



Medical Technology  
Association of Australia

# Training Calendar 2012

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The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered to the community for a healthier Australia.

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Medical Technology for a Healthier Australia

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**“I liked the module in general.  
It was self explanatory and  
very useful. Thanks.”**



## About the Professional Development Program

Ongoing professional development is essential for developing and maintaining a knowledgeable and sustainable medical technology workforce. Medical technology professionals require up to date knowledge, skills and understanding to deliver positive outcomes in an ever complex and changing healthcare environment.

Participating in the MTAA professional development program fosters excellence and provides a wide range of learning opportunities to specifically address individual learning needs.

### Not sure where to start?

Learning Pathways can help professionals identify current and future professional development trends in the medical technology industry.

More information about each training module is available on the MTAA website, where a promotional flyer is linked to each module title under course registration. This may be downloaded for future reference.

### Blended learning approach

MTAA offers training through a blended learning approach. This includes self-paced online modules, webinars, and face-to-face training. For modules aligned to a unit of competency, assessments are available.

### In-house training

In-house training is available for most MTAA face-to-face modules upon request. Where available, modules will be presented as a half day or full day session.

Please visit the Professional Development >> Training tab on the MTAA website for more information. To arrange in-house training, please complete the online form or contact the Professional Development Manager.

### Enquiries

Please refer all enquiries to the Professional Development Manager on P: (+612) 9900 0650 or E: [pd@mtaa.org.au](mailto:pd@mtaa.org.au)

### Registration

Registration for all MTAA training events, unless otherwise stated, must be made online using a credit card. To register or express an interest in a module, please visit the MTAA website [www.mtaa.org.au](http://www.mtaa.org.au). All module fees include 10% GST.

# Course and Module Descriptions

MTAA offers six training courses, each with a range of modules. Additional modules may become available during 2012. These will be promoted on the MTAA website.

## 1.0 Medical Technology Regulation and Clinical Activities

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

The Regulation of Medical Technology course consists of a series of modules designed to assist employees working in the regulatory and/or clinical areas.

- |            |  |             |  |
|------------|--|-------------|--|
| <b>1.1</b> | Introduction to the Regulation of Medical Technology in Australia              | <b>1.2</b>  | Advanced Review of the Regulation of Medical Technology in Australia                                     |
| <b>1.3</b> | Quality Management Systems and Conformity Assessment Procedures                | <b>1.4</b>  | Developing Technical Documentation for Medical Technology  |
| <b>1.5</b> | Understanding Clinical Evidence for Medical Technology                         | <b>1.6</b>  | Risk Analysis and the Development of Medical Technology  |
| <b>1.7</b> | Risk Management for Medical Technology Companies from a Regulatory Perspective | <b>1.8</b>  | Introduction to the Regulation and Design of Clinical Investigations for Medical Technology in Australia |
| <b>1.9</b> | Improving Your Clinical Investigations for Medical Technology                  | <b>1.10</b> | Biohazards and Sterilisation   |

Face-to-face regulatory training is for a half or full day.

	Half day	Full day		Half day	Full day
<b>Member fee:</b>	<b>\$550</b>	<b>\$950</b>	<b>Non-member fee:</b>	<b>\$850</b>	<b>\$1500</b>

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

An introduction to how medical technology is regulated in Australia.

#### Learning outcomes

- Understands the basics of legislative processes in Australia
- Develops a basic understanding of the Australian regulatory system for therapeutic goods
- Develops a basic understanding of the various acts and regulations used to regulate medical technology in Australia.

Presenter: Cliff Spong, MTAA  
Duration: Half day

### 1.2 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.

#### Learning outcomes

- Explores the Australian legislative framework for therapeutic products, in broad terms, and specifically, the regulatory requirements for medical technology
- Understands the roles and operation of the TGA
- Understands the basics for submitting an application to the TGA
- Considers the many acts and regulations affecting the supply of medical technology in Australia.

Presenter: Cliff Spong, MTAA  
Duration: Full day

## 1.3 Quality Management Systems (QMS) and Conformity Assessment Procedures

### Part 1: QMS for Medical Technology

An introduction to the use of ISO 13485:2003 QMS and how it relates to the design, development, manufacture and supply of medical technology.

#### Learning outcomes

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

Presenters: Cliff Spong, MTAA; Gary Burgess, TGA and Alan Edgecomb, Consultant  
Duration: Full day

### 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.

#### Learning outcomes

- Learns why conformity assessment procedures have to be used by all manufacturers of medical technology
- Understands conformity assessment procedures
- Gains insight into the auditing and certification processes used by the TGA.

1.4

### Developing Technical Documentation for Medical Technology

An examination of the role technical documentation plays in the development of medical technology to demonstrate regulatory compliance.

#### Learning outcomes

- Understands the relationship between product development and the need for technical documentation
- Understands the regulatory requirements for technical documentation
- Appreciates differing requirements for technical documentation by different regulatory jurisdictions.

Presenter: Ece Smrdelj, SeerPharma  
Duration: Full day

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.

#### Learning outcomes

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

Presenter: Cliff Spong, MTAA  
Duration: Half day

1.6

### 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.

#### Learning outcomes

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

Presenter: Louise White, SeerPharma  
Duration: Full day

1.7

### 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.

#### Learning outcomes

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

Presenter: Louise White, SeerPharma  
Duration: Full day

1.8

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

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.

Presenter(s): Dr Martin Devitt, Stefan Czyniecki and Suzanne M. Williams, Mobius Medical  
Duration: Full day

1.9

### Improving Your Clinical Investigations for Medical Technology

An interactive, problem-based learning workshop for participants to present specific issues confronted in relation to clinical investigations for medical technology.

#### Learning outcomes

- Problem-solves company based clinical investigations
- Learns strategies to improve clinical investigation development.

Presenter(s): Dr Martin Devitt, Stefan Czyniecki and Suzanne M. Williams, Mobius Medical  
Duration: Half day

1.10

### Biohazards and Sterilisation

An introduction to the risks associated with biohazardous materials, the manufacture of sterile medical devices, and the treatment and disposition of used medical devices.

#### Learning outcomes

- Understands personal risk and the role of WHS regulations when dealing with biological & chemical hazards
- Understands sterility assurance and the need for bioburden control
- Understands a range of cleaning, decontamination and sterilisation techniques.

Presenter: Louise White, SeerPharma  
Duration: Half day

## 2.0 MTA Code of Practice

The Code of Practice is a self-regulatory industry code and provides guidance on the medical technology industry's relationships with healthcare professionals and consumers. Industry has a long association of working with healthcare professionals. Under the Code, there are specific obligations that need to be noted to ensure companies are compliant.

This course reflects the latest edition of the Code of Practice. Three modules are available.

**2.1** Introduction to the Code of Practice (online)

**2.2** Complying with the Code of Practice

**2.3** Advertising Therapeutic Goods in Australia

All face-to-face Code training is for half a day.

**Member fee: \$350**

**Non-member fee: \$450**

2.1 Introduction to the Code of Practice is only available online. Fees are set on a sliding scale for members and non-members. Fees commence at \$125 for members and \$250 for non-members. Please visit the MTA website to view the full pricing schedule.

### 2.1 Introduction to the Code of Practice

An orientation to the Code of Practice.

#### Learning outcomes

- Develops a broad understanding of the Code of Practice
- Discusses the principles that underpin the Code.

Duration: Up to 2 hours self-paced online

### 2.2 Complying with the Code of Practice

An analysis of interactions with healthcare professionals, administration and compliance mechanisms under the Code of Practice.

#### Learning outcomes

- Unpacks the MTA Code of Practice in relation to interactions with healthcare professionals
- Interprets the principles to ensure compliance of the Code
- Understands compliance requirements
- Considers the implications of non-compliance.

Presenter: Alina Hughes, MTA

Duration: Half day

### 2.3 Advertising of Therapeutic Goods in Australia

An analysis of current regulations governing advertising requirements under the Therapeutic Goods Advertising Code (TGAC).

#### Learning outcomes

- Understands the current regulations of the TGAC in relation to medical devices
- Understands the Code of Practice as it applies to advertising
- Investigates potential future regulations.

Presenter: Alina Hughes, MTA

Duration: Half day



“The inclusive  
facilitative  
presentation style  
was engaging,  
excellent.”



Medical technology industry personnel often work closely with healthcare professionals. This requires a range of skills, knowledge and understanding that responds to the language of healthcare professionals and their work environments. In addition, visitors to the perioperative environment require an understanding of the ACORN Standards for authorised admission.

A range of modules reinforcing the skills required to work effectively with healthcare professionals are available.

- 3.1** Understanding Medical Terms (online)
- 3.2** Language of the Human Body (online)
- 3.3** Infection Prevention (online)
- 3.4** Hospital Protocols (online)
- 3.5** Introduction to Operating Theatre Protocols
- 3.6** Operating Theatre Protocols Update (online)
- 3.7** Professional Conduct (online)
- 3.8** Patient Privacy and Confidentiality (online)
- 3.9** Introduction to Anatomy and Physiology (online)
- 3.10** The Cardiovascular System (online)
- 3.11** The Digestive System (online)
- 3.12** The Endocrine System (online)
- 3.13** The Integumentary System (online)
- 3.14** The Lymphatic System (online)
- 3.15** The Muscular System (online)
- 3.16** The Nervous System (online)
- 3.17** The Reproductive System (online)
- 3.18** The Respiratory System (online)
- 3.19** The Skeletal System (online)
- 3.20** The Urinary System (online)

## Units of Competency

The following modules are aligned to one or more competencies. Successful completion of an assessment will result in a Statement of Attainment. Please see *Recognition of Competency* at the end of this course for further details.

### Modules

- 3.1** Understanding Medical Terminology
- 3.2** Language of the Human Body

#### Unit of Competency

BSBMED301A Use Advanced Medical Terminology

- 3.3** Infection Prevention

#### Unit of Competency

HLTIN1A Comply with Infection Control Policy and Procedures  
 HLTIN2A Maintain Infection Control Standards in Office Practice Settings  
 HLTIN3A Implement and Monitor Infection Control Policy and Procedures

- 3.9** Introduction to Anatomy and Physiology
- 3.10** The Cardiovascular System
- 3.11** The Digestive System
- 3.12** The Endocrine System
- 3.13** The Integumentary System
- 3.14** The Lymphatic System
- 3.15** The Muscular System
- 3.16** The Nervous System
- 3.17** The Reproductive System
- 3.18** The Respiratory System
- 3.19** The Skeletal System
- 3.20** The Urinary System

#### Unit of Competency

HLTAP401A Confirm Physical Health Status

Face-to-face training for this course is for a full day only.

**Member fee: \$950**

**Non-member fee: \$1500**

Unless otherwise stated, online self-paced modules follow a sliding scale for members and non-members. Fees commence at \$165 for members and \$330 for non-members. Please visit the MTAA website to view the full pricing schedule.

Modules *3.1 Understanding Medical Terminology* and *3.2 Language of the Human Body* are free to all registrants. Modules *3.3 Infection Prevention* and *3.9-3.20* from the *Anatomy and Physiology Series* are available at a fixed rate of \$145 per module. To register for the complete *Anatomy and Physiology Series* (modules 3.9-3.20), participants pay a reduced fee of \$1100. Please visit the MTAA website for the pricing schedule, or contact the Professional Development Manager for further information.



## Understanding Medical Terms

An introduction to where commonly used medical terms originate.

### Learning outcomes

- Understands the origins of medical terms
- Recognises basic word structure
- Learns correct pronunciation.

Duration: Up to 1 hour self-paced online



## Language of the Human Body

An introduction to language associated with the different body systems.

### Learning outcomes

- Recognises the main systems of the body
- Learns terms linked to different body systems.

Duration: Up to 1 hour self-paced online

**3.3****Infection Prevention****New**

An insight into preventing infection within the healthcare setting.

**Learning outcomes**

- Understands how healthcare associated infections occur
- Understands and applies standard precautions within the healthcare setting
- Recognises and mitigates the risks associated with infection prevention and control
- Becomes aware of relevant policies, procedures and guidelines.

Duration: Up to 1 hour self-paced online

**3.5****Introduction to Operating Theatre Protocols**

An introduction to the theoretical and practical training required by personnel who are new to the perioperative environment. This module is approved by the Australian College of Operating Room Nurses (ACORN).

**Learning outcomes**

- Learns aseptic techniques and associated principles of practice
- Understands the principles of infection control
- Investigates the handling of accountable items
- Explores OH&S issues
- Examines patient privacy and confidentiality requirements.

Presenters: State-based Nurse Educators

Duration: Full day

**3.4****Hospital Protocols**

An overview of the types of behaviours hospitals require of visiting medical technology industry professionals.

**Learning outcomes**

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

Duration: Up to 1 hour self-paced online

**3.6****Operating Theatre Protocols Update**

A review of current ACORN Standards with an opportunity to workshop industry specific issues relevant to the perioperative environment. This module is approved by ACORN.

**Learning outcomes**

- Explores relevant changes in policy
- Discusses topical issues and industry based challenges of the perioperative environment
- Revises hand washing techniques.

Duration: Up to 2 hours self-paced online

Please note, for modules 3.5 and 3.6 a photo identification card stating that the module has been approved by ACORN will be issued upon successful completion of the training.

**3.7****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.

**Learning outcomes**

- Understands the ethical professional boundaries that apply when working with healthcare professionals
- Examines the medico-legal implications when working with healthcare professionals.

Duration: Up to 1 hour self-paced online

**3.8****Patient Privacy and Confidentiality****New**

An overview of the importance of patient privacy and confidentiality for MCRs when entering the healthcare setting and/or working with healthcare professionals.

**Learning outcomes**

- Understands the broad concepts of patient privacy and confidentiality
- Lists the main pieces of legislation governing patient privacy and confidentiality
- Locates sources for further information about patient privacy and confidentiality in their state
- Describe basic obligations generally contained in patient privacy statements

Duration: Up to 1 hour self-paced online

**3.9****Introduction to Anatomy and Physiology**

An introduction to the anatomy and physiology of the human body.

**Learning outcomes**

- Understands the concepts of anatomy and physiology
- Learns about cell biology and the functions of life
- Learns of the different body systems.

Duration: Up to 1 hour self-paced online

**3.10****The Cardiovascular System**

An introduction to the anatomy and physiology of the cardiovascular system.

**Learning outcomes**

- Understands the anatomy and physiology of the cardiovascular system
- Recognises common disorders of the cardiovascular system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

**3.11****The Digestive System**

An introduction to the anatomy and physiology of the digestive system.

**Learning outcomes**

- Understands the anatomy and physiology of the digestive system
- Recognises common disorders of the digestive system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

**3.12****The Endocrine System**

An introduction to the anatomy and physiology of the endocrine system.

**Learning outcomes**

- Understands the anatomy and physiology of the endocrine system
- Recognises common disorders of the endocrine system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.13 The Integumentary System

An introduction to the anatomy and physiology of the integumentary system.

#### Learning outcomes

- Understands the anatomy and physiology of the integumentary system
- Recognises common disorders of the integumentary system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.15 The Muscular System

An introduction to the anatomy and physiology of the muscular system.

#### Learning outcomes

- Understands the anatomy and physiology of the muscular system
- Recognises common disorders of the muscular system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.17 The Reproductive System

An introduction to the anatomy and physiology of the reproductive system.

#### Learning outcomes

- Understands the anatomy and physiology of the reproductive system
- Recognises common disorders of the reproductive system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.19 The Skeletal System

An introduction to the anatomy and physiology of the skeletal system.

#### Learning outcomes

- Understands the anatomy and physiology of the skeletal system
- Recognises common disorders of the skeletal system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.14 Operating Theatre Protocols Update

An introduction to the anatomy and physiology of the lymphatic system.

#### Learning outcomes

- Understands the anatomy and physiology of the lymphatic system
- Recognises common disorders of the lymphatic system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.16 The Nervous System

An introduction to the anatomy and physiology of the nervous system.

#### Learning outcomes

- Understands the anatomy and physiology of the nervous system
- Recognises common disorders of the nervous system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.18 The Respiratory System

An introduction to the anatomy and physiology of the respiratory system.

#### Learning outcomes

- Understands the anatomy and physiology of the respiratory system
- Recognises common disorders of the respiratory system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

### 3.20 The Urinary System

An introduction to the anatomy and physiology of the urinary system.

#### Learning outcomes

- Understands the anatomy and physiology of the urinary system
- Recognises common disorders of the urinary system
- Recognises supportive medical technology.

Duration: Up to 1 hour self-paced online

## Recognition of Competency

Recognition of competency is available through successful completion of specified assessment tasks.

Modules 3.1 and 3.2

Participants will be assessed against the unit of competency *BSBMED301A Use Advanced Medical Terminology*. If deemed competent, the participant will be issued with a nationally recognised Statement of Attainment for the unit.

It is recommended that the participant complete the two free online modules before completing the assessment. Assessment involves the participant submitting three items of evidence to the assessor.

1. A portfolio of evidence
2. Written assessment task wherein the candidate answers a series of questions
3. A supervisor's report.

Assessment is conducted by the MTAA's training partner, VHIA Training. Full information about the unit of competency and the assessment requirements is provided to the participant prior to them undertaking an assessment.

The assessment service is available at \$550 per person (incl. GST). Individuals interested in undertaking assessment should contact VHIA Training on P: (+ 613) 9861 4000 or E: [training@vhia.com.au](mailto:training@vhia.com.au)

Module 3.3

This module is aligned to VET competencies *HLTIN1A Comply with Infection Control Policy and Procedures*, *HLTIN2A Maintain Infection Control Standards in Office Practice Settings*, and *HLTIN3A Implement and Monitor Infection Control Policy and Procedures* in the *HLT07 Health Training Package*. For information on how to complete an assessment that will lead to a Statement of Attainment, please contact MTAA.

Modules 3.9-3.20

Each module is aligned to VET competency *HLTAP401A Confirm Physical Health Status* in the *HLT07 Health Training Package*. It is recommended that the participant complete all modules before completing the assessment. For information on how to complete an assessment that will lead to a Statement of Attainment, please contact MTAA.

## 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 contributes significantly 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 consists of four modules to support employees working in the reimbursement area.

**4.1** Introduction to Reimbursement of Medical Devices in Australia (online)

**4.2** Achieving a Successful Application for the Prostheses List

**4.3** Understanding the MSAC Process

**4.4** Preparing an MSAC Submission

Face-to-face regulatory training is for a half or full day.

	Half day	Full day		Half day	Full day
<b>Member fee:</b>	<b>\$550</b>	<b>\$950</b>	<b>Non-member fee:</b>	<b>\$850</b>	<b>\$1500</b>

Online self-paced modules follow a sliding scale for members and non-members. Fees commence at \$165 for members and \$330 for non-members. Please visit the MTAA website for a pricing schedule.

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

An overview of the healthcare environment and the linkages across reimbursement pathways.

#### Learning outcomes

- Develops a broad understanding of the healthcare sector and how funding works
- Understands 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 (MBS) and its significance and relationship to reimbursement pathways affecting medical devices (i.e. the Medical Services Advisory Committee (MSAC) process and its impact on the Prostheses List and other significant reimbursement pathways)
- Understands the basic operations of major medical device reimbursement schemes including the Prostheses List, 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
- Understands the associated challenges.

Duration: Up to 2 hours self-paced online

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

An overview of the Prostheses List process and instruction for preparing successful applications.

#### Learning outcomes

- Understands the Prostheses List process
- Understands and maps the application process
- Learns how to achieve the most appropriate listing.

Presenters: David Ross, MTAA and Dr Sue O'Malley, Medical Intelligence

Duration: Full day

### 4.3 Understanding the MSAC Process

An introduction to the importance of a successful Medical Services Advisory Committee (MSAC) application and resulting MBS numbers.

#### Learning outcome

- Understands the new MSAC application process including the significance of all the stages of the process.

Presenter: Dr Sue O'Malley, Medical Intelligence

Duration: Half day

### 4.4 Preparing an MSAC Submission

An introduction to preparing an MSAC application and submission, including when one should be used in preference to another.

#### Learning outcomes

- Understands the data and evidence requirements
- Learns about the most critical aspects of preparing an MSAC application/submission.

Presenter: Dr Sue O'Malley, Medical Intelligence

Duration: Half day

## 5.0 Workforce Development

Workforce development is seen as critical to enable employees to meet the constant challenges of the medical technology industry and to address the strategic goals of the company. A number of modules are available to address this learning need.

The Workforce Development course currently consists of series of modules.

- 5.1** Introduction to the Medical Technology Industry (online)
- 5.2** Introduction to Leadership and Management (online)
- 5.3** Management & Leadership Essentials (online)
- 5.4** Implementing a Workplace Wellness Program (online)
- 5.5** The Emotionally Intelligent Leader (online)
- 5.6** High Performing Teams (online)
- 5.7** Managing Work Priorities and Delegation (online)
- 5.8** Conducting Challenging Conversations (online)
- 5.9** Managing Conflict in the Workplace (online)
- 5.10** Bullying and Harassment: Avoiding a David Jones Situation (online)
- 5.11** Planning Projects (online)
- 5.12** WHS Fundamentals (online)
- 5.13** Interpreting Medical Technology Industry Data (online)
- 5.14** Summarising Statistical Distributions for the Medical Technology Industry (online)
- 5.15** Media Skills
- 5.16** Customer Focus (online)

### Units of Competency

The following modules are aligned to one or more competencies. Successful completion of an assessment will result in a Statement of Attainment. Please see *Recognition of Competency* at the end of this course for further details.

Modules	
<b>5.2</b>	Introduction to Leadership and Management
<b>5.3</b>	Management & Leadership Essentials
<b>5.4</b>	Implementing a Workplace Wellness Program
<b>5.5</b>	The Emotionally Intelligent Leader
<b>5.6</b>	High Performing Teams
<b>5.7</b>	Managing Work Priorities and Delegation
<b>Unit of Competency</b> BSBMGT605B Provide Leadership Across the Organisation	
<b>5.11</b>	Planning Projects
<b>Unit of Competency</b> BSBHR502A Manage Human Resource Management Information Systems	
<b>5.12</b>	WHS Fundamentals
<b>Unit of Competency</b> UEENEEE001B Apply OHS Practices in the Workplace	
<b>5.16</b>	Customer Focus
<b>Unit of Competency</b> BSBCUS402A Address Customer Needs	

Face-to-face training for this course is for a full day only.

**Member fee: \$950 Non-member fee: \$1500**

#### Online fees are as follows.

5.1 *Introduction to the Australian Medical Technology Industry* and 5.2 *Introduction to Leadership and Management* are offered online at no cost to participants. To access these modules, please visit the MTAA website.

Online modules 5.3 *Introduction to Leadership and Management*, 5.13 *Interpreting Medical Technology Industry Data* and 5.14 *Summarising*

*Statistical Distributions for the Medical Technology Industry* follow a sliding scale for members and non-members. Fees commence at \$165 for members and \$330 for non-members. Please visit the MTAA website to view the full pricing schedule. Modules 5.11 *Planning Projects*, 5.12 *OHS Fundamentals* and 5.16 *Customer Focus* are available at a fixed rate of \$145 per participant.

Webinars are available at the following rates.

	Member	Non-member
<b>Per webinar:</b>	<b>\$115</b>	<b>\$230</b>
<b>Entire series:</b>	<b>\$685</b>	<b>\$1370</b>

### 5.1 Introduction to the Australian Medical Technology Industry

An orientation for new employees, students, media or those with a general interest in the medical technology industry.

#### Learning outcomes

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

Duration: Up to one hour self-paced online

### 5.2 Introduction to Leadership and Management

An introduction to the transition from 'technical expert' to manager of a business unit.

#### Learning outcomes

- Provides an overview of the role of manager and leader
- Supports the transition to manager by highlighting the key responsibilities undertaken; and the changes in working relationships.

Duration: Up to one hour self-paced online

### 5.3 Management & Leadership Essentials

An "essentials checklist" for those becoming a manager for the first time.

#### Learning outcomes

- Appreciates the management functions model
- Recognises the link between strategic planning and effective management.

Duration: Up to one hour self-paced online

### 5.4 Implementing a Workplace Wellness Program

An overview of the key activities required for planning and implementing a workplace wellness program.

#### Learning outcome

- Describes the key activities for planning and implementing a workplace wellness program.

Presenter: Merv Neal, VHIA  
Duration: 1 hour webinar

### 5.5 The Emotionally Intelligent Leader

An introduction to emotional intelligence for leaders and managers.

#### Learning outcome

- Describes emotional intelligence and applies strategies for using it in the workplace.

Presenter: Monica Karwan, VHIA

Duration: 1 hour webinar

### 5.6 High Performing Teams

An introduction to strategies for developing and leading high performing teams.

#### Learning outcome

- Describes activities and strategies for developing high performing teams.

Presenter: Stephen Greaves, VHIA

Duration: 1 hour webinar

### 5.7 Managing Work Priorities and Delegation

An introduction to strategies for leaders and managers to effectively manage their workloads and priorities.

#### Learning outcome

- Describes methods for prioritising time at work to meet personal and organisational goals.

Presenter: David Strangward, VHIA

Duration: 1 hour webinar

### 5.8 Conducting Challenging Conversations



An insight into the art of conducting challenging and productive conversations.

#### Learning outcome

- Describes various strategies for conducting challenging conversations.

Presenter: Merv Neil, VHIA

Duration: 1 hour webinar

### 5.9 Managing Conflict in the Workplace

An overview of conflict in the workplace and practical strategies for managing it.

#### Learning outcome

- Describes and applies a variety of practical strategies for dealing with conflict in the workplace.

Presenter: David Strangward, VHIA

Duration: 1 hour webinar

### 5.10 Bullying and Harassment: Avoiding a David Jones Situation

An overview of what can and should be done to prevent and manage bullying and harassment in the workplace.

#### Learning outcome

- Describes basic legal obligations for addressing bullying and harassment in the workplace.

Presenter: Anna Pannuzzo, VHIA

Duration: 1 hour webinar

### 5.11 Planning Projects



An introduction to general project management principles and how to apply the skills to the project planning processes during the initiate and plan phase of the project life cycle.

#### Learning outcomes

- Explores general project management principles
- Learns how to apply these skills to the project planning processes during the initiate and plan phase of the project life cycle.

Duration: Up to 1 hour self-paced online

### 5.12 WHS Fundamentals



An overview of work, health and safety (WHS) fundamental principles.

#### Learning outcomes

- Understands the fundamental principles of WHS
- Recognises government legislation that PBCAs and workers must comply with
- Understands their own role and responsibilities with workplace safety.

Duration: Up to 1 hour self-paced online

### 5.13 Interpreting Medical Technology Industry Data

An introduction to understanding statistics in order to interpret relevant data for the industry.

#### Learning outcomes

- Understands the purpose of statistics and sources of data
- Gains an overview of the types of statistical data
- Practices data analysis.

Duration: Up to 1 hour self-paced online

### 5.14 Summarising Statistical Distributions for the Medical Technology Industry

An introduction to summarising statistical distributions relevant to the industry.

#### Learning outcomes

- Reads statistical data
- Summarises statistical distributions relevant to the industry.

Duration: Up to 2 hours self-paced online

## 5.15 Media Skills

An overview of how the media works and what journalists are looking for in response to an enquiry.

### Learning outcomes

- Understands the news cycle and how the media works
- Appreciates the importance of monitoring the media
- Develops skills to create a media strategy and policy.

Presenter: Sue Driscoll, Health Communications

Duration: Full day

## Recognition of Competency

Recognition of competency is available through successful completion of specified assessment tasks. If deemed competent, the participant is issued with a nationally recognised *Statement of Attainment* for the unit.

Modules 5.2-5.7

For the unit of competency *BSBMGT605B Provide Leadership Across the Organisation*, it is recommended that the participant complete as a minimum the free online module *5.2 Introduction to Leadership and Management* and the following leadership and management modules before completing the assessment.

**5.3** Management and Leadership Essentials

**5.4** Implementing a Workplace Wellness Program

**5.5** The Emotionally Intelligent Leader

**5.6** High Performing Teams

**5.7** Managing Work Priorities and Delegation

## 5.16 Customer Focus

New

An introduction to how best to work directly with customers.

### Learning outcomes

- Recognises the characteristics and practices of customer focused organisations
- Understands key strategies used to identify customer needs and expectations
- Understands the processes for responding to customer requirements
- Manages customer complaints.

Duration: Up to 1 hour self-paced online

Assessments involve the participant submitting four items of evidence to the assessor.

1. Self assessment
2. Written report of between 600 - 1000 words
3. Report of the mentoring process
4. Supervisors' report.

Assessment for this unit of competency is conducted by the MTAA's training partner, VHIA Training. Full information about the unit of competency and the assessment requirements is provided to the participant prior to undertaking the assessment.

The assessment service is available at \$550 per person (incl. GST). Individuals or companies interested in undertaking assessment should contact VHIA Training on P: (+613) 9861 4000 or E: [training@vhia.com.au](mailto:training@vhia.com.au)

Module *5.11 Project Planning* is aligned to VET competency *BSBHR502A Manage Human Resource Management Information Systems*, module *5.12 WHS Fundamentals* is aligned to VET competency *UEENEE001B Apply OHS Practices in the Workplace*, and module *5.16 Customer Focus* is aligned to VET competency *BSBCUS402A Address Customer Needs*. For information on how to complete an assessment that will lead to a *Statement of Attainment* for any of these competencies, please contact MTAA.

## Commercial Practices

Developing skills, knowledge and understanding in how better commercial practices support the work of medical technology companies.

There are currently two modules available.

**6.1** Government Health Procurement: Agencies and Processes (online) **6.2** Government Health Procurement: Responding to Proposals

Face-to-face training for this course is for a half day.

**Member fee: \$550**      **Non-member fee: \$850**

Self-paced modules follow a sliding scale for members and non-members. Fees commence at \$165 for members and \$330 for non-members. Please visit the MTAA website to view the full pricing schedule.

## 6.1 Government Health Procurement: Agencies and Processes

An overview of the Australian government procurement processes relevant to the medical technology industry by state.

### Learning outcomes

- Recognises that each Australian state government has different routines for the submission of applications
- Understands the structure of public procurement in each state
- Gains some awareness of procurement ethics and probity.

Duration: Up to 1 hour online

## 6.2 Government Health Procurement: Responding to Proposals

An overview of how to respond to procurement proposals and tenders.

### Learning outcomes

- Develops a basic understanding of responding to procurement proposals (e.g. request for tenders, request for quotes)
- Gains an understanding of the Competition and Consumer Act and ACCC limitations (e.g. bundled product offers).

Duration: Half day



## Presenter Profiles

**Presenter:** Gary Burgess  
**Organisation:** Therapeutic Goods Administration (TGA)  
**Module:** 1.3 Quality Management Systems and Conformity Assessment Procedures

Gary Burgess is a qualified biomedical engineer, who has spent several years in the private sector developing electronic equipment and medical devices, before moving to Canberra to join the TGA as a medical device assessor.

Gary has six years experience at the TGA dealing with conformity assessments of medical device manufacturers. He has attended QMS audits of manufacturers as a technical specialist, and has represented the Australian regulator on Study Group 1 of the Global Harmonization Task Force (GHTF), which is concerned with pre-market evaluation of medical devices, including conformity assessment.

Gary is currently the Director of the Conformity Assessment section in the Office of Devices Authorisation (ODA) at the TGA.

**Presenter:** Margaret Butler  
**Organisation:** State-based Nurse Educator  
**Module:** 3.5 Introduction to Operating Theatre Protocols

Margaret Butler is a registered nurse whose qualifications include Perioperative Certificate, Bachelor of Nursing and Master Adult Education.

Margaret is a Perioperative Nurse Educator in the operating suite of St Vincent's Hospital, Sydney. In this role she coordinates several perioperative nursing education programs including the Perioperative Nursing Clinical Program, which includes students from St Vincent's Hospital and St Vincent's Private Hospital operating suites.

Margaret is also an Honorary Clinical Fellow of the Australian Catholic University School of Nursing (NSW & ACT) and is the Coordinator of Perioperative & Anaesthetic and Recovery Room Specialty Practice Units for the ACU National Master of Health Science - Clinical Practice.



**Presenter:** Stefan Czyniecki  
**Organisation:** Mobius Medical  
**Modules:** 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

Graduating with a bachelor degree in Medical Science from the University of Sydney in 2000, Stefan worked as a research assistant for an orthopaedic surgeon.

In 2003, Stefan joined the clinical research team at Fornier Pharma (now Solvay Pharmaceuticals/Abbott) and was based at the Clinical Trial Centre at the NHMRC. Stefan worked as a clinical research associate and data manager on the FIELD study, a multi-centre, international, phase III study.

In 2006, Stefan moved back into the device space working as a Senior Clinical Research Associate and later as Clinical Affairs Manager at Ventracor. Stefan was placed in charge of the clinical dossier for CE Marking of the VentrAssist, which was achieved in December 2006.

Stefan is a founding member of Mobius Medical and is the company's Clinical Affairs Director. Stefan brings with him a sound knowledge and experience of clinical trial management and regulatory report submission requirements required for device approval. His experience includes clinical trial design, database design, project management and regulatory reporting requirements.



**Presenter:** Dr Martin Devitt  
**Organisation:** Mobius Medical  
**Modules:** 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

Dr Martin Devitt graduated with a Bachelor of Medicine from the University of Newcastle (Australia) in 1997. He initially became a registrar in anaesthetics and intensive care, but in 2000 joined the Therapeutic Goods Administration (TGA) as Head of the Clinical Section in the Office of Devices, Blood and Tissues. His role included the provision of high level advice on clinical considerations in the regulation of medical devices; participation on the TGA's Medical Devices Expert Committee (MDEC) and Medical Device Incident Review Committee (MDIRC); the development of legislation and policy initiatives both nationally and internationally, including input into the workings of the Global Harmonisation Task Force (GHTF); participation as a member on a committee of Standards Australia; and the auditing of quality management systems to ISO 13485.

In 2005, he joined Cook Australia as Medical Director in a global capacity, providing high-level clinical advice on pre- and post-market safety, quality, performance, and marketing issues pertaining to the manufacture and supply of medical devices.

Martin is a founding member of Mobius Medical and is the company's Medical Director. He brings medical devices experience from both the regulator and the industry including clinical and regulatory input into all aspects of medical device research and development, manufacturing, and commercialisation, including clinical trials, clinical evidence, and post-marketing issues; health technology assessment of medical devices for reimbursement; and quality management system auditing to ISO 13485 and clinical trial auditing to ICH GCP.

Martin is a Director on a number of Boards and provides corporate advisory services to companies pursuing the commercialisation of medical devices. Martin also practices emergency medicine part-time.



**Presenter:** Sue Driscoll  
**Organisation:** Health Communications  
**Module:** 5.15 Media Skills

Sue Driscoll is the Chief Executive Officer of Health Communications, an associate of Victorian Hospitals Industrial Association. Health Communications specialises in providing public relations and marketing support to all areas of the Australian healthcare sector.



Sue is an experienced practitioner who worked in major metropolitan Melbourne hospitals and Victorian health agencies for around 20 years. During this time she coordinated hospital and network responses to major crises that face a Victorian public hospital.

Sue has taught strategic communication planning and community relations to Masters students as well as writing and editing courses at undergraduate and postgraduate levels. In addition she has provided industry training for health and PR managers on communication planning, issues and crisis management, and of course media management.

An ex-journalist, she is a former President of the Public Relations Institute of Australia (Victoria) and has been a regular commentator on public relations and communications on ABC Radio.

**Presenter:** Alan Edgecomb  
**Organisation:** Alan Edgecomb Consulting  
**Module:** 1.3 Quality Management Systems and Conformity Assessment Procedures

Alan Edgecomb has more than 30 years experience in the medical device industry. Alan has worked as a service engineer for Siemens Medical Systems and Philips Medical in South Africa and for General Electric Medical Systems in Australia.



Alan was the Quality and Regulatory Affairs Manager for the South East Asia region of General Electric Medical Systems, the Quality and Service Manager for an Australian start-up company, ImpediMed Limited, and currently is the Quality and Regulatory Affairs Manager for Abacus ALS in Brisbane. Alan also provides consulting services to various medical device companies in Brisbane.

Alan has been involved with ISO 9001 and ISO 13485 quality management systems for the last 15 years having implemented and managed QMS at various sites in Australia. Alan has been running QMS training courses for the past 8 years.

**Presenter:** Stephen Greaves  
**Organisation:** Victorian Hospitals Industrial Association (VHIA)  
**Module:** 5.6 High Performing Teams

An award winning (2001 Prime Ministers Award for Business and Community Partnerships) business professional, Stephen Greaves is a Partner of Two + You Leadership Design, a leadership design consultancy firm based in Melbourne.



Stephen has over 25 years corporate experience working as a business performance advisor and coach in a mix of organisations ranging from multinational to micro-enterprises. Organisations that Stephen has worked for include Coles/Myer, St Laurence Community Services, Telstra, Origin Energy, Westpac, Barwon Health and The Gordon Institute of TAFE.

Stephen was also a Board Member and Vice President of the Geelong Chamber of Commerce and holds qualifications in management, social science, training, marketing and project management. Stephen is also a long term member of the Australian Institute of Management and Australian Institute of Project Managers.

**Presenter:** Alina Hughes  
**Organisation:** MTAA  
**Modules:** 2.2 Complying with the Code of Practice  
2.3 Advertising of Therapeutic Goods in Australia

Alina Hughes joined MTAA in 2010 and is the Code of Practice Manager.



Alina has worked in the field of corruption prevention, ethics and compliance since 2004.

After graduating from the University of New South Wales with a Bachelor of Arts and Bachelor of Laws, Alina initially worked as a solicitor for Minter Ellison Lawyers in Sydney. From 2003-08, Alina worked for the NSW Independent Commission Against Corruption, firstly in the Complaints Assessment area and then in the Corruption Prevention, Education and Research Division. From 2008-10 she worked in the Corruption Prevention Unit at RailCorp. In 2010, she rejoined the ICAC on a temporary basis to work on an inquiry that it was holding into lobbying.

Alina has provided advice and training on ethics and compliance issues to a wide range of audiences. In 2007, she presented a paper at the Australian Public Sector Anti-Corruption Conference. Alina also holds a Master of Laws from the University of Sydney.

**Presenter:** Monika Karwan  
**Organisation:** Victorian Hospitals Industrial Association (VHIA)  
**Module:** 5.5 The Emotionally Intelligent Leader

As a performance coach, facilitator and advisor, Monika Karwan develops people with an ambition to go somewhere and do something extraordinary. Whether it's emerging leaders, bankers, photographers or magicians, Monika consistently moves, touches and inspires performance excellence.



Monika offers clients over 20 years of corporate and creative industry experience, wisdom and storytelling in the areas of training and development, media, marketing, public relations, customer service and event management.

Monika has worked for a diverse range of organisations including Levi Strauss, the Commonwealth Bank of Australia, the EJ Whitten Legends Game and recently the City of Greater Geelong Council, where Monika was a key contributor to winning an Achievement Award in training.

**Presenter:** Helen Kierce  
**Organisation:** Victorian Hospitals Industrial Association (VHIA)  
**Module:** Webinar Facilitator

Helen Kierce manages the Training Services Unit at the Victorian Hospitals Industrial Association (VHIA). She has over 13 years experience as a manager, consultant and trainer in the field of professional, personal and workplace based training. Helen's current role involves leading the development the VHIA's training program, including overseeing the strategic direction and expansion of the training business to meet the needs of the members of the Association. She manages a small team of full-time staff supplemented by a broad range of associate trainers and training partners.



Helen graduated with a Bachelor of Economics Degree from Monash University in 1983 and has since completed a Graduate Diploma of Business (Organisational Behaviour), a Master of Professional Education; and Training and a Certificate IV Training and Assessment. Helen's focus is on devising relevant, responsive and engaging professional development programs that enable employees and managers to reach their full potential at work.

**Presenter:** Michelle Loth (Brisbane)  
**Organisation:** State-based Nurse Educator  
**Module:** 3.5 Introduction to Operating Theatre Protocols

Michelle Loth has worked as a registered nurse in operating theatres for over 10 years. Her qualifications include Bachelor of Nursing, Graduate Certificate in Nursing (Perioperative) and Certificate IV in Workplace Training & Assessment.



Michelle has worked at the Royal Brisbane & Women's, Holy Spirit Northside and The Prince Charles Hospitals. She has experience in elective and emergency surgery, particularly focusing in the speciality areas of urology, vascular and burns. She has worked in a variety of roles including registered nurse, clinical nurse, clinical pathways project manager and nurse educator. Currently she is the Perioperative and Procedural Areas Nurse Educator at The Prince Charles Hospital, Chermside. Her role includes the education of staff in the operating theatre, recovery, sterilising department and endoscopy unit, as well as corporate education for all hospital staff.

**Presenter:** Merv Neal  
**Organisation:** Victorian Hospitals Industrial Association (VHIA)  
**Modules:** 5.4 Implementing a Workplace Wellness Program  
5.8 Conducting Challenging Conversations

Merv Neal has owned and operated his own businesses for more than 30 years, and is presently the CEO of Laughteryoga International. He is an Associate Fellow of the Australian Institute of Management and an Affiliate Member of the National Speakers Association, where he received the Mentor of the Year for 2004, and Speaker of the Year nominee for 2006.



Merv now spends his time as a professional speaker, trainer and facilitator in the areas of strategic business planning, leadership, culture and stress management.

**Presenter:** Dr Patricia Nicholson (Melbourne)  
**Organisation:** State-based Nurse Educator  
**Module:** 3.5 Introduction to Operating Theatre Protocols

Patricia Nicholson comes with a wealth of experience in perioperative nursing and education. She coordinates the Master of Advanced Nursing Practice Degree at the University of Melbourne's School of Health Science. Patricia teaches across a range of nursing subjects, including perioperative nursing and midwifery.



Patricia is an Executive member of the Victorian Perioperative Nurses Group. She was the Victorian representative on the Australian College of Operating Room Nurses Board for 4 years. During this time she chaired the review of the 2010 – 11 ACORN Standards. Patricia has recently completed her PhD in education, which was focused on the development and validation of clinical competencies.

**Presenter:** Dr Sue O'Malley  
**Organisation:** Medical Intelligence  
**Modules:** 4.2 Achieving a Successful Application for the Prostheses List  
4.3 Understanding the MSAC Process  
4.4 Preparing an MSAC Submission

Dr O'Malley is the principal consultant and founder of Medical Intelligence, a consulting business specialising in all areas of Australian health technology assessment (HTA) excluding pharmaceuticals. In recent years Medical Intelligence has become one of the few specialist consultancies covering reimbursement for surgical, diagnostic and pathology procedures, medical devices and prostheses. Sue submitted her first application to the Medical Services Advisory Committee (MSAC) for Medicare Benefits Schedule (MBS) funding in 1999 and by 2011 has been involved in more applications than any other individual. She has also submitted numerous applications to the Prostheses and Devices Committee (PDC), now Prostheses List Advisory Committee (PLAC), for the funding of a wide variety of prostheses through listing on the Prostheses List.



Dr O'Malley started as a Health Economist in 1993, as Principal Economist for the Northern Sydney Area Health Service. This appointment followed several years working as a senior public servant working as both an Economist and a Policy Coordinator. Since starting in the health industry she has worked in biotechnology, pharmaceutical and medical devices companies. She holds a Masters Degree in Public Economics and has recently been awarded a Doctorate of Philosophy based on a thesis by publication titled Funding issues of new and emerging medical technology in Australia.

**Presenter:** Anna Pannuzzo  
**Organisation:** Victorian Hospitals Industrial Association (VHIA)  
**Module:** 5.10 Bullying and Harassment: Avoiding a David Jones Situation

Anna Pannuzzo is the Senior HR Consultant and Manager of the HR Services Unit at the Victorian Hospitals Industrial Association (VHIA). In addition, Anna delivers training on a number of VHIA's core HR and Management courses. She brings to her training and consulting over 20 years experience in senior Human Resource roles.



Prior to joining VHIA, Anna worked in aged care, health and community services, local government, TAFE, higher education and the Accident Compensation Commission. Anna has a Diploma of Science Nursing, Bachelor of Business (Human Resources and Industrial Relations) and Certificate IV Training and Assessment. She is a member of the Australian Human Resources Institute and an Associate Fellow of the Australian College of Health Service Executives.

**Presenter:** David Ross  
**Organisation:** MTA  
**Module:** 4.2 Achieving a Successful Application for the Prostheses List

David Ross is the Director Healthcare Access at MTA. His role is to encourage the development of strategies to improve patient access to new medical technology.



Since joining the industry association in 2001, he has been heavily involved in providing industry's input to proposed reforms of prostheses benefits arrangements leading to the current Prostheses List arrangements. He has also participated in preparation of the MTA's submissions to the Government's Health Technology Assessment Review.

David was a member of the Prostheses and Devices Committee from its inception in 2004 to its last meeting in June 2010. He is a member of the Prostheses List Advisory Committee.

His first career was in the Australian Army where he experienced a range of staff, regimental and training appointments in Australia and overseas. He has an MBA from Southern Cross University, has been a board member of Research Australia and is currently on the board of Sunshine Homes.

**Presenter:** Ece Smrdelj  
**Organisation:** SeerPharma  
**Module:** 1.4 Developing Technical Documentation for Medical Technology

Ece Smrdelj has over 20 years experience in the pharmaceutical and medical device industries having worked both locally and internationally.

Ece's expertise is in quality assurance, validation, training, new product registration and introduction, pre-approval inspections, vendor inspections and manufacturing including API, biologics and sterile and non-sterile dosage forms. She has wide experience in quality management system development, implementation and improvements, device conformity assessment, ISO 13485 implementation GAP analysis, design control and training in Australia & SE Asia.



**Presenter:** Cliff Spong  
**Organisation:** MTAA  
**Modules:** 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  
 1.5 Understanding Clinical Evidence for Medical Technology

Cliff Spong joined MTAA in late 2005 and is Director of Regulatory and Scientific Affairs.

Cliff has a Bachelor of Engineering and Master of Biomedical Engineering degrees from the University of New South Wales. He is a Fellow of the Institution of Engineers Australia. Following his Masters degree, Cliff established the first rehabilitation engineering department in a public hospital in eastern Australia at Royal South Sydney Hospital in conjunction with the University of New South Wales. During this time he also lectured in post graduate biomechanics at the University.



After working for Telectronics as Head of the Biomechanical Research Group; and Telstra, in the areas of occupational health and safety and risk management, Cliff moved to the Therapeutic Goods Administration where he spent 12 years in various senior positions in the medical devices regulatory program.

**Presenter:** David Strangward  
**Organisation:** Victorian Hospitals Industrial Association (VHIA)  
**Modules:** 5.7 Managing Work Priorities and Delegation  
 5.9 Managing Conflict in the Workplace

David Strangward has consulted to many of Australia's largest organisations in banking, insurance, mining, training, telecommunications in a variety of roles from project management, large IT systems implementation, customer relationship management and training.

David has extensive and varied business, IT and training experience. He is a CEO and Managing Director of two organisations and in these roles uses his extensive leadership and management skills while focusing on strategy development and implementation, business strategy development, and staff development and training.

His leadership skills, team focus and integrity continue to earn him the respect of his colleagues and clients.



**Presenter:** Louise White  
**Organisation:** SeerPharma  
**Modules:** 1.6 Risk Analysis and the Development of Medical Technology  
 1.7 Risk Management for Medical Technology Companies from a Regulatory Perspective  
 1.10 Biohazards and Sterilisation

Louise White has over 20 years experience in the biotech and the pharmaceutical industries in sterile manufacturing, Quality Assurance (QA) and consulting. Louise has provided QA oversight over a variety of validation projects, as well as preparing validation documentation associated with many capital works projects. She has conducted GMP compliance audits and gap analysis for international companies. Louise has developed many GMP training courses including self-paced computer-based training.



Louise's areas of expertise include GxP training program development and delivery, FDA/TGA and EU cGMP compliance and gap analysis, quality management systems and validation across devices, pharmaceuticals and biologics.

**Presenter:** Suzanne M. Williams  
**Organisation:** Mobius Medical  
**Modules:** 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

Suzanne studied Applied Biological Science at Manchester University in the UK graduating in 1993. Suzanne joined ICON Clinical Research (UK), as a Clinical Research Associate, enjoying exposure to many therapeutic areas within the pharmaceutical clinical trials arena. A year later, Suzanne moved to Australia to help establish ICON's new Sydney office in 1997. She went on to gain extensive experience of 'big pharma' clinical trials management at Searle, Pharmacia and Pfizer.



In 2003, Suzanne set up a consulting business independently contracting for several overseas companies, solely in the area of medical device clinical trial management. Managing the local sites for a number of diverse studies, Suzanne gained expertise in medical device clinical trials in a diverse range of therapeutic areas including cardiovascular, gynaecology and reproductive medicine. In 2006, Suzanne joined the clinical team at Ventracor, assisting with the successful completion of the pivotal trials that enabled the company to obtain the CE mark of the device.

Suzanne is one of the founding members of Mobius Medical Pty Ltd and her role focuses on liaising with clients and the clinical investigational staff to develop, initiate, resource and project-manage a wide variety of medical device clinical trials. Armed with her thorough understanding of theoretical and practical aspects of GCP, Suzanne offers advice and conducts training programs for clinical research personnel.

# Career Pathways for the Medical Technology Industry

Fostering life-long learning

## Initial Qualification

Completed undergraduate tertiary studies available through tertiary providers e.g. universities, TAFE colleges

## Workplace Experience

One or more initial postgraduate years in the work place.

## Short Courses

MTAA courses designed for the medical technology industry

- 1.0 Medical Technology Regulation and Clinical Activities**  
→ Regulatory, Quality Assurance
- 2.0 MTAA Code of Practice**  
→ Medical Company Representatives, Marketing, Communications, Customer Service
- 3.0 Working with Healthcare Professionals**  
→ Medical Company Representatives, Biomedical Engineering
- 4.0 Reimbursement of Medical Technology**  
→ Reimbursement
- 5.0 Workforce Development**  
→ All
- 6.0 Commercial Practices**  
→ Commercial

## Post-graduate Courses

- Certificate/Diploma
- Masters/PhD

## Personal and Career Development

# Learning Pathways

Stage of Professional Development	Target Audience	Area of Responsibility	Modules for Completion
<i>To be completed during the:</i>			
<b>First six months working in the medical technology industry</b>	Newly recruited staff to the medical technology industry or tertiary students	<ul style="list-style-type: none"> <li>Marketing and Sales</li> <li>Regulatory</li> <li>Reimbursement</li> <li>Quality Assurance</li> <li>Research</li> <li>Commerce</li> <li>Customer Service</li> <li>Technical Services</li> <li>IT</li> <li>HR</li> <li>Professional Development</li> <li>Administration</li> </ul>	5.1 Introduction to the Australian Medical Technology Industry 2.1 Introduction to the Code of Practice
<b>First year working in the medical technology industry</b>	Staff that require an initial understanding of medical technology industry systems	<ul style="list-style-type: none"> <li>Marketing and Sales</li> <li>Regulatory</li> <li>Reimbursement</li> <li>Quality Assurance</li> <li>Research</li> <li>Commerce</li> <li>Customer Service</li> <li>Technical Services</li> <li>IT</li> <li>HR</li> <li>Professional Development</li> <li>Administration</li> </ul>	1.1 Introduction to the Regulation of Medical Technology in Australia 2.2 Complying with the Code of Practice 4.1 Introduction to Reimbursement of Medical Devices in Australia 5.12 WHS Fundamentals
<b>First year working with the media</b>	Staff that require an understanding of media skills who have no formal training in PR or communications	<ul style="list-style-type: none"> <li>Marketing</li> <li>PR</li> <li>Communications</li> </ul>	5.15 Media Skills
<b>Continued practice in the medical technology industry</b>	Staff continuing to work in the medical technology industry	<ul style="list-style-type: none"> <li>Marketing and Sales</li> <li>Regulatory</li> <li>Reimbursement</li> <li>Quality Assurance</li> <li>Research</li> <li>Commerce</li> <li>Customer Service</li> <li>Technical Services</li> <li>IT</li> <li>HR</li> <li>Professional Development</li> <li>Administration</li> </ul>	5.4 Implementing a Workplace Wellness Program 5.8 Conducting Challenging Conversations 5.9 Managing Conflict in the Workplace 5.10 Bullying and Harassment: Avoiding a David Jones Situation 5.11 Planning Projects
<b>First six months working directly with healthcare professionals</b>	Staff interacting with healthcare professionals who are not from a healthcare or science background	<ul style="list-style-type: none"> <li>Administration</li> <li>Marketing and Sales</li> <li>Customer Service</li> <li>Commerce</li> <li>IT</li> <li>HR</li> <li>Professional Development</li> </ul>	3.1 Understanding Medical Terms 3.2 Language of the Human Body 3.9 Introduction to Anatomy and Physiology 3.10 The Cardiovascular System 3.11 The Digestive System 3.12 The Endocrine System 3.13 The Integumentary System 3.14 The Lymphatic System 3.15 The Muscular System 3.16 The Nervous System 3.17 The Reproductive System 3.18 The Respiratory System 3.19 The Skeletal System 3.20 The Urinary System

Stage of Professional Development	Target Audience	Area of Responsibility	Modules for Completion
<i>To be completed during the:</i>			
<b>First year working directly with healthcare professionals and/or hospitals</b>	Staff interacting with healthcare professionals and/or entering the perioperative environment	<ul style="list-style-type: none"> <li>Medical Company Representatives</li> <li>Technical Services</li> </ul>	3.3 Infection Prevention 3.4 Hospital Protocols 3.7 Professional Conduct 3.8 Patient Privacy and Confidentiality
<b>First six months entering the perioperative environment</b>	Medical company representatives new to entering the perioperative environment	<ul style="list-style-type: none"> <li>Medical Company Representatives</li> </ul>	3.5 Introduction to Operating Theatre Protocols
<b>Continued practice in the perioperative environment</b>	Experienced medical company representatives entering the perioperative environment.	<ul style="list-style-type: none"> <li>Medical Company Representatives</li> </ul>	3.6 Operating Theatre Protocols Update
<b>First six months working in marketing, sales or regulatory affairs</b>	Staff wishing to advertise medical technology	<ul style="list-style-type: none"> <li>Marketing and Sales</li> <li>Regulatory</li> </ul>	2.3 Advertising Therapeutic Goods in Australia
<b>First two years working in regulatory affairs</b>	Regulatory affairs professionals needing to understand the regulatory controls in Australia	<ul style="list-style-type: none"> <li>Regulatory</li> </ul>	1.2 Advanced Review of the Regulation of Medical Technology in Australia 1.3 Quality Management Systems and Conformity Assessment Procedures (QMS & CA) 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
<b>First two years working in reimbursement</b>	Reimbursement professionals needing to understand the associated policies and processes	<ul style="list-style-type: none"> <li>Reimbursement</li> <li>Research</li> </ul>	4.2 Achieving a Successful Application for the Prostheses List 4.3 Understanding the MSAC Process 4.4 Preparing an MSAC Submission
<b>First two years working in commercial issues</b>	Professionals needing to understand commercial issues	<ul style="list-style-type: none"> <li>Commerce</li> <li>Risk Management</li> </ul>	6.1 Government Health Procurement: Agencies and Processes 6.2 Government Health Procurement: Responding to Proposals
<b>First two years working in customer support</b>	Professionals unraveling requirements for meeting customer needs	<ul style="list-style-type: none"> <li>Customer Support</li> </ul>	5.16 Customer Focus
<b>First year working in management</b>	New managers	<ul style="list-style-type: none"> <li>Managers</li> </ul>	2.2 Complying with the Code of Practice 5.2 Introduction to Leadership and Management 5.3 Management and Leadership Essentials 5.4 Implementing a Workplace Wellness Program 5.5 The Emotionally Intelligent Leader 5.6 High Performing Teams 5.7 Managing Work Priorities and Delegation

“The presenter used lots of examples to assist me to understand a very complicated process, very good!”

## Modules by Month

Date	Module Title	Location	Time
February	17 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm
March	12 3.5 Introduction to Operating Theatre Protocols	Brisbane	9:30 – 10:30 am
April	11 5.4 Implementing a Workplace Wellness Program	Online	9:30 – 10:30 am
	20 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm
May	9 5.5 The Emotionally Intelligent Leader	Online	9:30 – 10:30 am
June	13 5.6 High Performing Teams	Online	9:30 – 10:30 am
July	11 5.7 Managing Work Priorities and Delegation	Online	9:30 – 10:30 am
August	8 5.8 Conducting Challenging Conversations	Online	9:30 – 10:30 am
	17 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm
September	12 5.9 Managing Conflict in the Workplace	Online	9:30 – 10:30 am
	14 3.5 Introduction to Operating Theatre Protocols	Melbourne	9:30 am – 4:30 pm
October	10 5.10 Bullying and Harassment: Avoiding a David Jones Situation	Online	9:30 – 10:30 am
	12 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm
	29 3.5 Introduction to Operating Theatre Protocols	Brisbane	9:30am – 4:30 pm
November	16 3.5 Introduction to Operating Theatre Protocols	Melbourne	9:30 am – 4:30 pm
December	7 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm

## Face-to-face modules available through Expressions of Interest

Interested participants can register an Expression of Interest for any of the modules listed below by emailing [pd@mtaa.org.au](mailto:pd@mtaa.org.au). Dates will be provided to registrants when minimum numbers to hold a module have been reached. The location will depend on 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 Regulation of Medical Technology	Sydney
1.2 Advanced Review of the Regulation of Medical Technology	Sydney
1.3 Quality Management Systems and Conformity Assessment Procedures (QMS and CA)	Sydney, Brisbane
1.4 Developing Technical Documentation for Medical Technology	Sydney, Melbourne
1.5 Understanding Clinical Evidence for Medical Technology	Sydney
1.6 Risk Analysis and the Development of Medical Technology	Sydney, Melbourne
1.7 Risk Management for Medical Technology Companies from a Regulatory Perspective	Sydney, Melbourne
1.8 Introduction to the Regulation and Design of Clinical Investigations for Medical Technology in Australia	Sydney
1.9 Improving Your Clinical Investigations for Medical Technology	Sydney
1.10 Biohazards and Sterilisation	Sydney, Melbourne
<b>2.0 MTAA Code of Practice</b>	
2.2 Complying with the Code of Practice	Sydney
2.3 Advertising of Therapeutic Goods in Australia	Sydney
<b>4.0 Reimbursement of Medical Technology</b>	
4.2 Achieving a Successful Application for the Prostheses List	Sydney
4.3 Understanding the MSAC Process	Sydney
4.4 Preparing an MSAC Submission	Sydney
<b>5.0 Workforce Development</b>	
5.15 Media Skills	Sydney, Melbourne
<b>6.0 Commercial Practices</b>	
6.2 Government Health Procurement: Responding to Proposals	Sydney

# Frequently Asked Questions (FAQs)

## Q1. What types of activities fall under the MTAA professional development program?

There are a range of activities that can be attended. These included course modules, MedTech Forums, MedTech Seminars, Webytes, CEO Forums and industry special interest events. For some training events, pre-requisite modules or equivalent industry experience is recommended.

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

All MTAA activities must be registered to and paid for via the online registration system, unless otherwise stated. All course modules are available under *Professional Development* on the MTAA website ([www.mtaa.org.au](http://www.mtaa.org.au)).

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

Attendance at a professional development event may be cancelled up to 5 working days in advance. Attendees from the same organisation may be swapped up to 2 days in advance if MTAA is advised and has agreed in writing.

To make a cancellation or swap an attendee, please contact reception by P: +612 9900 0650 and/or E: [pd@mtaa.org.au](mailto:pd@mtaa.org.au). No refunds are offered within 5 working days of a training event. Please ensure that you always refer to the individual cancellation policy on the booking page prior to registering.

## Q4. Do I receive proof of participation at a course module?

For every module you complete, a *Certificate of Participation* will be awarded (excluding module 5.1). For the Operating Theatre Protocol modules, an MTAA photo ID card will be issued pending a successful assessment, where a digital passport photograph is provided via email to [pd@mtaa.org.au](mailto:pd@mtaa.org.au) by the due date.

Participants that complete training online will receive their *Certificate of Participation* by email. Those completing training face-to-face will receive it on the day, excluding module 3.5 *Introduction to Operating Theatre Protocols* who will receive it by email after the training, pending successful completion of assessments.

## For Face-to-Face Training

### Q5. Are meals included?

Morning tea is provided for morning sessions run from 9:30 am to 12:30 pm. For a full day program, morning tea, lunch and afternoon tea is provided.

Refreshments are provided 15 minutes before the commencement of the event. Special dietary requirements may be requested at the time of registration.

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

Public transport is regularly available in each capital city. For assistance, please contact reception on P: (+612) 9900 0650.

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

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

#### **Brisbane**

Please view the Brisbane Tourist Information website ([www.queenslandholidays.com.au](http://www.queenslandholidays.com.au)) for a range of accommodation options.

#### **Melbourne**

Please view the Visit Melbourne website ([www.visitmelbourne.com](http://www.visitmelbourne.com)) for a range of accommodation options.

#### **Sydney**

Training in Sydney is usually conducted at the MTAA office in North Sydney. Please view the Visit NSW website ([www.visitnsw.com](http://www.visitnsw.com)) 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 the training. If you are running late, please contact MTAA reception on P: (+612) 9900 0650.

Upon arrival, please ensure you sign in as a record of your attendance. This will ensure you receive a *Certificate of Participation* following the training.

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

### Q9. What should I wear on the day?

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

If you are attending module 3.5 *Introduction to Operating Theatre Protocols*, please wear comfortable protective footwear that is appropriate for entering the perioperative environment. You will be required to change into perioperative attire before entering the operating theatre.

# Registration Information

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

## Registration

Registration for all MTAA training modules must be made online using a credit card (American Express, Visa or Mastercard), unless otherwise stated. To register for a scheduled training module, please click on the selected date listed on the website course page. Complete your details and payment following the onscreen prompts.

For unscheduled face-to-face modules, please email MTAA your Expression of Interest. Please click the *Register Your Interest* link next to the requested module and include your full name, preferred location to attend the training, email address and phone number. To register Expressions of Interest for a number of company staff at once, please complete the [online form](#) available from the website.

## Training inclusions

All advertised module fees are inclusive of 10% GST, unless otherwise stated. Fees include all course materials. For face-to-face training, refreshments are provided.

## Fees

Fees to participate in training vary across modules according to the duration and delivery mode. Member and non-member rates apply to most modules.

## Changes and cancellations by registrants

Cancellations will be accepted until five working days prior to the event and are subject to a \$50 cancellation fee. No refunds are available for cancellations after this time. Substitutions are allowed up until two working days prior to the event if MTAA is advised and agrees in writing.

## Cancelled training

Training is developed for a minimum number of participants. This may vary according to the content of the module. 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 if an alternative date isn't suitable.

## Copyright

All materials, notes and content are subject to copyright and may not be reproduced, copied or otherwise in part or full without the written permission of MTAA.

## Recognition of competency

Recognition of competency is available through successful completion of specified assessment tasks where an MTAA module is aligned to a unit of competency. In this instance, participants will be assessed against the unit of competency. If deemed competent, the participant is issued with a nationally recognised *Statement of Attainment* for the unit.

For most aligned modules, assessment is conducted by the MTAA's training partner, VHIA Training. Individuals or companies interested in undertaking a VHIA assessment should contact VHIA Training on P: (+613) 9861 4000 or E: [training@vhia.com.au](mailto:training@vhia.com.au). For all other aligned modules, please contact MTAA by E: [pd@mtaa.org.au](mailto:pd@mtaa.org.au).

## Contact

For further information about MTAA professional development activities, please contact the Professional Development Manager on P: (+612) 9900 0650 or E: [pd@mtaa.org.au](mailto:pd@mtaa.org.au)

**“Excellent to have the module  
online and accessible whenever  
required. User friendly. Thanks.”**



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Association of Australia



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