

1.8 Introduction to the Regulation and Design of Clinical Investigations for Medical Technology in Australia

1.8 Introduction to the Regulation and Design of Clinical Investigations for Medical Technology in Australia module forms part of the **1.0 Medical Technology Regulation and Clinical Activities course** and introduces the regulation and design of clinical investigations.

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 reception@mtaa.org.au

What topics are covered in the module?

This module explores the practical issues surrounding the design, organisation, conduct, data management and reporting for medical technology clinical investigations.

Learning outcomes

- Understands clinical investigation protocols.
- Identifies and assesses clinical investigation sites.
- Prepares and submits ethics committee submissions.
- Initiates and commences enrolment in clinical investigation sites.
- Monitors clinical investigations and reports adverse events.
- Understands how to manage data, clinical investigation close-out activities and write reports.

Who should attend?

Medical technology industry employees working in clinical investigations should attend the training. Module 1.5 or equivalent industry experience are the recommended pre-requisites for this Level 1 module. **Participants are required to read [Note for Guidance on Good Clinical Practice](#)** published by the TGA, 2000 prior to the training.

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 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.