MDTI

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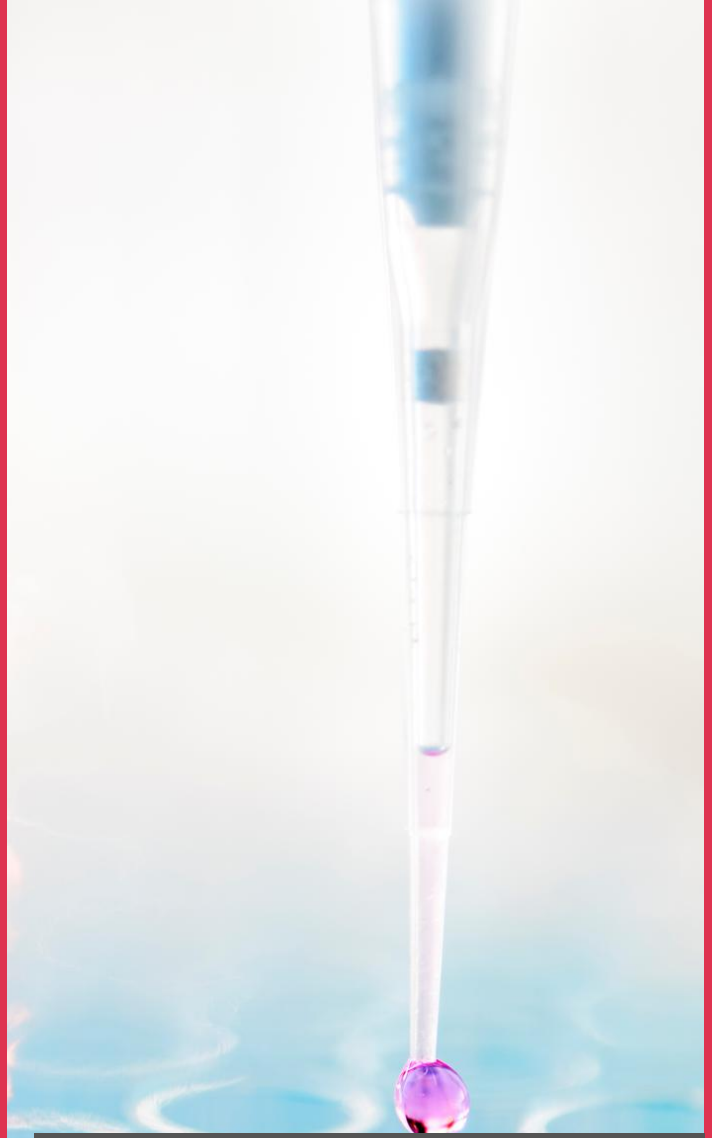
Medical Device Risk Management

9 - 12 November 2020

LIVE Online Academy

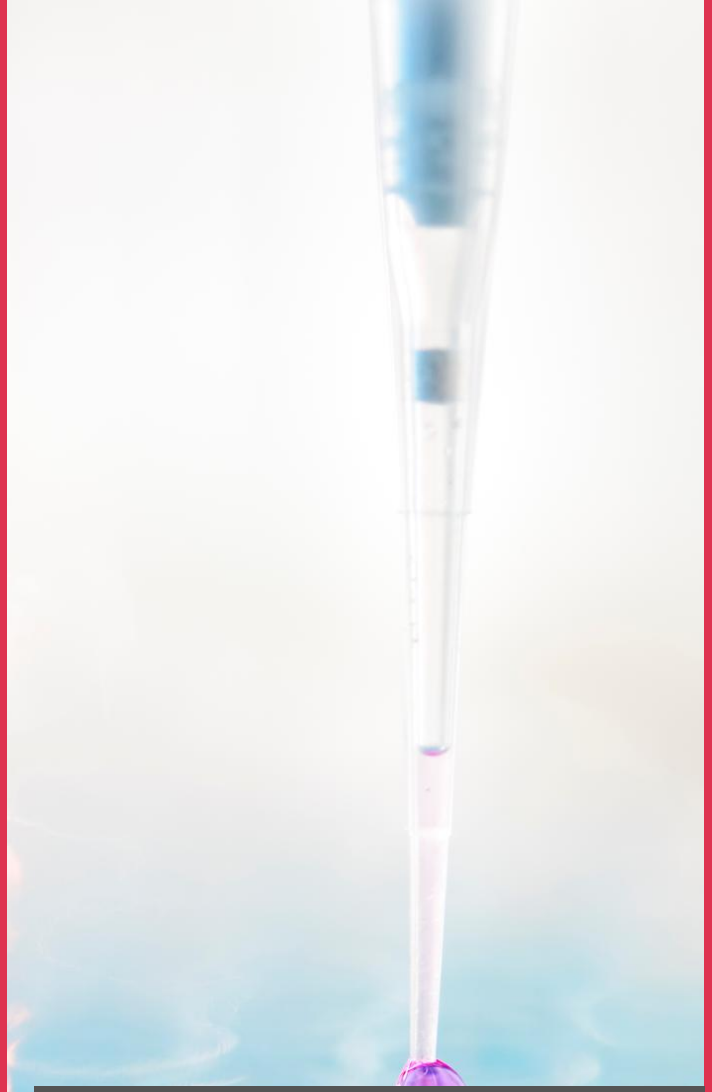


COURSE OVERVIEW

Risk Management is an important but difficult concept for lots of industries, but is particularly important within the medical field and hence within medical devices. In such a hazard-rich industry, risk must be considered from the beginning to the very end of a product lifecycle. Implementing risk has never been more challenging, as recent regulatory changes have made it problematic to harmonize risk management processes in product lifecycles. Therefore, it is imperative to understand how to coordinate an effective risk management strategy.

This interactive course offers a comprehensive overview of the regulatory requirements for risk management and provides an insight into a variety of tools and techniques to implement them into your own systems. Attendees will be provided with an in-depth outlook on ISO 14971:2019 and its overlap with ISO 13485:2016 and the new MDR, alongside gaining an informed insight into the intricacies of risk management planning. Overall, attendees will expect to be taken through the risk management process from start to finish.

Attendees will be able to cement this knowledge through case studies and practical exercises, with additional time on the course provided to discuss the implications of Brexit



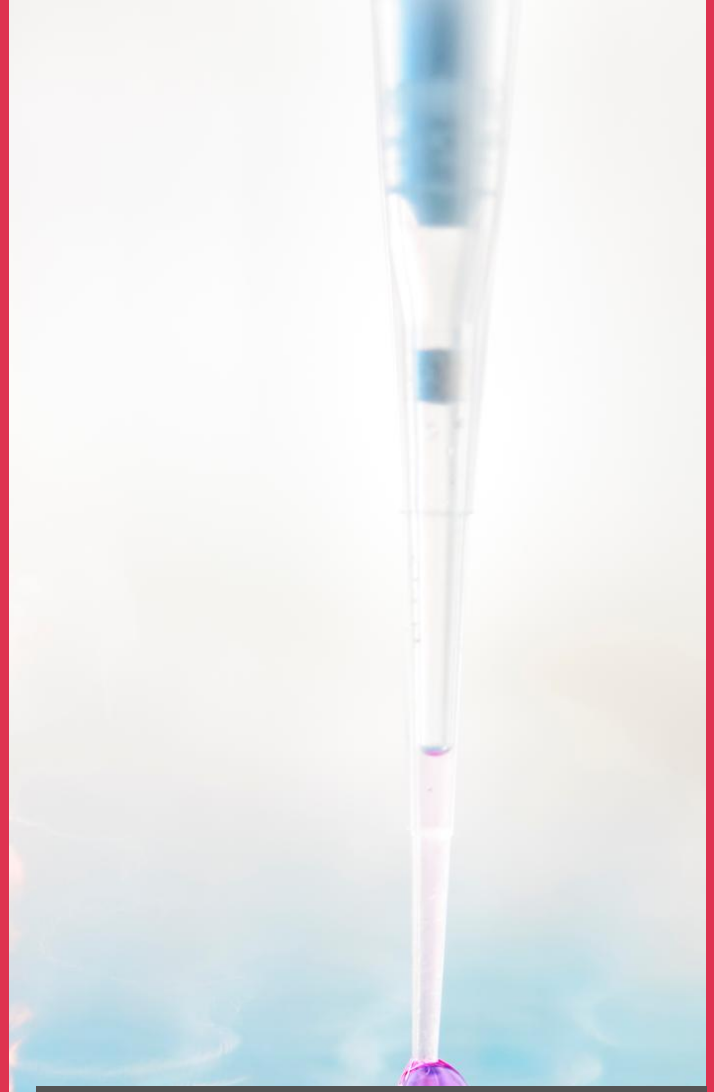
LIVE ONLINE COURSES

Gain real time access to a subject matter expert delivering online training in a structured virtual classroom environment.

What is a Live Online Course?

Live online courses are a new interactive and engaging education tool designed to provide training in real time with access to a subject matter expert (trainer). By using webinar technology, a virtual classroom is created providing direct contact with the trainer so you can ask questions, clarify complicated theories and fully understand the topicarea.

A live online course is broken down into manageable sessions that are delivered online at set times, providing a structured learning pathway for delegates. All sessions are recorded and uploaded to our virtual learning environment where you will have unlimited access to the materials for a month.



LIVE ONLINE COURSES

What are the benefits of studying a live online course?

- **Engagement & interaction**

All learning content is delivered in real time with our expert faculty, enabling you to have direct contact with the trainer during each session via live Q&A.

- **Structure & convenience**

Bitesize sessions are delivered at set times meaning there is minimal disruption on your day to day function.

- **Cost-effectiveness & accessibility**

No travel or accommodation costs required for your team to attend training. The course can be studied from any location, all that you need is an internet connection.

- **Speed & flexibility**

Live online courses are fast to organise and deliver meaning your team cam be upskilled quickly. Revisit materials as often as you like for a month after the course, as everything is recorded and hosted on our virtual learning environment.

MEET THE TRAINER

RICHARD YOUNG

Richard Young has over 20 years' experience in the medical device industry with products such as class 3 implants to electromedical infusion systems.

Richard has extensive experience in regulatory affairs, GMP (quality), GLP (laboratory testing) and clinical affairs. Richard has held various positions within industry such as QA/RA Manager and Director Quality Assurance and Regulatory Compliance at various companies including Biomet, Plasma Surgical and Zimmer Limited.

Agenda: Session 1

9 November 2020: 2pm - 4pm GMT

Overview of Risk Requirements of the Medical Device Regulation

- Manufacturers responsibilities
- Risk management and compliance with EUMDR, IVDR Annex 1 general safety & performance requirements
    - Detailed review of relevant articles and clauses
    - Relevance to combination products and pharmaceutical regulation
- Risk management and the design control process
- Discussion on future challenges and changes
- Harmonization of terminology and definitions
- Risk management concepts and considerations
- Examples of the different types of risks captured in the risk management process
- Establishing a risk management file ISO14971:2019
- Product risk and process risk (ISO 13485:2016)

Agenda: Session 2

10 November 2020: 2pm - 4pm GMT

The new ISO14971 standard

Overview of ISO 14971:2019 standard

- Essential definitions and terms
- Basic concepts
- Process Inputs
- Critical Process Outputs

The stages of risk management

- Risk management planning:
- Traceability of risks
- Top-down: hazard and harm identification TIR24971:2020
- Bottom-up: risk analysis (severities and probabilities)
- Risk evaluation
- Risk control and mitigation
- Benefit vs. risk analysis
- Residual risks
- Consequential risks
- Risk management report

Agenda: Session 3

11 November 2020: 2pm - 4pm GMT

Process Inputs

Usability engineering – ISO EN 62366 1 & 2 2015

- Critical process inputs
- Human Factors considerations
- History
- Perception
- Rationalisation
- The use of Instructions for Use
- Applying as a critical Risk Management Input
- Validation of Human Factors Considerations
- User interfaces
- Alarms
- Measurements
- Techniques
- Refusal to accept policies

Clinical evidence

- Clinical evaluation – when is a clinical investigation needed?
- Production and post-production requirements as part of ongoing PMS and vigilance activities
- Continued state of the art considerations?

Agenda: Session 4

12 November 2020: 2pm - 4pm GMT

Risk Lifecycle and wider management

Ongoing risk management in an ISO13485 system

- ISO 14971 and ISO 13485:2016
- Management review
  - Metrics
- Post production / post-market feedback

Quality management system and regulatory requirements

- Overview of ISO 13485:2016
  - How does this fit into my system?
- Recording, documenting and risk assessing processes in a QMS, principals of document control
  - EUMDR Annex II and technical documentation

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Register Now >>

For information or to book a course please contact our Training Consultants

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