

## 1.3 Quality Management Systems and Conformity Assessment Procedures

1.3 Quality Management Systems and Conformity Assessment Procedures module forms part of the 1.0 Medical Technology Regulation and Clinical Activities course and fosters these procedures.

### The Medical Technology Industry

The Australian medical technology industry includes Australian and overseas companies manufacturing and supplying medical devices, in-vitro diagnostics and medical imaging equipment. The medical technology industry makes a highly significant contribution to the quality of health care in Australia.

### What is the Medical Technology Regulation and Clinical Activities course?

The regulation of medical technology in Australia is similar, in principle, to that adopted in the European Union. However, there are differences. The Therapeutic Goods Administration (TGA) regulates the supply of therapeutic goods including medical technology. Before a sponsor can supply items of medical technology in Australia, the TGA must grant approval and enter the product in the Australian Register of Therapeutic Goods (ARTG).

The *Medical Technology Regulation and Clinical Activities* course consists of a series of modules to assist employees working in the regulatory and clinical areas.

- 1.1 Introduction to the Regulation of Medical Technology in Australia
- 1.2 Advanced Review of the Regulation of Medical Technology in Australia
- 1.3 Quality Management Systems and Conformity Assessment Procedures
- 1.4 Developing Technical Documentation for Medical Technology
- 1.5 Understanding Clinical Evidence for Medical Technology
- 1.6 Risk Analysis and the Development of Medical Technology
- 1.7 Risk Management for Medical Technology Companies from a Regulatory Perspective
- 1.8 Introduction to the Regulation and Design of Clinical Investigations for Medical Technology in Australia
- 1.9 Improving Your Clinical Investigations for Medical Technology
- 1.10 Biohazards and Sterilisation

For further information about MTAA courses, please contact the Professional Development Manager on (02) 9900 0650 or email [pd@mtaa.org.au](mailto:pd@mtaa.org.au)

### What topics are covered in the QMS and CA module?

This module explores QMS and CA procedures.

#### Learning outcomes

##### Part 1: QMS for Medical Technology

- Learns about the use and application of the ISO 13485:2003 quality management system.
- Understands how the system relates to design, development, testing, manufacture and supply.
- Understands why a quality management system does not have to be applied to the manufacture of Class I medical devices.

##### Part 2: Conformity Assessment Procedures

- Learns why conformity assessment procedures have to be used by all manufacturers of medical technology.
- Understands conformity assessment procedures.
- Gains insight into the auditing and certification processes used by the TGA.

### Who should attend?

Sponsors and manufacturers of all medical devices, and especially those involved with Class IIa, IIb, III and Active Implantable Medical Devices should attend the training. Module 1.2 or equivalent industry experience are the recommended pre-requisites for this Level 1 module.

### How much does it cost?

The cost of this one day module including GST is \$950 for members and \$1500 for non-members. Once payment is accepted, applicants will be registered.

### How do I register?

All registrations to MTAA training modules are via the website. For this course, places will be offered to those that register an interest to attend a module. The city location of the training will be dependent on where the majority of those that have expressed an interest are based. Please visit *Training* under *Professional Development* on the MTAA website [www.mtaa.org.au](http://www.mtaa.org.au) to access course information and register your interest.

Following full registration, participants will be forwarded a program. Participants will receive a *Certificate of Participation* at the end of the training.