TRAINING
COURSES

Risk Management using ISO 14971:2019

This one-day course is designed to give delegates a fundamental understanding of risk management as it relates to medical device development and the associated regulations.

It includes content related to:

- **Risk management systems**
- **Benefit-Risk Evaluation**
- **Risk acceptability criteria and state-of-the-art**
- **ISO 14971:2019/BS EN ISO 14971:2019 in practice**
- **Risk assessment tools & techniques**
- **Failure Mode Effect Analysis in Action (FMEA)**
- **Risk control strategies and reporting**
- **The risk management life cycle**

Adherence to the harmonised standard ISO 14971:2019 ensures that regulatory requirements associated with risk management are met.

The course is delivered by our Director of Quality and Regulatory Affairs, Dr Edward Staunton, an IRCA Certified Lead Auditor who has trained numerous internal auditors, notified body auditors and lead auditors.

Personalised feedback is available for evaluation of training effectiveness if requested.

This course is available at your offices/facilities by arrangement.

For further details or to arrange a quote for training contact:

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