Medical Device TGA Update: Audit Program and Compliance Trends

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Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

Why do we need a QMS?

There are two key requirements of conformity assessment procedures for medical devices that a manufacturer must implement:

- A Quality Management System (QMS) for the design, production, packaging, labelling and final inspection of a device, and
- Inspection and quality assurance techniques that are to be applied during the production of a device

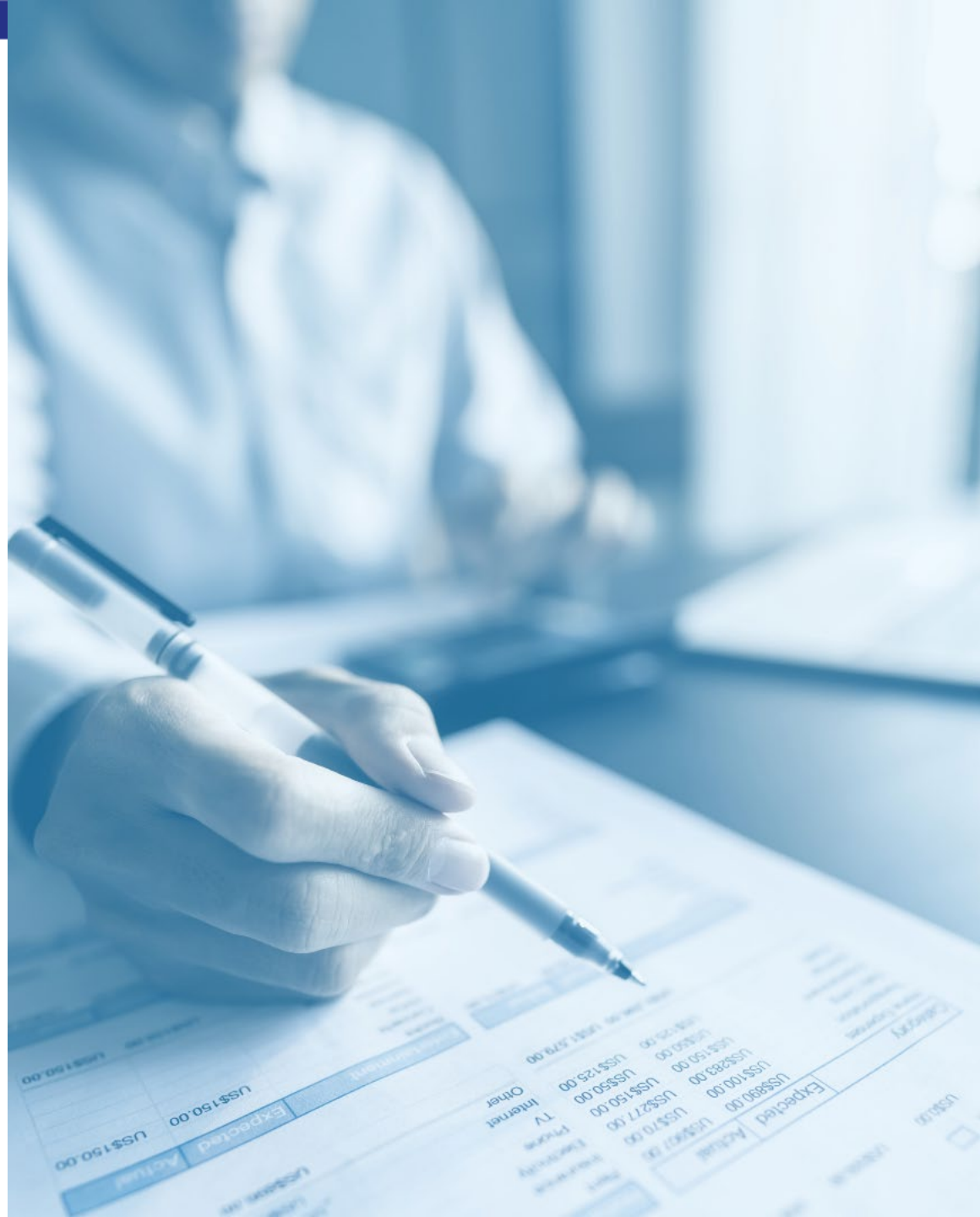
The Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019 specifies relevant medical device standards for quality management systems and medical devices intended to be supplied in a sterile state.

The Order ensures that if a manufacturer's QMS, or inspection and quality assurance techniques, comply with the relevant standards specified in the Order, the TGA will treat the QMS, or the inspection and quality assurance techniques, as if they comply with the parts of the conformity assessment procedures specified in the Order.

Auditing Criteria

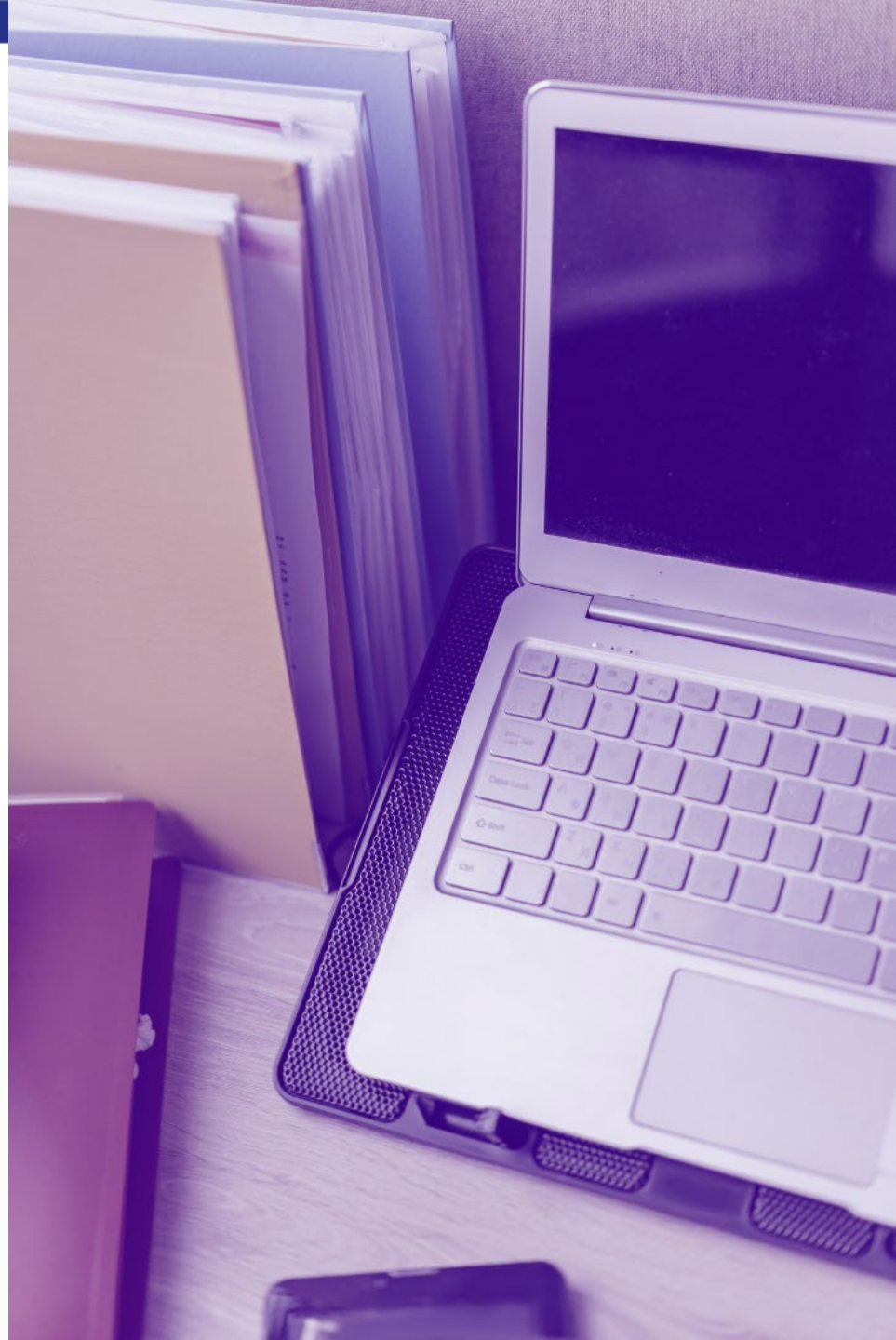
TGA audits are conducted to establish compliance with the following:

- *Therapeutic Goods Act 1989*
- *Therapeutic Goods (Medical Devices) Regulations 2002*
- ISO 13485:2016 Medical Devices
- Conditions of existing TGA issued certificates (if applicable)
- State of the art requirements



Medical Device Single Audit Program

- Aka “MDSAP”
- Allows recognised Auditing Organisations (private / commercial) to conduct audits of a medical device manufacturer that will satisfy the relevant Quality Management System requirements of multiple participating Regulatory Authorities.
- Is a single program of audits; Referred to as a “single” audit program
- Development from 2012 by the International Medical Device Regulators Forum (IMDRF)
- Now includes over 7,500 manufacturing sites from 83 countries
- 35,000+ audits conducted
- Approximately 80% audited against Australian regulations.
- Audits performed by 17 Auditing Organisations (AO’s)



MDSAP: International Consortium

MDSAP international consortium of countries:

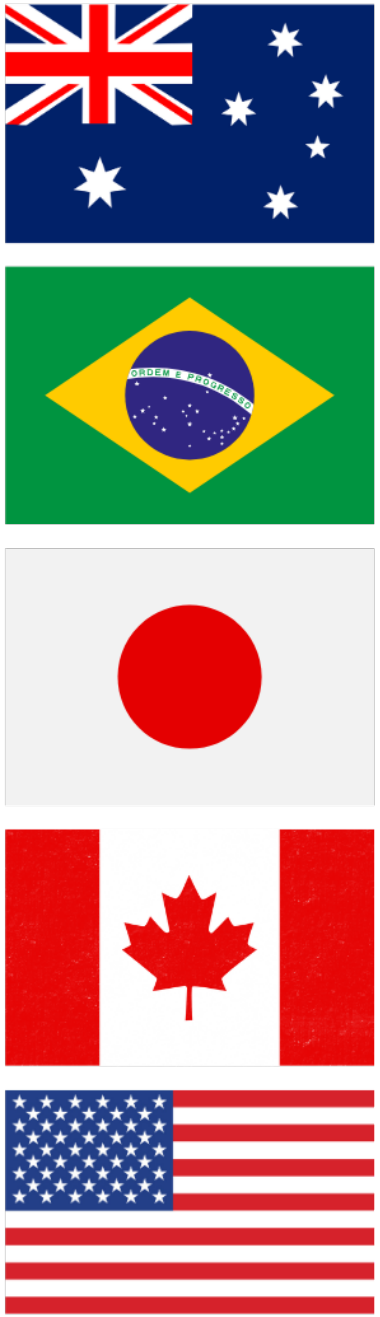
- Therapeutic Goods Administration (TGA) of Australia,
- Brazil's Agência Nacional de Vigilância Sanitária (ANVISA),
- Health Canada,
- Japanese Ministry of Health Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), and
- U.S. Food and Drug Administration (US FDA)

Observers:

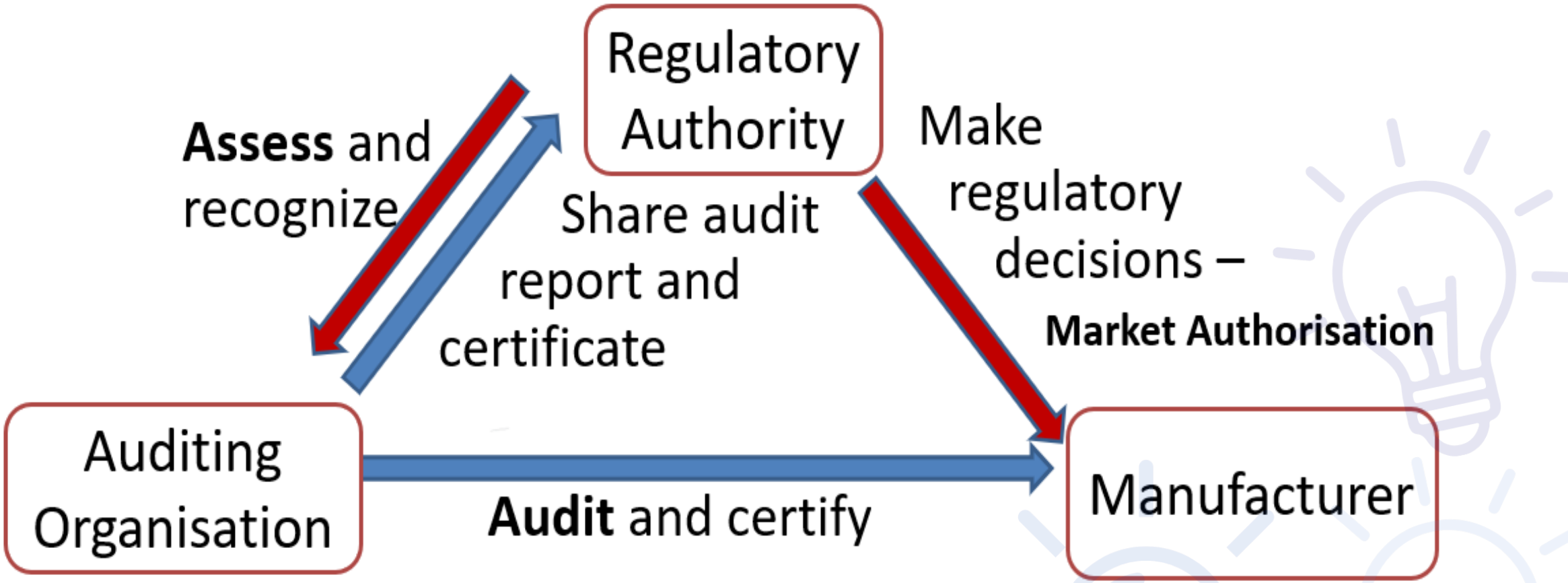
- World Health Organisation (WHO) Diagnostic Prequalification Program
- Singapore's Health Sciences Authority (HSA)
- European Union
- UK Medicines and Health Products Regulatory Agency (MHRA)

Affiliates:

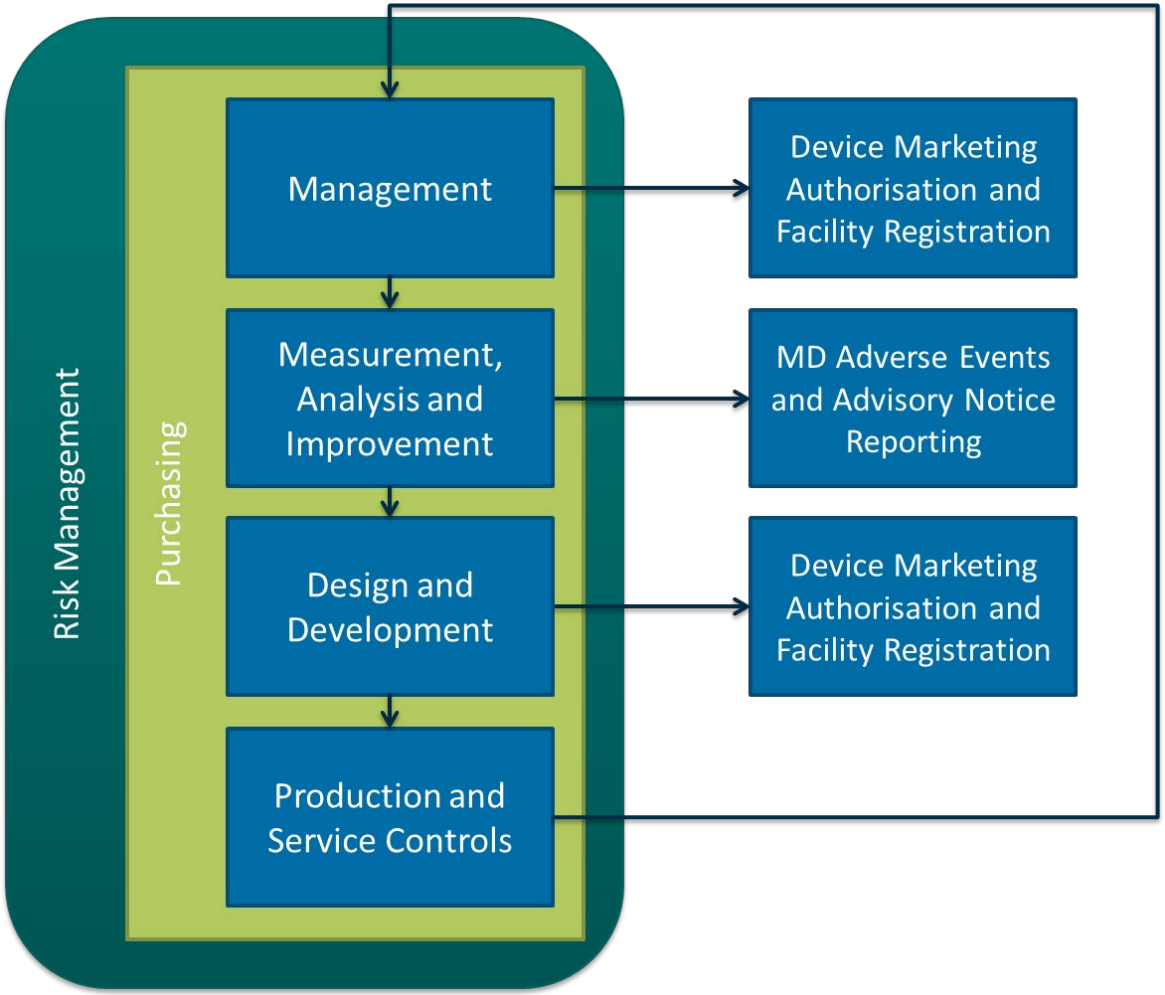
- Argentina, Israel, Kenya, South Korea, Mexico, and Taiwan regulators.



MDSAP Concept



MDSAP Audit Sequence

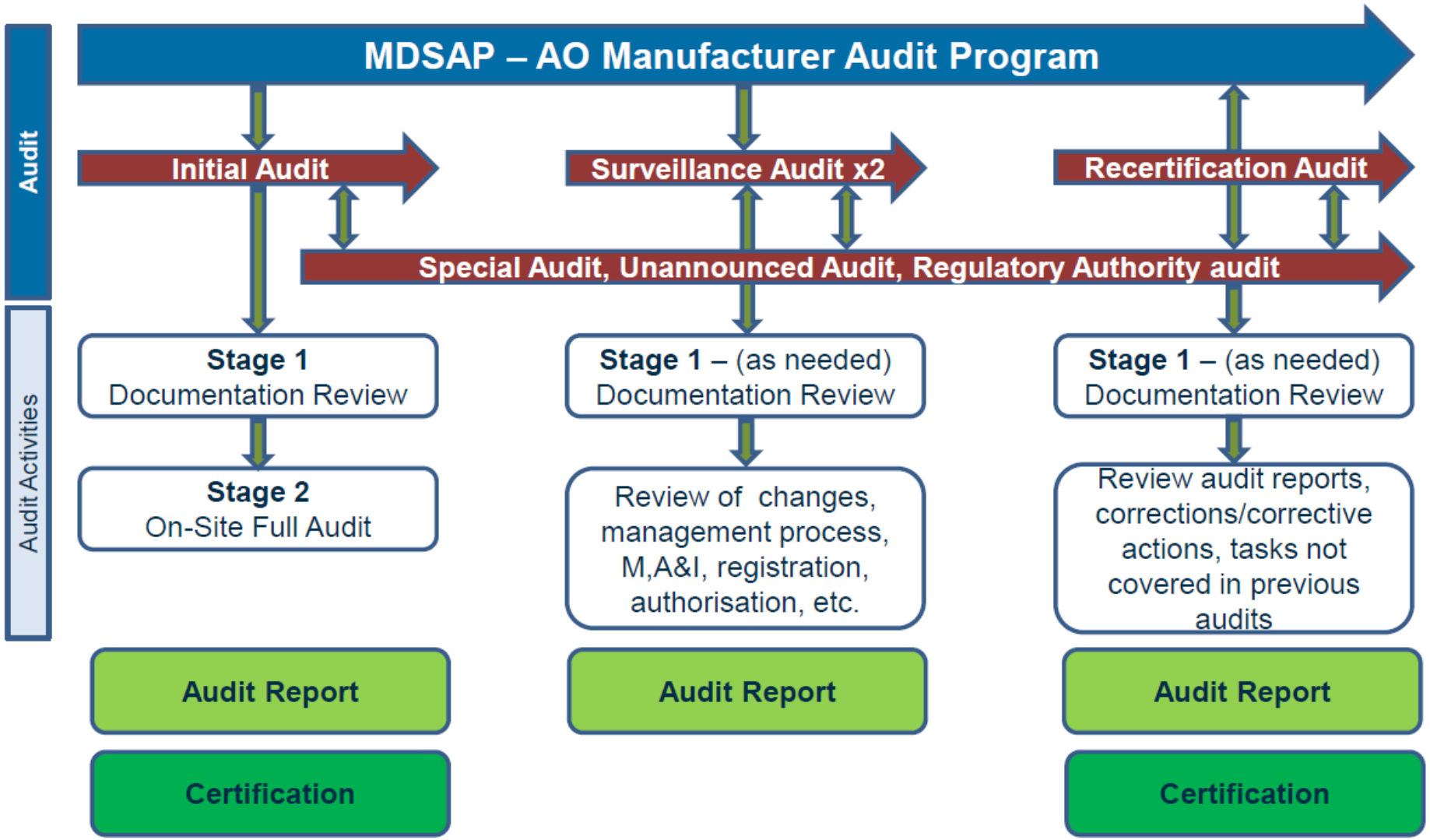


MDSAP	Policy Title: MDSAP AUDIT APPROACH	Document No: MDSAP AU P0002.010
		Revision Date: 2026-02-06

MDSAP
Medical Device Single Audit Program

AUDIT APPROACH

Typical 3 Year Audit Program Cycle



TGA Use of MDSAP

Pre-market

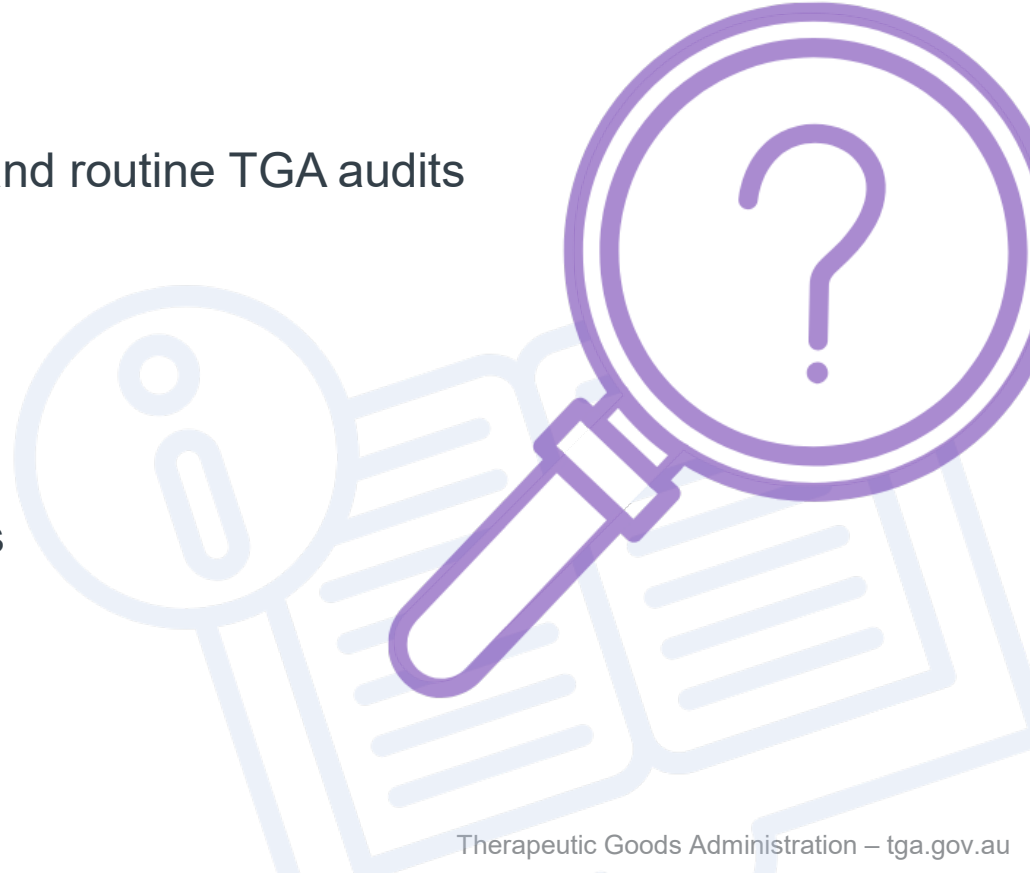
- Accept MDSAP certificates as manufacturing evidence (certificate has to include Australian jurisdiction in scope)
- Consider MDSAP Audit Reports to abridge TGA Conformity Assessment

TGA Audits

- TGA may accept MDSAP Reports as a substitute for initial and routine TGA audits

Post Market Surveillance

- 5 day notices reported (based on high grade nonconformities issued, cases of fraud or public risk)
- Access to audit packages as another input for data analytics
- For-cause audits by regulatory authorities



Class IIb (Regulation 3.7)	TGA	CAC - MD Regulations Schedule 3[1]	Part 1 – Full Quality Assurance (excluding clause 1.6 Design Examination)	N/A
			Part 3 – Verification (for non-sterile devices), or Part 4 – Production Quality Assurance, or Part 5 – Product Quality Assurance (for non-sterile devices)	Part 2 – Type Examination
	EU	EU MDD 93/42/EEC[2]	Annex II.3	N/A
			Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V, or Annex VI (for non-sterile devices)	Annex III – Type Examination
		EU 90/385/EEC (AIMDD) for AIMD[3]	Annex 2.3	N/A
		EU MDR[4]	Annex IX, Chapter I (QMS)	For a relevant implantable medical device[5]—an EU technical documentation assessment certificate issued under Chapter II of Annex IX of the EU medical devices regulation
			Annex XI (Product Conformity Verification)	Annex X – Type Examination
	UK	UK MDR 2002 under applied directive 93/42[5] (MDD)	Annex II.3	N/A
			Annex IV (for non-sterile devices where specific batches are included on the certificate), or Annex V, or Annex VI (for non-sterile devices)	Annex III – Type Examination
		UK MDR 2002 under applied directive 90/385[3] (AIMDD)	Annex 2.3	N/A
	Japan	Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency	QMS certificate, or MDSAP Certificate	Pre-market certificate
	Health Canada	MDR SOR/98-282[7]	MDSAP Certificate	Medical device licence Class III
	FDA	DeNovo	MDSAP Certificate	De Novo Decision Summary
		Premarket Notification - 510(k)		510(k) – Summary
		Premarket Approval (PMA)	MDSAP Certificate (or PMA)	PMA
	Singapore	Health Sciences Authority (HSA)	Extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C medical device	N/A

Use of Comparable Overseas Evidence

For MDSAP certificates and audit reports to be considered, the Australian regulatory requirements must have been covered in the audit(s), and certificates must show that the manufacturer has been assessed and found to comply with the relevant aspects of the Therapeutic Goods (Medical Devices) Regulations 2002

https://www.tga.gov.au/resources/guidance/use-market-authorisation-evidence-comparable-overseas-regulators-and-assessment-bodies-medical-devices-including-ivds

Risk signals

- Looking for areas of risk
- Post-market signals
- Reviewing MDSAP reports

Non-duplicative

- Accounting for areas already reviewed by third parties
- Addressing outstanding concerns

Technical

- Regulatory compliance
- Product and process technologies

TGA Audit Program

Current directions

- Agile audit program
- Account for equivalent evidence
- Remove duplication
- Incorporate risk-based signals

Review of Nonconformities in TGA Audits

- Overseas & domestic audits FY 2021 – 2023
- On-site and remote (desktop audits excluded)
- Manufacturers of all categories

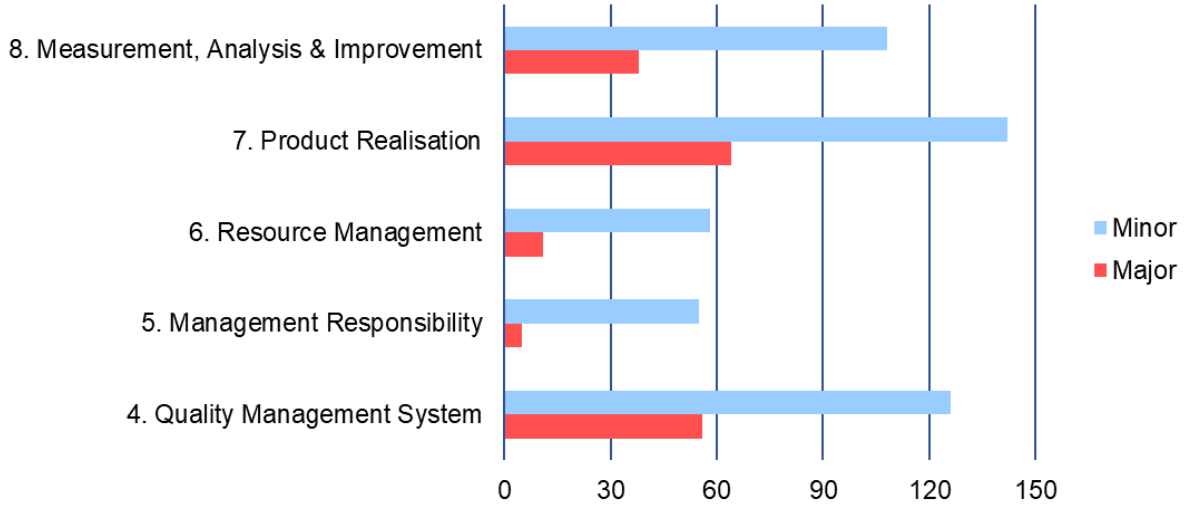
Number of audits conducted		
	FY 2021-22	FY 2022-23
Domestic	24	17
Overseas	4	14

Overall Nonconformity Trends

Nonconformities per Audit

	Domestic	Overseas	Combined
Major NCs per Audit	3.4	1.9	2.9
Minor NCs per Audit	8.4	7.9	8.3

ISO 13485 Nonconformities



Essential Principles

General

1. Use of medical devices without compromise to health and safety
2. Design and construction of devices to confirm with safety principles
3. Suitability for intended purpose
4. Long-term safety
5. Safe transport and storage
6. Benefits to outweigh undesirable effects

Other

7. Chemical, physical and biological properties(for hardware devices)
8. Infection and microbial contamination (for hardware devices)
9. Construction and environmental properties (applies to all)
10. Medical devices with a measuring function (for non-IVD devices with a measuring capability)
11. Protection against radiation (for medical devices that generate radiation)
12. Medical devices connected to or equipped with an energy source (‘active’ medical devices)
13. Provided information (applies to all)
14. Clinical evidence (applies to all)
15. Principles applying to IVD medical devices (IVDs only)

Standards Applied – Essential Principle 2

Most common nonconformity - Cl 4.2.1 & Cl 4.1

2 Design and construction of medical devices to conform with safety principles

(1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.

(2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:

(a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and

(b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and

(c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and

(d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.

(3) In paragraph (2)(d):

residual risk, for a medical device, means the risk remaining after the measures described in paragraphs (2)(a), (b) and (c) have been applied.

State-of-the-art is generally enforced as International (e.g. ISO) or National (e.g. EN, AS) standards

Standards Applied – Essential Principle 2

Sterile Devices

- ISO 11135 (Ethylene Oxide)
- ISO 11137 (Gamma)
- ISO 13408 (Aseptic)
- ISO 17665 (Steam)
- ISO 11607 (Sterile barriers)

Risk Management

- ISO 14971

Device Requirements

- IEC 62304 (software)
- IEC 60601 (electrical)
- ISO 10993 (biocompatibility)
- ISO 22442 (animal origin)
- ISO 18562 (ventilators)
- PIC/S PE009-16 (medicinal)

Testing & Environments

- ISO 11737 (micro, sterility, endotoxin)
- ANSI/AAMI ST 72 (endotoxin)
- EN IS 17141 (biocontamination)
- ISO 14644 (cleanrooms)
- USP/BP/EP (monographs)

1. 7.4.1 Purchasing
2. 8.5.2 Corrective Action
3. 7.5.1 Production and Service Control
4. 8.2.4 Internal Audit

Common Nonconformities

Other Common Nonconformities

- **Purchasing**
  - Evaluation criteria
  - Supplier monitoring
- **Corrective action**
  - Corrections instead of corrective action
  - Delays
  - Unclear investigations
  - No evidence of planning
- **Production and service control**
  - Process control and traceability
  - Equipment qualification
- **Internal audit**
  - Auditor competence
  - Including narrative
  - Objectivity and impartiality
  - State-of-the-art requirements

When is software (including AI) a medical device

Manufacturer's intended purpose is critical

Software is a medical device when the manufacturer *intends* for their product to be used for:

- diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury or disability
- compensation for an injury or disability
- investigation of the anatomy or of a physiological process
- to control conception

Software that is an accessory to another medical device.

Excluded software

There are 15 conditional exclusions (in 6 groups) that may capture certain software-based devices:

Consumer health products
(e.g. wellness apps, fitness heart rate monitors, medication reminders)

Digitisation
(e.g. digital versions of paper-based patient surveys)

Population-based analytics
(e.g. research or population-based screening – bowel cancer program)

Digital mental health tools
(e.g. meditation and mindfulness applications, CBT)

Enabling technology
(e.g. telehealth and eScript software)

Laboratory Information Management Systems
(e.g. workflow automation software, pathology reporting)

https://www.tga.gov.au/products/medical-devices/software-and-artificial-intelligence-ai/overview/software-based-medical-device-exclusions

Exempt software

There is an exemption for certain Clinical Decision Support System (CDSS) software that are:

- **intended** to be for the sole purpose of **providing or supporting** a **recommendation** to a **health professional** about preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; and

Sponsors **MUST** notify the TGA of their exempt CDSS devices using the:

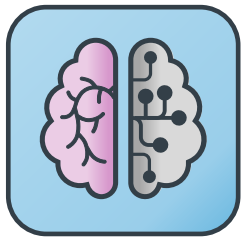
Notification form: Clinical decision support software exemption

- **not intended** by its manufacturer to **directly process or analyse** a medical image or signal from another medical device; and
- **not intended** by its manufacturer to **replace the clinical judgement of a health professional** in relation to making a clinical diagnosis or decision about the treatment of patients

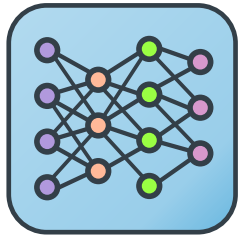
AI is regulated as a subset of medical devices

What do we consider as artificial intelligence (AI)?

AI-based systems are a subset of software that use computer programming to perform tasks that mimic human capabilities, such as understanding language, recognising objects and sounds, learning and problem solving.



Machine learning (ML)



Deep Learning

Generative AI

Large language models (LLM)

Neural networks

The regulations that apply to software-based medical devices also apply to **all subsets of AI-based software systems** that meet the **definition of a medical device.**

Evidence of compliance

Evidence generally expected for software:

IEC 62304 – Medical device software — Software life cycle processes

ISO 13485 – Medical devices — Quality management systems — Requirement for regulatory purposes

ISO 14971 – Medical devices — Application of risk management to medical devices

IEC/ISO 42001 - Information technology — Artificial intelligence — Management system

IEC/ISO 24027 - Information technology – Artificial intelligence (AI) - Bias in AI systems and AI aided decision making

This is in addition to any other standards that you identify as applicable to your product

IEC/ISO 42001 references many other applicable standards for data and model assurance, security and privacy, risk management and safety that may also apply

Meeting Types

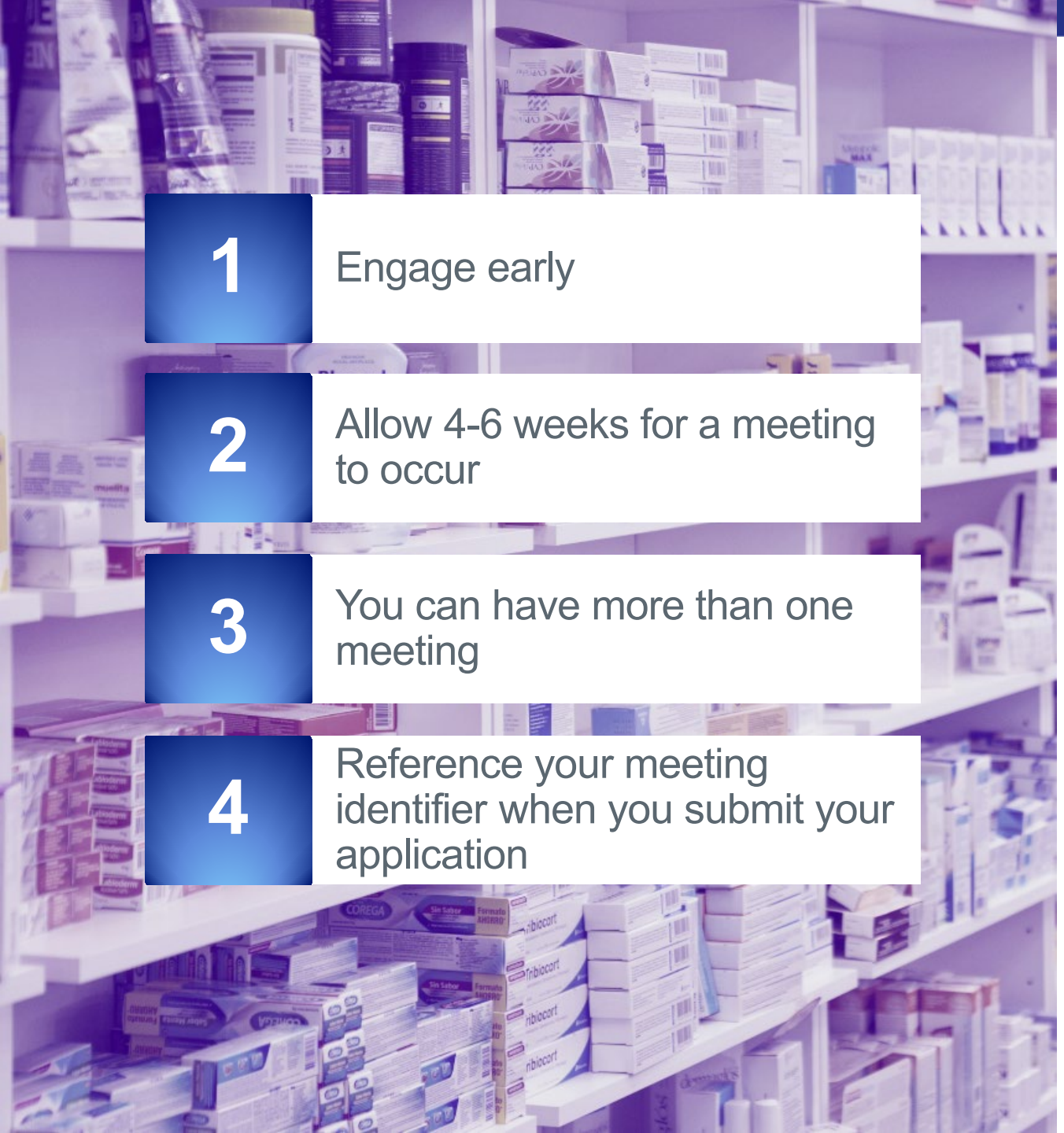
We hold a variety of meeting types under the term ‘Regulatory Engagement’, to help applicants navigate the Regulatory Framework, either at the beginning of the device journey and ongoing throughout the device lifecycle (excluding post market surveillance activities).

Scoping

Development of a medical device, understanding of Australia’s regulatory framework and expectations over this device development cycle.

Pre-submission

Discussion with the TGA regarding one or two specific concerns relating to a specific kind of medical device.



Regulatory Engagement Meetings

Take Home Messages

- To request a regulatory engagement meeting:
  - Via our guidance page, including request forms at Medical device regulatory engagement meetings | Therapeutic Goods Administration (TGA).
  - The team will acknowledge and contact you in response.

General inquiries regarding devices can be sent to devices@tga.gov.au.

Software enquiries can be sent to digital.devices@tga.gov.au.

Questions?

www.tga.gov.au

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration