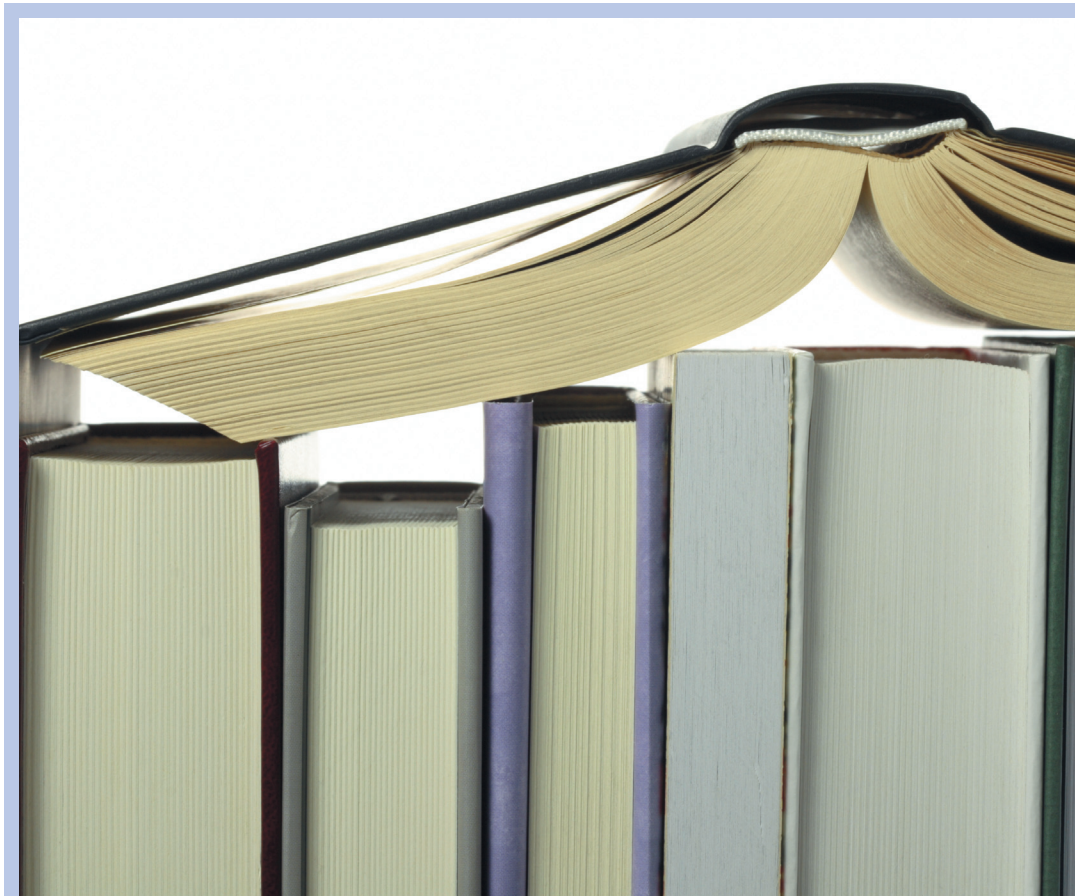




Medical Technology  
Association of Australia



# Learning Pathways for the Medical Technology Industry

# Contents

---

Learning Pathways for the Medical Technology Industry

Introduction 3

Course Descriptions 4

Learning Pathway Overview 6



Medical Technology Association of Australia Ltd • Level 12, 54 Miller Street, North Sydney NSW 2060 • PO Box 2016, North Sydney NSW 2059  
Ph: +61 2 9900 0650 | Fax: +61 2 9900 0655 • Email: [reception@mtaa.org.au](mailto:reception@mtaa.org.au) • Website: [www.mtaa.org.au](http://www.mtaa.org.au)

# Introduction

---

The following learning pathways are designed to assist medical technology industry professionals identify current and future professional development directions. Each training module is available through the MTAA Professional Development Program and can be further complemented by a range of external post graduate or private courses. As additional MTAA courses and modules are developed, these will be added to the pathways.



# Course 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, whether relatively simple or extremely complex. Before a sponsor can supply items of medical technology in Australia, the TGA must 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 to support employees working in the regulatory area.

- 1.1 Introduction to the Australian Medical Technology Industry
- 1.2 Biohazards and Sterilisation
- 1.3 Introduction to the Regulation of Medical Technology in Australia
- 1.4 Advanced Review of the Regulation of Medical Technology in Australia
- 1.5 Understanding Clinical Evidence for Medical Technology
- 1.6 Developing Clinical Investigations for Medical Technology
- 1.7 Quality Management Systems and Conformity Assessment Procedures
- 1.8 The Australian Regulatory System: the DEAL and GMDN Systems
- 1.9 TGA Decisions and Appeals Processes
- 1.10 Risk Analysis and the Development of Medical Technology

- 1.11 Risk Management for Medical Technology Companies from a Regulatory Perspective
- 1.12 Developing Technical Documentation for Medical Technology

## Medical Devices (MD) Regulatory and Quality E-learning DISCover Series

The MTAA, in association with SeerPharma, has created a new and innovative online Medical Devices (MD) Regulatory and Quality e-learning series. This series provides up to 45 minutes of interactive online training, links to supporting information, online assessments and a *Certificate of Completion*. It has been developed by industry experts and covers regulatory compliance to all major international cGMPs such as FDA, EU, PIC/s, TGA and ISO 13485/CFR 820. This program delivers best-practice and effective e-learning to the workplace.

The Medical Devices (MD) Regulatory and Quality E-learning DISCover Series includes the following modules. Additional modules will become available online as they are developed.

- MD-G 1: Global Regulation of Medical Devices
- MD-G 2: Quality Management Systems - Requirements
- MD-G 3: Risk Management
- MD-A 1: Australian Regulatory Affairs Overview
- MD-A 2: Requirements for Registration
- MD-U 1: USA Regulatory Affairs Overview
- MD-U 2: Quality Systems Requirements - 21 CFR 820
- MD-Q 1: Managing a Quality Management System (QMS)
- MD-Q 2: Documentation and Records



# Course Description

---

## **2.0 The 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.

A series of modules are available:

- 2.1 Introduction to the Code of Practice
- 2.2 Unpacking the Code of Practice
- 2.3 Complying with the Code of Practice
- 2.4 Advertising Therapeutic Goods in Australia

## **3.0 Working with Healthcare Professionals**

Medical technology industry personnel often need to work directly with healthcare professionals. Effective communication skills appropriate to the differing learning styles of healthcare professionals are essential. 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

- 3.2 Communicating Effectively with Healthcare Professionals
- 3.3 Professional Conduct
- 3.4 Hospital Protocols
- 3.5 Introduction to Operating Theatre Protocols
- 3.6 Operating Theatre Protocols Update

## **4.0 Reimbursement of Medical Technology**

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. Medical technology industry personnel new to the industry or specialising in the area of medical technology reimbursement need to gain an understanding of the reimbursement process that operates within Australia.

The Reimbursement of Medical Technology course consists of a series of modules to support employees working in the reimbursement area.

- 4.1 Introduction to Reimbursement of Medical Devices in Australia
- 4.2 Reimbursement for IVDs
- 4.3 Achieving a Successful Application for the Prostheses List
- 4.4 Medical Devices and Surgical Procedure Reimbursement

For further descriptions regarding each module, please refer to the MTAA Semester 2 2008 Training Calendar, available on the MTAA website [www.mtaa.org.au](http://www.mtaa.org.au)



# Learning Pathways Overview

Stage of Professional Development - to be completed during the:	Target Audience	Area of Responsibility	Modules for Completion
First six months working within the medical technology industry.	Newly recruited staff to the medical technology industry or tertiary students	Marketing and Sales Regulatory Reimbursement Quality Assurance Research Commerce Customer Service Technical Services IT HR Professional Development Administration	1.1 Introduction to the Australian Medical Technology Industry 2.1 Introduction to the Code of Practice <b>E-learning DISCover Series</b> MD-A 1 Australian Regulatory Affairs Overview MD-G 1 Global Regulation of Medical Devices
First year working within the medical technology industry.	Staff that require an initial understanding of medical technology industry systems.	Marketing and Sales Regulatory Reimbursement Quality Assurance Research Commerce Customer Service Technical Services IT HR Professional Development Administration	1.3 Introduction to the Regulation of Medical Technology in Australia 2.2 Unpacking the Code of Practice 4.1 Introduction to Reimbursement of Medical Devices in Australia <b>E-learning DISCover Series</b> MD-G 2: Quality Management System Requirements
First year working directly with healthcare professionals and/or hospitals.	Staff interacting with healthcare professionals and/or entering the peri-operative environment.	Marketing and Sales Research Technical Services Customer Service	3.1 Interpreting Medical Terminology 3.2 Communicating Effectively with Healthcare Professionals 3.3 Professional Conduct 3.4 Hospital Protocols
First six months entering the peri-operative environment.	Staff new to entering the peri-operative environment who are not registered nurses with a surgical background.	Marketing and Sales Research Technical Services Customer Service	3.5 Introduction to Operating Theatre Protocols



# Learning Pathways Overview

Stage of Professional Development - to be completed during the:	Target Audience	Area of Responsibility	Modules for Completion
First six months entering the peri-operative environment.	Staff who are registered nurses from a surgical background with the last two years.	Marketing and Sales Research Technical Services Customer Service	3.5 Introduction to Operating Theatre Protocols (assessment only)
Continued practice in operating theatres.	Staff entering the peri-operative environment that have previously completed module 3.5 or have relevant industry experience or are a registered nurse from a surgical background more than two years ago.	Marketing and Sales Research Technical Services Customer Service	3.6 Operating Theatre Protocols Update
First six months working within marketing and sales or regulatory affairs.	Staff wishing to advertise devices or diagnostic products to the community or ad companies.	Marketing and Sales Regulatory	2.4 Advertising Therapeutic Goods in Australia
First two years working within regulatory affairs.	Regulatory affairs professionals needing to understand the regulatory controls in Australia	Regulatory	1.2 Biohazards and Sterilisation 1.4 Advanced Review of the Regulation of Medical Technology in Australia 1.5 Understanding Clinical Evidence for Medical Technology 1.6 Developing Clinical Investigations for Medical Technology 1.7 Quality Management Systems and Conformity Assessment Procedures (QMS & CA) 1.8 The Australian Regulatory System: the DEAL and GMDN Systems 1.9 TGA Decisions and Appeal Processes 1.10 Risk Analysis and the Development of Medical Technology 1.12 Developing Technical Documentation for Medical Technology <b>E-learning DISCover Series</b> MD-A 2 Requirements for Registration MD-G 2 Quality Management System Requirements MD-Q 1 Managing a Quality Management System MD-Q 2 Documentation and Records



# Learning Pathways Overview

Stage of Professional Development - to be completed during the:	Target Audience	Area of Responsibility	Modules for Completion
First year focusing on other nations within regulatory affairs.	Regulatory affairs professionals needing to understand regulatory controls in other nations	Regulatory	<b>E-learning DISCover Series</b> MD-U 1 USA Regulatory Affairs Overview MD-U 2 Quality Systems Requirements – 21 CFR 820
First year as a Regulatory Affairs Manager.	Regulatory Affairs Managers working in the new regulatory system.	Regulatory Research	1.11 Risk Management for Medical Technology Companies from a Regulatory Perspective 2.3 Complying with the Code of Practice <b>E-learning DISCover Series</b> MD-G 3 Risk Management
First year working in reimbursement and/or IVDs.	Staff needing to gain an understanding of reimbursement.	Reimbursement Research	4.2 Reimbursement for IVDs
First two years working in reimbursement of medical devices.	Reimbursement professionals needing to understand the associated policies and processes	Reimbursement Research	4.3 Achieving a Successful Application for the Prostheses List 4.4 Medical Devices and Surgical Procedure Reimbursement
First year working within senior management.	New senior managers	Marketing managers Senior managers	2.3 Complying with the Code of Practice

