

## 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** introduces the regulation and design of clinical investigations. It is provided by Mobius Medical, an MTAA training partner.

### 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.

This module is offered by Mobius Medical, a training partner of MTAA. It compliments the MTAA **Medical Technology Regulation and Clinical Activities course**, designed as a series of modules to assist employees working in the regulatory and clinical areas.

### 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 trial. Workshop content covers:

1. Overview of medical device regulations.
2. Overview of clinical evidence.
3. Clinical investigations and use of unapproved medical devices in Australia and New Zealand (i.e., overview of the CTN/CTX schemes).
4. Standards used in medical device development (i.e., ICH GCP and ISO 14155, including terminology differences cf. pharma.).
5. History of clinical investigation regulation and GCP.
6. GCP by sections (i.e., major points of each of the eight (8) sections, as participants are expected to have pre-read GCP).
7. Clinical investigation development:
  - Protocol and other essential documents
  - Ethics submissions
  - Regulatory submissions in the region
  - Site selection
  - Budgets
8. Clinical investigation monitoring:
  - Pre-investigation
  - Initiation
  - Monitoring (consent, protocol deviations, safety reporting)
  - Close-out.
9. Auditing (by whom, what, when).
10. Handling of unapproved medical devices:
  - Device accountability.
  - Shipping procedures.

This interactive one day training course also includes practical scenarios for discussion.

### 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. The recommended pre-requisite for this Level 1 module is to have downloaded from the internet and 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. Once payment is accepted, applicants will be registered.

### How do I register?

For details on how to register for the training, please email Mobius Medical [info@mobiusmedical.com.au](mailto:info@mobiusmedical.com.au).

Please visit Training under Professional Development on the MTAA website [www.mtaa.org.au](http://www.mtaa.org.au) to access further MTAA course information.

For further information, please contact Mobius Medical by email [info@mobiusmedical.com.au](mailto:info@mobiusmedical.com.au)