

ISO 14971 Risk Management for the Medical Devices Industry Training Course

What is it?

ISO 14971 is a state-of-the-art, international standard that is quickly being recognized as one of the best processes to ensure that all aspects of risk management are considered throughout the product lifecycle for medical devices.

ISO 14971 for the application of risk management is designed to help manufacturers introduce safe medical devices into the market place.



Why do I need it?

The manufacturer is responsible for identifying and controlling not only the risks associated with their medical device, but evaluating interactions with other devices. The standard recognizes that even though medical devices are never without some level of risk, manufacturers still need a structured discipline to ensure that product benefits outweigh the risk, and that all risks have been reduced to an acceptable level. In addition it provides an excellent risk management model that focuses on entire life cycle of the medical device.

How will I benefit?

BSI's "ISO 14971:2007" training course is designed to provide participants with an in-depth understanding of the impact that ISO 14971:2007 has on the decision making process at medical device manufacturing firms. This training course helps medical device professionals gain an understanding of how ISO 14971:2007 can improve their business and risk management efforts. Participants will also understand how ISO 14971:2007 and ISO 14971:2001 apply to ISO 13485:2003.

What will I learn?

Upon completion of course, you will gain an understanding of the role of risk management in the medical devices industry, the basics of risk management, and be able to interpret and apply the clauses of ISO 14971 to ISO 13485. In addition, you will also learn about the impact of ISO 14971 implementation on the medical devices industry, and the importance of management involvement throughout the implementation process.

You can now download our course schedule by visiting www.bsigroup.sg/training or call us at **+65 6270 0777** today

How will I learn?

Quickly. We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context.

The training includes exercises, and participants will have the chance to ask questions about how ISO 14971:2007 and risk management apply to their organizations. Particular focus is on the changes to the 2007 version and how the changes impact the risk management process.

Your tutors are the best in their field and will make sure your learning needs are met. You can choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Any prerequisite for the course?

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 13485:2003.

Who are we?

As the world's first National Standards body, our expertise in shaping business standards spans more than a century. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries world-wide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

What our customers say

"Excellent course and I have some great tools and ideas to take back with me. Thank you."

"I felt I was learning from the tutor's expertise while using new skills to think and apply answers."

"The course was extremely well delivered and catered for all levels of knowledge and experience within the group."

Where will I learn?

You won't have to travel far to our first class venues. Our training venue is conveniently located in the Central Business District at AIA Tower, and is within a 5 minutes walk from the Raffles Place MRT.

Next step

To book this course, call one of our dedicated training experts at **+65 6270 0777** or download our course schedule at **www.bsigroup.sg/training**

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