



Medical Technology
Association of Australia

Training Calendar 2011



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.

Medical Technology for a Healthier Australia

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**“I gained something extra...
despite the fact I have been in
the industry for 33 years!
It was excellent!”**



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. A promotional flyer is linked to each module title on the website under course registration and may be downloaded for future reference.

Blended learning approach

MTAA offers training through a blended learning approach. This includes online self-paced modules, online small group facilitated sessions, webinars, mentored online sessions and face-to-face training. For accredited modules, 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: reception@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. All module fees are inclusive of 10% GST.

Course and Module Descriptions

MTAA offers six training courses with a range of modules. Additional modules may become available during 2011. 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 Technology course consists of a series of modules designed to assist employees working in the regulatory and/or clinical areas.

- | | | | |
|------------|--|-------------|--|
| 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 | 1.4 | 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 |

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

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

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 eventual 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; 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: Half 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, MTA
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: Steve Williams, 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: Steve Williams, 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 & the role of OH&S 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 MTAA/MTANZ 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 also available online. Fees are set on a sliding scale for members and non-members. Please visit the MTAA website for the 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 MTAA/MTANZ 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, MTAA

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, MTAA

Duration: Half day

“Liked the sharing of experiences from different backgrounds”



Working with Healthcare Professionals

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** Interpreting Medical Terminology
- 3.4** Hospital Protocols
- 3.5** Introduction to Operating Theatre Protocols
- 3.6** Operating Theatre Protocols Update (online)
- 3.7** Professional Conduct
- 3.8** Communicating Effectively with Healthcare Professionals
- 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)

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

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

Online self-paced modules follow a sliding scale for members and non-members. Fees commence at \$165 for members and \$330 for non-members.

Modules 3.1 and 3.2 are free to all registrants. Modules 3.9-3.20 from the Anatomy and Physiology Series are available at a fixed price 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.

Please note: 3.1 Understanding Medical Terminology, 3.2 Language of the Human Body and 3.3 Interpreting Medical Terminology are aligned to the unit of competence BSBMED301A: Use advanced medical terminology. Successful completion of the assessment will result in a Statement of Attainment. Modules 3.9 through to 3.20 are aligned to VET competency HLTAP401A Confirm Physical Health Status in the HLT07 Health Training Package.

3.1

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

3.2

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

Interpreting Medical Terminology

An insight into understanding commonly used medical terms.

** Please note that modules 3.1 and 3.2 are the recommended prerequisites for participants not from a healthcare or science background who are new to the industry.*

Learning outcomes

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

Presenters: Natasha Fletcher, VHIA

Duration: Half 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.

Presenters: Natasha Fletcher and David Wenban, VHIA

Duration: Half day

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 endorsed 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

3.7

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.

Presenter: David Wenban, VHIA

Duration: Half day

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

3.11

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

3.6

Operating Theatre Protocols Update

A review of current ACORN Standards with an opportunity to workshop industry specific issues relevant to the perioperative environment.

Learning outcomes

- Explores other 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 attended has been approved by ACORN will be issued upon successful completion.

3.8

Communicating Effectively with Healthcare Professionals

An evidence-based workshop on how to effectively communicate with clinicians.

Learning outcomes

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

Presenter: Professor Stewart Dunn, University of Sydney

Duration: Full day

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

3.12

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

Recognition of competence

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

Modules 3.1-3.3

Participants will be assessed against the unit of competence *BSBMED301A Use advanced medical terminology*. If deemed competent, the participant is issued with a nationally recognised Statement of Attainment for the unit.

It is recommended that the participant complete the two free online modules (3.1 and 3.2) or 3.3 face-to-face 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.

3.14 The Lymphatic System

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

Assessment is conducted by the MTAA's training partner, VHIA Training. Full information about the unit of competence 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 or companies interested in undertaking assessment should contact VHIA Training on P: (+613) 9861 4000 or E: training@vhia.com.au

Modules 3.9-3.20

All eleven modules are 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 for competency HLTAP401A, 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 three 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** Medical Devices and Surgical Procedure Reimbursement

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

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

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 a listing at the most appropriate reimbursement price.

Presenter(s): TBA
Duration: Full day

4.3 Medical Devices and Surgical Procedure Reimbursement

An analysis of the linkages between a successful MSAC application and other reimbursement pathways.

Learning outcomes

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

Presenter(s): TBA
Duration: Half day

“I found it extremely user friendly”

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 The Emotionally Intelligent Leader (online)
5.5 Building Effective Teams (online)	5.6 Negotiation: A Framework for Successful Communication (online)
5.7 Managing Conflict in the Workplace (online)	5.8 Bullying and Harassment: Avoiding a David Jones Situation (online)
5.9 Effective Performance Management (online)	5.10 Meaningful Performance Feedback (online)
5.11 Managing Work Priorities and Delegation (online)	5.12 Implementing a Workplace Wellness Program (online)
5.13 Interpreting Medical Technology Industry Data (online)	5.14 Summarising Statistical Distributions for the Medical Technology Industry (online)
5.15 Media Skills	

Fees

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

	<i>Full day</i>
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 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 further details.

Webinars are available at the following rates.
 Member fee: \$115
 Non-member fee: \$230

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 and team leader 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 The Emotionally Intelligent Leader

An introduction to emotional intelligence and how it can be applied by a leader.

Learning outcomes

- Understands emotional intelligence as it applies to leadership.

Presenter: Paula Cunniffe, VHIA
 Duration: 1 hour webinar

5.5 Building Effective Teams

An overview of the key activities involved in managing teams, team development phases and interventions to assist teams at various development stages.

Learning outcomes

- Cites interventions to assist teams at various development stages.

Presenter: David Strangward, VHIA
 Duration: 1 hour webinar

5.6 Negotiation: A Framework for Successful Communication

An examination of negotiation styles and appropriate interventions for different situations.

Learning outcomes

- Describes various communication strategies for successful negotiation.

Presenter: Merv Neal, VHIA
 Duration: 1 hour webinar

5.7 Managing Conflict in the Workplace

An overview of how communication styles affect conflict in the workplace and practical strategies for dealing with conflict.

Learning outcomes

- Is aware of the affect of communication styles on conflict in the workplace
- Appreciates a variety of practical strategies for dealing with conflict.

Presenter: Stephen Greaves, VHIA
Duration: 1 hour webinar

5.9 Effective Performance Management

An overview of successful performance appraisal and management systems, the steps involved and strategies for implementation.

Learning outcomes

- Cites the main elements of successful performance management systems.

Presenter: Paul Cunniffe, VHIA
Duration: 1 hour webinar

5.11 Managing Work Priorities and Delegation

An introduction to managing your own time, prioritisation and delegation.

Learning outcomes

- Appreciates methods for prioritising time at work to meet personal and organisational goals
- Understands the steps required to delegate work.

Presenter: David Strangward, VHIA
Duration: 1 hour webinar

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

5.8 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 outcomes

- Is aware of basic legal obligations for addressing bullying and harassment in the workplace
- Appreciates a variety of practical strategies for dealing with conflict.

Presenter: Richard Corboy, VHIA
Duration: 1 hour webinar

5.10 Meaningful Performance Feedback

An examination of a practical and universally accepted model for giving feedback in the workplace and during a performance appraisal interview.

Learning outcomes

- Describes a model for providing meaningful performance feedback in the workplace.

Presenter: Paula Cunniffe, VHIA
Duration: 1 hour webinar

5.12 Implementing a Workplace Wellness Program

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

Learning outcomes

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

Presenter: Merv Neal, VHIA
Duration: 1 hour webinar

5.14 Summarising Statistical Distributions

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

“Nicely paced and explained
with useful examples”

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 competence through VHIA assessment services

Recognition of competency is available through successful completion of specified assessment tasks. Participants will be assessed against the unit of competence *BSBMGT605A Provide Leadership Across the Organisation*. If deemed competent, the participant is issued with a nationally recognised *Statement of Attainment* for the unit.

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** The Emotionally Intelligent Leader
- 5.5** Building Effective Teams
- 5.9** Effective Performance Management
- 5.10** Meaningful Performance Feedback
- 5.11** Managing Work Priorities and Delegation
- 5.12** Implementing a Workplace Wellness Program

Assessment involves 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 is conducted by the MTAA's training partner, VHIA Training. Full information about the unit of competence 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

6.0 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

6.2 Government Health Procurement: Responding to Proposals

Fees

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

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

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.

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 Vendor Initiated Proposals (VIPs).

Learning outcomes

- Develops a basic understanding of responding to procurement proposals (e.g. Request for Tenders, Request for Quotes)
- Gains an understanding of the TPA and ACCC limitations (e.g. bundled product offers)
- Understands the requirements of VIPs.

Presenter(s): TBA
Duration: Half day



Presenter Profiles

Presenter:	Ruth Berghan
Organisation:	Victorian Hospitals Industrial Association (VHIA)
Module:	3.3 Interpreting Medical Terminology

Ruth Berghan has extensive business experience at executive support level in a wide range of sectors including the corporate, legal, finance and health. In addition, she has experience as a Director in the small business sector.

Ruth's experience in the health sector includes working in the Sub-Acute and Allied Health Unit, Corporate Services Unit and the Legal Office of a major Melbourne metropolitan health service.

Ruth holds a Graduate Certificate in Business and Certificate IV Training & Assessment.

Presenter:	Margaret Butler
Organisation:	State-based Nurse Educator on behalf of MTAA
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:	Richard Corboy
Organisation:	Victorian Hospitals Industrial Association (VHIA)
Module:	5.8 Bullying and Harassment: Avoiding a David Jones Situation

Richard Corboy has worked in the health industry since 1976, holding senior management positions with HR, IR, training and development and OHS responsibilities at various health services. Immediately prior to joining VHIA, Richard worked for VECCI as a Senior IR Consultant.

Richard's field of expertise includes human resource management, training, industrial relations, occupational health and safety and workers compensation. Richard's qualifications include studies in Graduate Certificate in Human Resource Management and a Certificate IV in Assessment and Workplace Training.

Presenter:	Paula Cunniffe
Organisation:	Victorian Hospitals Industrial Association (VHIA)
Modules:	5.4 The Emotionally Intelligent Leader 5.9 Effective Performance Management 5.10 Meaningful Performance Feedback 5.15 Motivating Others at Work

Paula Cunniffe is an experienced trainer/mentor/coach who has worked in management and development roles for over 20 years. She has designed and delivered management development programs across a range of industries, including clients in the health sector. Having been a practitioner in management/staff development programs, providing guidance and support to managers and teams, Paula is skilled in delivering workshops that focus on interpersonal skills such as mentoring, coaching, staff counselling, conflict resolution and mediation.

Paula also facilitates a Leadership Program for Leadership Management Australia, focussing on the development of effective leadership and management skills. She manages a program called Bizness Babes which is sponsored by the Wise Foundation and supported by The Body Shop.

Paula's qualifications include: Graduate Diploma of Business (Organisation Dynamics) from Swinburne University of Technology; Bachelor of Social Sciences (Hons) from University College, Dublin and Certificate IV in Workplace Training. Paula is also an accredited Myers-Briggs Type facilitator.

Presenter:	Natasha Cushway
Organisation:	Victorian Hospitals Industrial Association (VHIA)
Module:	3.3 Interpreting Medical Terminology

Natasha Cushway holds dual qualifications in nursing and law. She is currently employed as an Employment/IR Consultant at VHIA specialising in nursing issues, employment and industrial law and the disability sector. Natasha is a Registered Nurse Division 1.

Natasha's background includes specialisations in acute surgical nursing in the areas of urology and gynaecology. She maintains currency in her nursing practice.

Presenter:	Stefan Czyniewski
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 Fournier Pharma (now Solvay Pharmaceuticals) 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:	Professor Stewart Dunn
Organisation:	University of Sydney
Module:	3.8 Communicating Effectively with Healthcare Professionals

Stewart Dunn is Professor of Medical Psychology at the Sydney Medical School, based at Royal North Shore Hospital, and Visiting Medical Psychologist at the Mater Hospital, North Sydney. He has extensive teaching commitments in the USyd Medical Program and has published widely on doctor-patient communication, and psychological predictors of morbidity and mortality in medical illness. His clinical specialty is the psychological care of cancer patients and their families. He is Director of the Pam McLean Centre, which develops evidence-based simulations of difficult cancer communication situations for health professionals, using professional actors.

Presenter:	Alan Edgecomb
Organisation:	Alan Edgecomb
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 and most recently the Quality and Service Manager for an Australian start-up company, ImpediMed Limited.

Alan has been involved with ISO 9001 and ISO 13485 quality management systems for the last 13 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)
Modules:	5.5 Building Effective Teams 5.7 Managing Conflict in the Workplace

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 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.

Two + You Leadership Design coaches and leads individuals and organisations in developing strong leadership capabilities including team development.

Presenter:	Alina Hughes
Organisation:	Medical Technology Association of Australia (MTAA)
Modules:	2.2 Complying with the Code of Practice 2.3 Advertising of Therapeutic Goods in Australia

Alina Hughes joined the 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 2003-2008, 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 2008-2010 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:	Helen Kierce
Organisation:	Victorian Hospitals Industrial Association (VHIA)
Modules:	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 on behalf of MTAA
Modules:	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, Chermshire. 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:	5.6 Negotiation: A Framework for Successful Communication 5.12 Implementing a Workplace Wellness Program

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:	Patricia Nicholson (Melbourne)
Organisation:	State-based Nurse Educator on behalf of MTAA
Module:	3.5 Introduction to Operating Theatre Protocols

Patricia Nicholson comes with a wealth of experience in nursing education. Patricia teaches adult acute care (majoring in perioperative and anesthetic nursing), as well as general nursing and midwifery at the University of Melbourne's School of Nursing and Social Work, where she holds the position of Coordinator of Postgraduate Specialty Programs.

Patricia is an Executive member of the Victorian Perioperative Nurses Group and is the Victorian Director for the Australian College of Operating Room Nurses including current Chair for the ACORN 2010 – 2011 Standards. Patricia is currently on a leave of absence from the University in order to complete her PhD.

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:	Medical Technology Association of Australia (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)
Module:	5.11 Managing Work Priorities and Delegation

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 utilises his extensive leadership and management skills whilst focusing on:

- strategy development and implementation
- business strategy development
- staff development and training.

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

Presenter:	David Wenban
Organisation:	Victorian Hospitals Industrial Association (VHIA)
Modules:	3.3 Professional Conduct 3.4 Hospital Protocols

David Wenban is Principal Legal Consultant for the Victorian Hospitals Industrial Association; Director, Health Financial Pty Ltd; and Director VHIA Health Communications.

David brings a wealth of health sector experience to his current roles. With his unique combination of knowledge and qualifications in executive management, legal and clinical aspects of the industry David is well placed to train and advise on professional conduct and hospital protocols.

David's previous postings include Corporate Counsel, Western Health and Chief Executive Officer, Cobram District Hospital.

Presenter:	Louise White
Organisation:	SeerPharma
Module:	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:	Steve Williams
Organisation:	SeerPharma
Modules:	1.4 Developing Technical Documentation 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

Steve Williams has over 35 years experience in the Life Sciences industry in Quality Assurance, Manufacturing and Consulting. He has conducted numerous FDA and TGA/PICs compliance audits and gap analysis for many international companies as well as developed multiple training courses for GMP, GLP, Validation, Risk Management, HACCP and Medical Devices. He regularly presents at conferences and industry seminars on a range of subjects relating to QA, Risk Management and GMP compliance. Steve also specialises in e-Learning compliance training solutions for intranet delivery within the Life Sciences industry.

Steve has consulted in QA, GMP, GLP and Validation since 1989 and has prepared many companies for regulatory inspections. Steve is also a registered auditor for the Australian Pesticides and Veterinary Manufacturing Authority (APVMA) and in this role, conducts GMP licensing audits on behalf of the Australian government.

Steve's areas of expertise include Risk Assessment, FDA/TGA and EU cGMP Compliance & Gap Analysis, Quality Assurance, Quality Management Systems (QMS) and Medical Device QMS, e-Learning/training specialist, Validation, Sterile Products, Good Laboratory Practices (GLPs), Hazard Analysis and Critical Control Point (HACCP) and GMP, GLP and validation training.

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.

“The open discussion of experiences in different situations was terrific”

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/MTANZ 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>			
First six months working in the medical technology industry	Newly recruited staff to the medical technology industry or tertiary students	<ul style="list-style-type: none"> Marketing and Sales Regulatory Reimbursement Quality Assurance Research Commerce Customer Service Technical Services IT HR Professional Development Administration 	5.1 Introduction to the Australian Medical Technology Industry 2.1 Introduction to the Code of Practice
First year working in the medical technology industry	Staff that require an initial understanding of medical technology industry systems	<ul style="list-style-type: none"> Marketing and Sales Regulatory Reimbursement Quality Assurance Research Commerce Customer Service Technical Services IT HR Professional Development Administration 	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
First year working with the media	Staff that require an understanding of media skills who have no formal training in PR or communications	<ul style="list-style-type: none"> Marketing PR Communications 	5.15 Media Skills
Continued practice in the medical technology industry	Staff continuing to work in the medical technology industry	<ul style="list-style-type: none"> Marketing and Sales Regulatory Reimbursement Quality Assurance Research Commerce Customer Service Technical Services IT HR Professional Development Administration 	5.6 Negotiation: A Framework for Successful Communication 5.7 Managing Conflict in the Workplace 5.8 Bullying and Harassment: Avoiding a David Jones Situation 5.11 Managing Work Priorities and Delegation 5.12 Implementing a Workplace Wellness Program
First six months working directly with healthcare professionals	Staff interacting with healthcare professionals who are not from a healthcare or science background	<ul style="list-style-type: none"> Administration Marketing and Sales Customer Service Commerce IT HR Professional Development 	3.1 Understanding Medical Terms 3.2 Language of the Human Body 3.3 Interpreting Medical Terminology 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>			
First year working directly with healthcare professionals and/or hospitals	Staff interacting with healthcare professionals and/or entering the perioperative environment	<ul style="list-style-type: none"> Medical Company Representatives Technical Services 	3.4 Hospital Protocols 3.7 Professional Conduct 3.8 Communicating Effectively with Healthcare Professionals
First six months entering the perioperative environment	Medical company representatives new to entering the perioperative environment	<ul style="list-style-type: none"> Medical Company Representatives 	3.5 Introduction to Operating Theatre Protocols
Continued practice in the perioperative environment	Experienced medical company representatives entering the perioperative environment.	<ul style="list-style-type: none"> Medical Company Representatives 	3.6 Operating Theatre Protocols Update
First six months working in marketing, sales or regulatory affairs	Staff wishing to advertise medical technology	<ul style="list-style-type: none"> Marketing and Sales Regulatory 	2.3 Advertising Therapeutic Goods in Australia
First two years working in regulatory affairs	Regulatory affairs professionals needing to understand the regulatory controls in Australia	<ul style="list-style-type: none"> Regulatory 	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
First two years working in reimbursement	Reimbursement professionals needing to understand the associated policies and processes	<ul style="list-style-type: none"> Reimbursement Research 	4.2 Achieving a Successful Application for the Prostheses List 4.3 Medical Devices and Surgical Procedure Reimbursement
First two years working in commercial issues	Professionals needing to understand commercial issues	<ul style="list-style-type: none"> Commerce Risk Management 	6.1 Government Health Procurement: Agencies and Processes 6.2 Government Health Procurement: Responding to Proposals
First year working in management	New managers	<ul style="list-style-type: none"> Managers 	5.2 Introduction to Leadership and Management 5.3 Management and Leadership Essentials 5.4 The Emotionally Intelligent Leader 5.5 Building Effective Teams 5.9 Effective Performance Management 5.10 Meaningful Performance Feedback 5.11 Managing Work Priorities and Delegation 5.12 Implementing a Workplace Wellness Program 2.2 Complying with the Code of Practice

Modules by Month

Date	Module Title	Location	Time
February	18 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm
March	9 5.4 The Emotionally Intelligent Leader	Online	9:30 – 10:30 am
April	1 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm
	13 5.5 Building Effective Teams	Online	9:30 – 10:30 am
May	9 3.5 Introduction to Operating Theatre Protocols	Brisbane	9:30 am – 4:30 pm
	11 5.6 Negotiation: A Framework for Successful Communication	Online	9:30 – 10:30 am
June	8 5.7 Managing Conflict in the Workplace	Online	9:30 – 10:30 am
July	1 3.5 Introduction to Operating Theatre Protocols	Melbourne	9:30 am – 4:30 pm
	13 5.8 Bullying and Harassment: Avoiding a David Jones Situation	Online	9:30 – 10:30 am
August	10 5.9 Effective Performance Management	Online	9:30 – 10:30 am
September	7 5.10 Meaningful Performance Feedback	Online	9:30 – 10:30 am
	9 3.5 Introduction to Operating Theatre Protocols	Sydney	9:30 am – 4:30 pm
October	12 5.11 Managing Work Priorities and Delegation	Online	9:30 – 10:30 am
	21 3.5 Introduction to Operating Theatre Protocols	Melbourne	9:30am – 4:30 pm
November	7 3.5 Introduction to Operating Theatre Protocols	Brisbane	9:30 am – 4:30 pm
	9 5.12 Implementing a Workplace Wellness Program	Online	9:30 – 10:30 am
December	9 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 reception@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
1.0 The Regulation of Medical Technology	
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	Melbourne
1.5 Understanding Clinical Evidence for Medical Technology	Sydney
1.6 Risk Analysis and the Development of Medical Technology	Melbourne
1.7 Risk Management for Medical Technology Companies from a Regulatory Perspective	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	Melbourne
2.0 MTA/MTANZ Code of Practice	
2.2 Complying with the Code of Practice	Sydney
2.3 Advertising of Therapeutic Goods in Australia	Sydney
3.0 Working with Healthcare Professionals	
3.3 Interpreting Medical Terminology	Melbourne
3.4 Hospital Protocols	Melbourne
3.7 Professional Conduct	Melbourne
3.8 Communicating Effectively with Healthcare Professionals	Sydney
4.0 Reimbursement of Medical Technology	
4.2 Achieving a Successful Application for the Prostheses List	Sydney
4.3 Medical Technology and Surgical Procedure Reimbursement (MSAC)	Sydney
5.0 Workforce Development	
5.15 Media Skills	Sydney, Melbourne
6.0 Commercial Practices	
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 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 activities through the MTAA 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).

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

Attendance at a professional development 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 in writing.

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

Q4. Are meals included at face-to-face training?

Morning tea is provided for morning sessions run from 9:30 am to 12:30 pm. Afternoon sessions from 1:30pm to 4:30pm include afternoon tea. For a full day's training or where participants are attending a morning and afternoon session on the same day, morning tea, lunch and afternoon tea is provided.

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

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

For every module you complete a Certificate of Participation will be awarded (excluding 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 reception@mtaa.org.au by the due date.

Q6. How do I get to the training site?

Public transport is regularly available in each capital city. For assistance, please contact reception on 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

MTAA training is currently conducted at the Stamford Hotel, pending venue availability. Hotel accommodation is available onsite or in close proximity to the venue. Please view the Brisbane Tourist Information website (www.queenslandholidays.com.au) for a range of accommodation options.

Melbourne

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

Sydney

The closest hotel to the MTAA office is the Harbourview Hotel in North Sydney. A range of hotels are available in Sydney. Please view the Visit NSW website (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 to face-to-face training?

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 *3.5 Introduction to Operating Theatre Protocols*, please wear comfortable shoes that are 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 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 (face-to-face only), email address and phone number. To register Expressions of Interest for a number of company staff at once, please complete the [online form](#) available on the website.

Training inclusions

All advertised module fees are inclusive of 10% GST, unless otherwise specified. 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.

Changes and cancellations by registrants

Cancellations will be accepted until 5 days prior to the event and are subject to a cancellation fee of \$50. No refunds are available for cancellations after this time. Substitutions are allowed until 48 hours prior to the event.

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.

Copyright

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Recognition of competency (accredited modules only)

Recognition of competency is available through successful completion of specified assessment tasks. Participants will be assessed against the unit of competence. If deemed competent, the participant is issued with a nationally recognised Statement of Attainment for the unit.

For most accredited modules, assessment is conducted by the MTAA's training partner, VHIA Training. Individuals or companies interested in undertaking assessment should contact VHIA Training on P: (+613) 9861 4000 or E: training@vhia.com.au

Contact

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

“The fact that you can leave at any stage and come back to where you left is excellent”



Medical Technology Association of Australia

30 YEARS SUPPORTING MEDICAL TECHNOLOGY IN AUSTRALIA



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