# MPD Training Course: Risk Management

AGENDA

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|---|---|
| 9.30 | Introductions & housekeeping |
| 9.45 | Overview, Why Risk Management? |
| 9.55 | What is Risk Management all about? |
| 10.25 | Why Manage Risks in Medical Devices |
| 10.40 | How do we Process Information |
| 11.00 | Refreshment break |
| 11.15 | Processing Information cont. |
| 11.35 | Human Error and the Performance Continuum |
| 12.00 | Lunch & Networking |
| 12.40 | Risk Assessment and the Standards |
| 13.40 | ISO14971 |
| 14.10 | The FDA and Risk Management |
| 14.20 | Risk Assessment Techniques |
| 14.30 | Risk Benefit Analysis |
| 15.10 | Refreshment Break |
| 15.20 | Workshop Session: Reviewing Risk Benefit and Risk Management Reports |
| 16.20 | An Overview of the Day - Q&A Session |
| 16.30 | Event Close |

# DID YOU KNOW?

**The concepts of risk management are particularly important in relation to medical devices because of the variety of stakeholders, including; medical practitioners, the organisations providing health care, governments, industry, patients and members of the public.**

Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and its severity. It is accepted that the concept of risk has two components:

- The probability of occurrence of harm

- The consequences of that harm, that is, how severe it might be.

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