General Requirements for Risk Management • Risk Analysis • Risk Analysis Tools • Risk Evaluation Throughout the day there will be case studies, and exercises to reinforce learning and provide opportunities for participants to apply the concepts and techniques covered in the course.
Day 2	• Risk Control • Evaluation of overall Residual risk • Risk management Review • Production and post-production information. • The relationship between ISO 14971 and other key regulatory standards and requirements for medical devices, including ISO 13485, 21CFR820, MDSAP, and EU MDR. • Best practices for integrating Risk Management into Quality Management Systems Throughout the day there will be case studies, and exercises to reinforce learning and provide opportunities for participants to apply the concepts and techniques covered in the course.