

APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES

Course Outline

2-day course

Meddev Solutions Limited are delighted to offer a 2 day in-depth interactive overview of the application of Risk Management to Medical Devices. It focuses on the application of various risk management tools to meet the requirements of the harmonised standard BS EN ISO 14971:2012.

The current law, Medical devices directive 93/42/EC requires implementation of the state of the art, implementation of the harmonised standard provides presumption of conformity. This course goes further and compares BS EN ISO 14971:2012 with the requirements of Regulation (EU) 2017/745, the new Medical device regulation.

BS EN ISO 13485:2016 requires medical device manufacturers to implement a Quality Management System that has a greater emphasis on risk. This course for medical device manufacturers has been developed to meet this more rigorous focus on risk management.

Learning objectives include:

- Enhance understanding of risk management, utilize the tools for effective risk management and risk requirements of ISO 14971:2012.

Course overview:

- Introduction to ISO 14971:2012
- Regulation and the Z-Annexes
- The procedure and plan
- FMEAs and fault trees
- Application to ISO 13485

Relationship with other standards:

- The 60601/61010 series
- Usability (EN 62366)
- Biocompatibility (ISO 10993)

Upon successful completion of the course, each delegate will receive a Meddev Training course certificate and detailed course notes.

Purpose built teaching facility



This course is hosted at 3form Design:
The Chapel, 58 London Street, Whitchurch, RG28 7LN

Who should attend:

The content will have great value to individuals who are involved in any aspect of implementing or maintaining a QMS.

- Quality assurance professionals
- Quality Engineers
- Research and design Engineers
- Internal Auditors
- Quality Managers
- Manufacturing Engineers
- Regulatory professionals

Find out more:

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