



Medical Technology  
Association of Australia

# MTAA Training Calendar

## SEMESTER 2, 2008



Ensuring the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

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# General Information

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This training calendar may be subject to changes. Please check the website for the latest updates.

## **Not Sure Where to Start?**

Visit the MTAA website and access the MTAA Learning Pathways. This is designed to assist medical technology industry professionals identify current and future professional development directions. A promotional flyer is linked to each module title on the website under course registration and may be downloaded.

## **Training Inclusions**

All advertised course prices are inclusive of GST. Prices include course materials and refreshments.

## **Changes & Cancellations**

Cancellations will be accepted until 7 days prior to the event and are subject to a cancellation fee of \$50. No refunds are available for cancellations after this time. Substitutions are allowed until 48 hours prior to the event. MTAA reserves the right to cancel or postpone a module to an alternative date. All registered participants affected by such changes will receive a full refund or be offered the opportunity to transfer to the next available training date.

## **In-house training**

In-house training for MTAA member companies is available through the MTAA for most training modules. This is dependent upon requested dates and availability of the trainer(s). Modules will be presented in their current form as a half day or full day session. For prices, please visit Professional Development, Training on the MTAA website. To arrange in-house training, please contact the Professional Development Manager on (02) 9900 0650 or email [reception@mtaa.org.au](mailto:reception@mtaa.org.au).

## **Copyright**

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## **Enquiries**

Please refer all enquiries to the Professional Development Manager on (02) 9900 0650 or email [reception@mtaa.org.au](mailto:reception@mtaa.org.au).

# Course & Module Description



## 1.0 THE REGULATION OF MEDICAL TECHNOLOGY

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 in Australia, including medical technology. Before a sponsor can supply items of medical technology in Australia, the TGA has to grant an approval and enter the product in the Australian Register of Therapeutic Goods (ARTG).

The Regulation of Medical Technology course consists of a series of modules designed to support employees working in the regulatory area.

## 1.1 Introduction to the Australian Medical Technology Industry

An orientation for new employees working in the medical technology industry for the first time. While completing this module, participants will have the opportunity to:

- understand the breadth and diversity of the medical technology industry sector in Australia;
- understand the economic value of the sector for Australia; and
- learn about the Medical Technology Association of Australia (MTAA).

PRESENTER(S)	MTAA Secretariat
DURATION	Evening
MEMBER FEE	\$50
NON-MEMBER FEE	\$75

## 1.2 Biohazards and Sterilisation

An introduction to understand the implications of handling, managing or transporting biohazardous materials or sterile products, and any associated sterilisation processes. While completing this module, participants will have the opportunity to:

- understand best practice skills when handling, managing or transporting biohazardous materials; and
- understand a range of cleaning and sterilisation techniques.

PRESENTER(S)	Louise White/ Steve Williams, SeerPharma
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

## 1.3 Introduction to the Regulation of Medical Technology in Australia

An introduction to how medical technology is regulated in Australia. While completing this module, participants will have the opportunity to:

- understand the basics of legislative processes in Australia;
- develop a basic understanding of the Australian regulatory system for therapeutic goods; and
- develop a basic understanding of the various Acts and Regulations used to regulate medical technology in Australia.

PRESENTER(S)	Cliff Spong, MTAA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

## 1.4 Advanced Review of the Regulation of Medical Technology in Australia

A detailed review of how medical technology is regulated in Australia including the legislative framework for therapeutic products, regulatory model for medical devices, the operations of the TGA, how to make an application to supply a medical device and the relevant Acts and regulations. While completing this module, participants will have the opportunity to:

- explore the Australian legislative framework for therapeutic products, in broad terms, and specifically, the regulatory requirements for medical technology;
- understand the roles and operation of the Therapeutic Goods Administration (TGA);
- understand the basics for submitting an application to the TGA; and
- consider the many Acts and Regulations affecting the supply of medical technology in Australia.

PRESENTER(S)	Cliff Spong, MTAA
DURATION	One Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

## 1.5 Understanding Clinical Evidence for Medical Technology

An introduction to the use of clinical evidence to confirm that medical technology is safe and fit for purpose. While completing this module, participants will have the opportunity to:

- understand the different clinical trial needs for medical technology and medicines;
- understand the relationship between product development and the need for clinical evidence; and
- understand the role clinical evidence plays as part of the regulatory requirements to supply medical technology.

PRESENTER(S)	Cliff Spong, MTAA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

# Course & Module Description

## 1.0 THE REGULATION OF MEDICAL TECHNOLOGY

### 1.6 Developing Clinical Investigations for Medical Technology

An introduction to the design and conduct clinical trials and clinical investigations for medical technology. While completing this module, participants will have the opportunity to:

- understand the relationships between product development and clinical investigations;
- learn how to develop effective and appropriate clinical investigation plans; and
- understand how to conduct clinical investigations and assess the results.

PRESENTER(S)	TBA
DURATION	One Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

### 1.7 Quality Management Systems and Conformity Assessment Procedures

#### Part 1: QMS for Medical Technology

An introduction to the use of ISO 13485:2003 quality management system and how it relates to the design, development, manufacture and eventual supply of medical technology. While completing this module, participants will have the opportunity to:

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

#### Part 2: Conformity Assessment Procedures

A description of the conformity assessment procedures which must be carried out by manufacturers of medical technology and how these are audited and certified by the TGA. While completing this module, participants will have the opportunity to:

- learn why conformity assessment procedures have to be used by all manufacturers of medical technology;
- understand conformity assessment procedures; and
- gain insight into the auditing and certification processes used by the TGA.

PRESENTER(S)	Cliff Spong, MTAA
DURATION	One Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

### 1.8 The Australian Regulatory System: the DEAL and GMDN Systems

An overview of how to use the DEAL system to build an application to the TGA, followed by an understanding of the GMDN system. While completing this module, participants will have the opportunity to:

#### Part 1: The DEAL System

- submit manufacturer's evidence;
- apply for Conformity Assessment Certification from the TGA; and
- complete an application to supply a medical device.

#### Part 2: The GMDN System

- understand the development of the GMDN system;
- view a selection of GMDN codes; and
- gain insight into how choices of GMDN codes affect TGA applications.

PRESENTER(S)	Cliff Spong, MTAA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### 1.9 TGA Decisions and Appeals Processes

An overview of how legislative decisions are made by the TGA and how a review of a decision or an appeal can be requested. While completing this module, participants will have the opportunity to:

- understand decision making processes by government departments;
- understand the legislative controls and powers delegated to government departments and officials; and
- learn about the ways decisions made by government departments can be questioned and challenged.

PRESENTER(S)	Cliff Spong, MTAA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### 1.10 Risk Analysis and the Development of Medical Technology

An overview of how to identify and assess potential risks associated with the development and manufacturing of medical technology. While completing this module, participants will have the opportunity to:

- understand the relationship between product development and the need to assess the risks of using the products;
- consider various methods of assessing risks and their consequences; and
- understand the regulatory requirements for risk analysis.

PRESENTER(S)	TBA
DURATION	One Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

# Course & Module Description

## 1.0 THE REGULATION OF MEDICAL TECHNOLOGY

### 1.11 Risk Management for Medical Technology Companies from a Regulatory Perspective

An overview of the processes used by a medical technology manufacturer to identify hazards, to estimate and evaluate the associated risks, to control these risks and to monitor the effectiveness of the controls throughout the life-cycle of a medical device. While completing this module, participants will have the opportunity to:

- appreciate differing requirements for managing the risks in operating a business;
- understand how specific risk management programs fit with broader risk management strategies; and
- learn how to plan, implement and monitor effective risk management plans.

PRESENTER(S)	Steve Williams, SeerPharma
DURATION	One Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

### 1.12 Developing Technical Documentation

An examination of the role technical documentation has with the development of medical technology to demonstrate regulatory compliance. While completing this module, participants will have the opportunity to:

- understand the relationship between product development and the need for technical documentation;
- understand the regulatory requirements for technical documentation; and
- appreciate differing requirements for technical documentation by different regulatory jurisdictions.

PRESENTER(S)	TBA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

Registration for all MTAA training events must be made online using a credit card. To register or express an interest in a module, please visit

[www.mtaa.org.au](http://www.mtaa.org.au)

Click on Professional Development, then Training to select the course title then module. Complete your details and payment following the onscreen prompts.

# Course & Module Description



## 2.0 MTAA/MIANZ CODE OF PRACTICE (EDITION 3)

The 3rd edition MTAA/MIANZ Code of Practice was adopted by Members in May 2008. The Code is self regulated by industry and provides guidance on the medical technology industry's relationships with health care practitioners and consumers.

Industry has a long association of working with clinical professionals. Under the Code of Practice, there are specific obligations which need to be noted to ensure that member companies are compliant with the Code.

The Code of Practice course has been recently revised to reflect Edition 3.

## 2.1 Introduction to the Code of Practice

An orientation for newly appointed medical technology industry employees to the content of the Code of Practice. While completing this module, participants will have the opportunity to:

- develop a broad understanding of the Code of Practice; and
- discuss the principles that underpin the Code.

PRESENTER(S)	Sandra Russell, MTAA
DURATION	Half Day
MEMBER FEE	\$350
NON-MEMBER FEE	\$450

## 2.2 Unpacking the Code of Practice

An analysis of the Code of Practice and the implications for medical technology companies. While completing this module, participants will have the opportunity to:

- understand specific areas of the Code of Practice where breaches are more likely to occur; and
- interpret the principles to ensure compliance of the Code.

PRESENTER(S)	Sandra Russell, MTAA
DURATION	Half Day
MEMBER FEE	\$350
NON-MEMBER FEE	\$450

## 2.3 Complying with the Code of Practice

An analysis of compliance mechanisms and the development of policies and procedures. While completing this module, participants will have the opportunity to:

- understand compliance requirements including complaints and sanctions of the Code of Practice; and
- consider the implications of non-compliance.

PRESENTER(S)	Sandra Russell, MTAA
DURATION	Half Day
MEMBER FEE	\$350
NON-MEMBER FEE	\$450

## 2.4 Advertising of Therapeutic Goods in Australia

An analysis of current regulations governing advertising requirements under the Code of Practice. While completing this module, participants will have the opportunity to:

- understand the current regulations;
- understand the Code of Practice as it applies to advertising; and
- investigate potential future regulations.

PRESENTER(S)	Sandra Russell, MTAA
DURATION	Half Day
MEMBER FEE	\$350
NON-MEMBER FEE	\$450

# Course & Module Description



## 3.0 WORKING WITH HEALTHCARE PROFESSIONALS

Medical technology industry personnel often need to work directly with healthcare professionals. A range of skills, knowledge and understanding that respond to differing learning styles of healthcare providers are required. In addition, understanding the ACORN Standards by visitors to the peri-operative environment is required for authorised admission. A range of modules reinforcing the skill sets required to work effectively with healthcare professionals are available.

### 3.1 Interpreting Medical Terminology

An insight into understanding commonly used medical terms. While completing this module, participants will have the opportunity to:

- understand basic medical terminology used in direct communications, including fundamental word structure, pronunciation and common abbreviations;
- review the parts of the body, basic systems and interrelated functions including common conditions, medical investigations and procedures; and
- practice terminology usage through practical examples in a safe environment with structured feedback provided to participants.

PRESENTER(S)	Paul Crosbie and Natasha Fletcher, VHIA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### 3.4 Hospital Protocols

An overview of the types of behaviours hospitals require of visiting professionals. While completing this module, participants will have the opportunity to:

- understand varying hospital protocols and how they may change across a range of sites;
- understand the types of behaviours hospitals require of visiting medical technology industry professionals; and
- develop strategies to use when working with hospital staff.

PRESENTER(S)	Paul Crosbie, Natasha Fletcher and/or David Wenban, VHIA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### 3.2 Communicating Effectively with Healthcare Professionals

An evidence-based workshop on how to effectively communicate with clinicians. While completing this module, participants will have the opportunity to:

- understand evidence-based communication strategies;
- develop theoretical knowledge of learning styles; and
- practice skills learnt using scenarios and role-plays in a safe environment with structured feedback provided by a trained facilitator.

PRESENTER(S)	Prof Stewart Dunn, University of Sydney
DURATION	Full Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

### 3.5 Introduction to Operating Theatre Protocols

Theoretical and practical training for personnel who are new to the peri-operative environment, endorsed by ACORN. Operating theatre registered nurses (within the last two years) new to the industry may apply for recognised prior learning pending a successful pre-assessment. While completing this module, participants will:

- learn aseptic techniques and associated principles of practice;
- understand the principles of infection control;
- investigate the handling of accountable items;
- explore OH&S issues; and
- examine patient privacy and confidentiality requirements.

PRESENTER(S)	Nurse Educators, on behalf of Alison Evans Consulting
DURATION	Full Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

### 3.3 Professional Conduct

An overview of the professional behaviour expected of medical technology employees when working with healthcare professionals, including professional relationships and medico-legal issues. While completing the module, participants will have the opportunity to:

- understand the ethical professional boundaries that apply when working with healthcare professionals; and
- examine the medico-legal implications when working with healthcare professionals.

PRESENTER(S)	Paul Crosbie and David Wenban, VHIA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### 3.6 Operating Theatre Protocols Update

A review of current ACORN Standards with an opportunity to workshop industry specific issues relevant to the peri-operative environment. While completing this module, participants will:

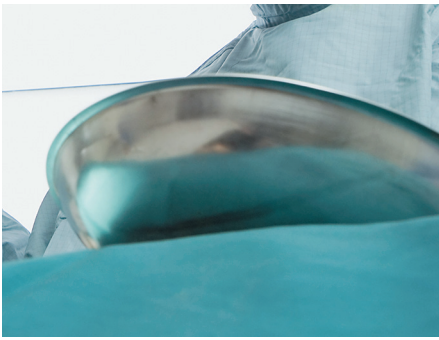
- review updates and changes to the ACORN standards for visitors to the peri-operative environment;
- explore other relevant changes in policy;
- discuss topical issues and industry based challenges of the peri-operative environment; and
- revise hand-washing techniques.

PRESENTER(S)	TBA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### Important note for modules 3.5 and 3.6

A photo identification stating that the module attended has been endorsed by ACORN will be issued upon successful completion of modules 3.5 and/or 3.6.

# Course & Module Description



## 4.0 REIMBURSEMENT OF MEDICAL TECHNOLOGY

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 healthcare in Australia. The reimbursement of medical technology in Australia is complicated and occurs in many forms. Some processes are interrelated, for example with Medicare; while others are stand alone schemes. The *Reimbursement of Medical Technology* course has been recently created to meet the needs of the medical technology industry. Four modules are available.

### 4.1 Introduction to Reimbursement of Medical Devices in Australia

An overview of the healthcare environment and the linkages across reimbursement pathways. While completing this module, participants will have the opportunity to:

- develop a broad understanding of the healthcare sector and how funding works;
- understand the basic elements of the Australian healthcare environment relevant to the reimbursement of medical devices including the significance of inclusion on the Australian Register of Therapeutic Goods (ARTG);
- develop an awareness of the Medicare Benefits Schedule and its significance and relationship to reimbursement pathways affecting medical devices (i.e. the MSAC process and its impact on the Prostheses List and other significant reimbursement pathways);
- understand the basic operations of major medical device reimbursement schemes, including but not limited to the Pharmaceutical Benefits Scheme (PBS); the Repatriation Pharmaceutical Benefits Scheme (RPBS); the National Diabetes Services Scheme (NDSS); the Stoma Appliance Scheme (SAS); the Continence Aids Assistance Scheme (CAAS); and reimbursement of public and private hospitals in respect of privately insured patients by registered health insurance funds; and
- understand the associated challenges.

PRESENTER(S)	TBA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### 4.2 Reimbursement for IVDs

An overview of reimbursement pathways for IVDs. While completing this module, participants will have the opportunity to:

- understand how IVDs are reimbursed;
- understand the Pathology Services Table (PST);
- learn how to prepare an Medical Services Advisory Committee (MSAC) application;
- understand the importance of a successful MSAC recommendation and MBS item number for market access;
- understand the pathology MOU; and
- discuss funding for non-MBS items.

PRESENTER(S)	TBA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

### 4.3 Achieving a Successful Application for the Prostheses List

Provides the conceptual context for the Prostheses List process and instruction for preparing successful applications. While completing this module, participants will have the opportunity to:

- understand the Prostheses List process;
- understand and map the application process; and
- learn how to achieve a listing at the most appropriate reimbursement price.

PRESENTER(S)	TBA
DURATION	Full Day
MEMBER FEE	\$950
NON-MEMBER FEE	\$1500

### 4.4 Medical Devices and Surgical Procedure Reimbursement

Presents the linkages between a successful Medical Services Advisory Committee (MSAC) application and other reimbursement pathways. While completing this module, participants will have the opportunity to:

- understand the importance of a successful MSAC recommendation and resulting MBS item number for market access to medical devices; and
- learn how to prepare an MSAC application.

PRESENTER(S)	TBA
DURATION	Half Day
MEMBER FEE	\$550
NON-MEMBER FEE	\$850

Registration for all MTAA training events must be made online using a credit card. To register or express an interest in a module, please visit [www.mtaa.org.au](http://www.mtaa.org.au)

# Course & Module Description



## E-LEARNING: REGULATORY AND QUALITY

The MTAA, in association with SeerPharma, is offering a new and innovative online Medical Devices (MD) Regulatory and Quality e-learning series. The MD series is specifically designed for managers, supervisors and professionals within the medical technology industry.

Understanding regulatory and quality requirements are integral parts of managing a medical device operation. The MD series has been designed to support and enhance industry professionals responsible for compliance and quality.

There are currently nine modules available, though more are in production. Details of all e-learning modules are available on the MTAA and SeerPharma websites. Many of the e-learning modules provide an introduction to the concepts taught face-to-face through the MTAA 1.0 Regulation of Medical Technology course.

Each module provides up to 45 minutes of 24/7 interactive online training, links to supporting information, online assessment and a *Certificate of Completion*. Training records are stored on a secure Learning Management System (LMS) managed by SeerPharma.

### MD-G 1 Global Regulation of Medical Devices

An overview of global medical device regulations. While completing this module, participants will have the opportunity to:

- define the term medical devices;
- describe the medical device classification system;
- recognise that medical device classification systems are based on risk;
- identify the major regulatory agencies;
- identify the regulatory requirements during a product's lifecycle;
- outline the steps required to ensure that a device meets registration requirements; and
- outline the steps required to obtain a license to manufacture.

### MD-G 2 Quality Management Systems - Requirements

An introduction to the requirements needed for a quality management system (QMS), or quality system (QS), in a medical device company. It looks at the QMS from a (global) regulatory perspective, as well as resources needed, roles, and QMS certification. While completing this module, participants will have the opportunity to:

- state how ISO 13485:2003 relates to the medical device industry;
- identify the key areas of and resources needed for the Quality Management System (QMS);
- identify some key roles in administration of the QMS; and
- recognise how the QMS is to be certified by an external auditing authority.

### MD-G 3 Risk Management

An introduction to the basics of risk management for medical device companies from a global perspective. Included topics are terminology, risk management processes and documentation required for risk management. While completing this module, participants will have the opportunity to:

- explain the terminology of risk management;
- identify the risk management processes;
- identify how risk can be calculated; and
- identify the documentation required for risk management.

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

Registration for all MTAA training events must be made online using a credit card. To register or express an interest in a module, please visit [www.mtaa.org.au](http://www.mtaa.org.au)

# Course & Module Description

## E-LEARNING: REGULATORY AND QUALITY

### MD-A 1 Australian Regulatory Affairs Overview

An overview of Australian regulatory affairs. While completing this module, participants will have the opportunity to:

- identify the Essential Principles;
- define the roles of the sponsor, manufacturer, and regulator; and
- describe the classification systems of medical devices.

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

### MD-A 2 Requirements for Registration

Introduction to the activities required before a medical device is ready to go to market. While completing this module, participants will have the opportunity to:

- explain the term “intended purpose”;
- explain the structure of the classification system;
- describe the impact of risk on classifications;
- explain what clinical evidence needs to be demonstrated; and
- describe the key sections of the technical file.

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

### MD-U 1 USA Regulatory Affairs Overview

An overview to important USA regulations, including the Code of Federal Regulations (CFRs) - 21 CFR Part 800 series. While completing this module, participants will have the opportunity to:

- define important medical device terminology;
- locate the medical device regulations pertaining to particular areas of the industry;
- describe the classification system of medical devices; and
- compare the characteristics of regulatory control required for each of the different classes of medical devices.

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

### MD-U 2 Quality Systems Requirements - 21 CFR 820

Provides a model to assimilate the knowledge required to implement a quality system in accordance with the 21 CFR 820 regulations. While completing this module, participants will have the opportunity to:

- state how 21 CFR 820 relates to the medical device industry;
- identify the requirements of the quality system;
- explain the role of key stakeholders in establishing and maintaining a quality system; and
- identify what documentation is required for quality systems.

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

### MD-Q 1 Managing a Quality Management System (QMS)

Overview of the requirements and maintenance of a Quality Management System (QMS). While completing this module, participants will have the opportunity to:

- list the key characteristics of a QMS;
- state the responsibilities of quality management roles;
- describe the elements of a quality audit program;
- relate how the internal audit affects the management role in the QMS; and
- recognise the importance of measuring performance.

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

### MD-Q 2 Documentation and Records

An introduction to medical device documentation records requirements and their controls. While completing this module, participants will have the opportunity to:

- list the objectives of thorough quality system documentation;
- explain the elements of quality system documentation requirements;
- discuss the requirements of a Device Master Record;
- discuss the requirements of a Device History File;
- list the regulatory requirements for documentation; and
- describe record and change control procedures.

PRESENTER(S)	Online only
DURATION	up to 45min
MEMBER FEE	POA
NON-MEMBER FEE	POA

# Scheduled Modules

by Month

Date	Module Title	Location	Registration Closes
<b>JULY</b>			
9	2.1 Introduction to the Code of Practice	Sydney	4 July
30	2.2 Unpacking the Code of Practice	Sydney	25 July
30	2.3 Complying with the Code of Practice	Sydney	25 July
31	2.4 Advertising of Therapeutic Goods in Australia	Sydney	25 July
<b>AUGUST</b>			
5	2.1 Introduction to the Code of Practice	Melbourne	1 August
5	2.2 Unpacking the Code of Practice	Melbourne	1 August
6	2.3 Complying with the Code of Practice	Melbourne	1 August
6	2.4 Advertising of Therapeutic Goods in Australia	Melbourne	1 August
14	3.6 Operating Theatre Protocols Update	Sydney	8 August
29	3.5 Introduction to Operating Theatre Protocols	Sydney	26 August
<b>SEPTEMBER</b>			
5	2.1 Introduction to the Code of Practice	Brisbane	29 August
5	2.2 Unpacking the Code of Practice	Brisbane	29 August
11	2.4 Advertising of Therapeutic Goods in Australia	Sydney	5 September
16	3.5 Introduction to Operating Theatre Protocols	Brisbane	12 September
<b>OCTOBER</b>			
2	2.4 Advertising of Therapeutic Goods in Australia	Brisbane	26 September
9	2.1 Introduction to the Code of Practice	Sydney	3 October
22	2.2 Unpacking the Code of Practice	Sydney	17 October
22	2.3 Complying with the Code of Practice	Sydney	17 October
24	3.6 Operating Theatre Protocols Update	Melbourne	20 October
<b>NOVEMBER</b>			
20	3.6 Operating Theatre Protocols Update	Brisbane	14 November
21	3.5 Introduction to Operating Theatre Protocols	Sydney	14 November

# Course Modules

## available through Expressions of Interest

Module dates will be provided to Expression of Interest Registrants when minimum numbers to hold an event have been reached. The location listed below will be dependent upon the home location of the majority of participants and venue availability where more than one location is named.

Module Title	Location
<b>1.0 The Regulation of Medical Technology</b>	
1.1 Introduction to the Medical Technology Industry	Sydney, Melbourne
1.2 Biohazards and Sterilisation	Sydney, Melbourne
1.3 Introduction to the Regulation of Medical Technology	Sydney, Melbourne
1.4 Advanced Review of the Regulation of Medical Technology	Sydney, Melbourne
1.5 Understanding Clinical Evidence for Medical Technology	Sydney, Melbourne
1.6 Developing Clinical Investigations for Medical Technology	Sydney, Brisbane
1.7 Quality Management Systems and Conformity Assessment Procedures (QMS and CA)	Sydney, Melbourne
1.8 The Australian Regulatory System: the DEAL and GMDN Systems	Sydney, Melbourne
1.9 TGA Decisions and Appeal Processes	Sydney, Melbourne
1.10 Risk Analysis and the Development of Medical Technology	Sydney
1.11 Risk Management for Medical Technology Companies from a Regulatory Perspective	Sydney, Melbourne
1.12 Developing Technical Documentation for Medical Technology	Sydney
<b>3.0 Working with Healthcare Professionals</b>	
3.1 Interpreting Medical Terminology	Sydney, Melbourne
3.2 Communicating Effectively with Healthcare Professionals	Sydney
3.3 Professional Conduct	Sydney, Melbourne
3.4 Hospital Protocols	Sydney, Melbourne
<b>4.0 Reimbursement of Medical Technology</b>	
4.1 Introduction to Reimbursement of Medical Devices in Australia	Sydney
4.2 Reimbursements for IVDs	Sydney
4.3 Achieving a Successful Application for the Prostheses List	Sydney
4.4 Medical Technology and Surgical Procedure Reimbursement	Sydney

# Frequently Asked Questions

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## **Q1. What types of activities fall under the professional development program of the Medical Technology Association of Australia?**

There are a range of activities that can be attended. These included training courses, seminars, sector updates and industry special interest meetings. For some training modules, pre-requisite modules or equivalent industry experience is recommended.

## **Q2. How do I register and pay to attend an activity?**

All activities through the MTAA must be registered to and paid for via the on-line registration system. All course modules are listed under the Professional Development page on the MTAA website.

## **Q3. Can I cancel my attendance if I am suddenly unable to attend?**

Attendance at a module may be cancelled up to 5 days in advance. Attendees from the same organisation may be swapped up to 2 days in advance if the MTAA is advised in writing.

To make a cancellation or swap an attendee, you must contact reception by phoning (02 9900 0650) and emailing [reception@mtaa.org.au](mailto:reception@mtaa.org.au). No refunds are offered within 5 working days of the training date. Please ensure that you always refer to the individual cancellation policy on the booking page prior to registering.

## **Q4. Are meals included?**

Morning tea is provided for morning sessions run from 9:30 am to 12:30 pm. Afternoon sessions from 1:30 pm to 4:30 pm include afternoon tea. For a full day's training or where participants are attending a morning and afternoon session on the same day, morning tea, lunch and afternoon tea is provided. Evening training sessions run from 5:00 pm to 6:30 pm. Refreshments are provided 15 minutes before the commencement of training. Special dietary requirements may be requested at time of registration.

## **Q5. Do I receive proof of attendance at a course module?**

For every module you complete a *Certificate of Participation* will be awarded. For the Operating Theatre Protocol modules, a photo ID card will be issued pending a successful assessment, where a digital passport photograph is provided via email to [reception@mtaa.org.au](mailto:reception@mtaa.org.au) by the due date.

## **Q6. How do I get to the training site?**

Public transport is regularly available in each capital city. For assistance, please contact reception on (02) 9900 0650.

## **Q7. Where can I stay near the venue?**

It is the responsibility of each participant to coordinate their own accommodation requirements.

### Brisbane

MTAA training is currently conducted at the Stamford Hotel, pending venue availability. Hotel accommodation is available onsite or within close proximity to the venue. Please view the Brisbane Tourist Information site for a range of accommodation options.

### Melbourne

MTAA training is currently conducted at the Ai Group in Melbourne. A range of hotels are available within close proximity to the venue. Please view the Visit Melbourne site for a range of accommodation options.

### Sydney

The closest hotel to MTAA office is the Harbourview Hotel in North Sydney. A range of hotels are available within Sydney. Please view the Visit NSW site for a range of accommodation options.

## **Q8. What is required of me on the day?**

Please arrive at the venue 15 minutes prior to the start time of an activity. If you are running late, please contact MTAA reception by phoning (02) 9900 0650.

Upon arrival, please ensure you sign in as a record of your attendance. This will ensure you receive a *Certificate of Participation* once the module is completed.

Each participant is expected to participate in activities as outlined by the trainer. Each participant is also required to complete a session feedback form before departing from the activity. This assists MTAA to ensure learner needs are being appropriately met.

## **Q9. What should I wear?**

Please wear comfortable business attire with something warm that can be added in case air conditioning is cool on the day.

# About MTAA

## Professional Development

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In addition to training MTAA also offers medical technology industry professionals a range of other opportunities in Professional Development:

### 1) Education

#### *For Industry*

MTAA has identified over 800 post-graduate courses relevant to the industry. These have been captured in a **Post-graduate Course Directory** available on the MTAA website. Personnel can search for university, TAFE or private courses across Australia that will further their qualifications.

#### *For Students*

MTAA has established a Medical Technology Industry **Workplace Learning Directory** on the MTAA website. Students from across Australia can access a list of MTAA member medical technology companies that offer workplace learning programs (work experience). By engaging in these programs, employers are supporting students to understand the workplace, while creating career opportunities within industry. To assist future students wishing to engage in a course that will equip them with the necessary qualifications to enter the medical technology industry, the MTAA **Undergraduate Course Directory** with over 800 relevant courses identified across Australia has been established on the MTAA website.

### 2) Information Sharing

#### *For Industry CEOs*

**CEO Forums** provide an opportunity for MTAA member senior executives to come together and discuss key issues of relevance to the medical technology industry. Lunchtime forums are held in Sydney and hosted by MTAA CEO Anne Trimmer. Chief Executive Officers, Vice Presidents, National Directors and Managing Directors are invited to attend.

#### *For Industry*

MTAA is hosting the **MedTech Seminar Series** to provide opportunities for industry to discuss key operational issues. Keynote speakers will be invited to present on a theme, and in some instances, will be supported by a panel discussion. A **Virtual Library** has been established on the member's only section of the MTAA website to enable members to access a wide range of online publications specific to the medical technology industry.

### 3) MTAA Annual Conference

The 2008 MTAA Annual Conference "Medical Technology and Innovation 2008" will be held on 24-25 September at Star City Hotel, Sydney.

The new 2 day program will include international and Australian speakers who will explore themes around development, registration and funding of medical technology in Australia. The detailed workshop program will provide industry employees opportunities to learn more about regulation, sales/marketing, reimbursement issues and the Code of Practice relating to the medical technology industry.

To find out more about MTAA Professional Development visit [www.mtaa.org.au](http://www.mtaa.org.au) or contact the MTAA Professional Development Manager on 02 9900 0650 or email [reception@mtaa.org.au](mailto:reception@mtaa.org.au)

