

1.0 The Regulation of Medical Technology

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).

What is the MTAAs Regulation of Medical Technology Course?

This course consists of twelve modules that support the regulatory area.

What modules are available this semester?

1.1 Introduction to the Australian Medical Technology Industry

Focus: Helps familiarise new employees with many features of the industry.

Presenter: Cliff Spong, MTAAs

1.2 Biohazards and Sterilisation

Focus: This module will help medical technology industry professionals understand the implications of handling, managing or transporting biohazardous materials or sterile products, and any associated sterilisation processes.

Presenters: Louise White and/or Steve Williams, SeerPharma

1.3 Introduction to the Regulation of Medical Technology in Australia

Focus: Supports medical technology industry professionals understand how medical technology is regulated in Australia.

Presenter: Cliff Spong, MTAAs

1.4 Advanced Review of the Regulation of Medical Technology in Australia

Focus: Assists medical technology industry professionals review in detail how medical technology is regulated in Australia.

Presenter: Cliff Spong, MTAAs

1.5 Understanding Clinical Evidence for Medical Technology

Focus: Explains the role of clinical evidence in confirming medical technology is safe and fit for purpose.

Presenter: Cliff Spong, MTAAs

1.6 Developing Clinical Investigations for Medical Technology

Focus: Explains how to design and conduct clinical trials and investigations for medical technology.

Presenter: TBA

1.7 Quality Management Systems and Conformity Assessment (QMS and CA)

Focus: Explores QMS and CA.

Presenter: Cliff Spong, MTAAs

1.8 The Australian Regulatory System: the DEAL and GMDN Systems

Focus: Explores the DEAL and GMDN systems.

Presenter: Cliff Spong, MTAAs

1.9 TGA Decisions and Appeal Processes

Focus: Introduces how legislative decisions are made by the TGA and how a review of a decision or an appeal can be requested.

Presenter: Cliff Spong, MTAAs

1.10 Risk Analysis and the Development of Medical Technology

Focus: Examines ways to identify and assess potential risks associated with the development and use of medical technology.

Presenter: TBA

1.11 Risk Management for Medical Technology Companies from a Regulatory Perspective

Focus: Reviews the processes used by a manufacturer to identify hazards, estimate and evaluate the associated risks, control these risks and monitor the effectiveness of the controls throughout the life-cycle of a medical device.

Presenter: Steve Williams, SeerPharma

1.12 Developing Technical Documentation for Medical Technology

Focus: Examines the role technical documentation has with the development of medical technology and demonstrating regulatory compliance.

Presenter: TBA

How do I register?

All registrations to MTAAs training modules are via the website. For this course, places will be offered to those that express an interest to attend a module. The training will be held in the city where the majority of those that have expressed an interest are based. Places are limited.

For further information about MTAAs courses or in-house training, please contact the Professional Development Manager on (02) 9900 0650 or email reception@mtaa.org.au