AUSTRALIA IVD REGULATORY MAP

A practical orientation for global RA teams entering Australia

START HERE: WHAT IS THE PRODUCT IN AUSTRALIA?

1 Confirm Australian regulatory identity

Confirm the intended purpose, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Determine the classification under the Australian IVD classification structure (TGA) and whether the device is a commercial IVD or in-house IVD.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS 1	CLASS 2	CLASS 3	CLASS 4
Lowest risk	Low–moderate risk	Moderate–high risk	Highest public-health risk
Low individual and public health risk. Generally subject to basic controls.	Moderate individual and low public health risk. Requires greater controls than Class 1.	High individual or moderate public health risk. Requires stronger conformity assessment and audit requirements.	High individual and high public health risk. Most stringent conformity assessment and audit requirements.

This is the Australian IVD classification structure under the TGA.
Most commercial IVDs require inclusion on the Australian Register of Therapeutic Goods (ARTG).
Higher classes face stronger conformity assessment and audit requirements.

3 Build the Australia market-access infrastructure

TGA framework / ARTG inclusion
Understand the Therapeutic Goods Act 1989, IVD Essentials, conformity assessment, and inclusion pathway on the ARTG.

Australian sponsor / local representation
Appoint an Australian sponsor (or authorised representative) responsible for compliance, ARTG maintenance, and TGA communications.

Conformity assessment evidence & QMS readiness
Compile required technical documentation and evidence. Ensure QMS meets TGA expectations; be ready for audits and inspections.

English labeling / commercialization readiness
Prepare English labeling, instructions for use (IFU), claims, and promotional materials compliant with TGA requirements.

4 Build the evidence stack

Administrative
Device description, intended use, indications, market claims, and regulatory history.

Quality / QMS
QMS aligned with ISO 13485 and TGA expectations; stability and shelf-life evidence.

Analytical performance
Method performance, precision, accuracy, reportable range, interference, and comparability.

Clinical / scientific performance
Clinical performance evidence or scientific evidence supporting intended use, risk controls, and claims.

Labeling & IFU
English labeling and IFU, symbols, safety warnings, claims, and user instructions.

RA TRAP TO AVOID

Do not begin with "What is the Australia timeline?" Begin with product identity → classification → Australian sponsor → evidence → ARTG route. The timeline is the result of those decisions.

STRATEGIC INSIGHT:

In Australia, sponsor setup, correct classification, and audit expectations drive the timeline. Plan early to avoid costly delays.

AUSTRALIA IVD: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch

A Program flow

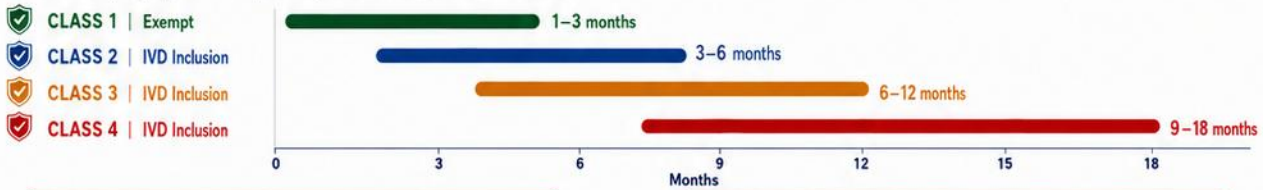
1. **Scope** — Define intended use and product family
2. **Classify** — Apply Australian IVD classification (Class 1–4)
3. **Sponsor setup** — Appoint an Australian Sponsor and confirm obligations
4. **Conformity assessment strategy** — Determine evidence requirements and assessment pathway
5. **Evidence** — Generate and evaluate performance, analytical and clinical evidence
6. **Submit / include in ARTG** — Include the device in the ARTG via TGA (IVD inclusion)
7. **Launch / maintain** — Market authorization, post-market controls, changes, vigilance

B What gets heavier as the class rises?

Signal	CLASS 1	CLASS 2	CLASS 3	CLASS 4
Pathway intensity	Exempt (self-assessment) ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Analytical performance expectations	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Clinical / scientific support	Not usually required ○ ○ ○ ○ ○	Limited ● ● ○ ○ ○	Moderate ● ● ● ○ ○	Extensive ● ● ● ● ●
QMS readiness	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Post-market control	Lower ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	Higher ● ● ● ○ ○	Highest ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product complexity, evidence quality, application completeness, audit outcomes, and TGA workload.



Exempt (Class 1) IVDs are not included in the ARTG, but must comply with all applicable requirements.

ARTG inclusion timelines are guidance only; actual times vary by product, evidence, audit, and TGA workload.

D Labeling & language essentials

English-language support
All labeling and IFU must be in English. Translations must be accurate and validated.

Product labeling
Labels must include required information, warnings, cautions, precautions, and symbols per TGA guidance.

Instructions for use
Provide complete IFU for safe use, including intended use, limitations, and step-by-step instructions.

Claims control
Claims must be supported by evidence and consistent with intended use.

Product identifier / traceability documentation
Include UDI where required and maintain traceability records as per obligations.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- **Therapeutic Goods Administration (TGA) – Medical devices overview**
  https://www.tga.gov.au/medical-devices
- **TGA – In vitro diagnostic medical devices inclusion in the ARTG (IVD inclusion)**
  https://www.tga.gov.au/inclusion-ivd-in-artg
- **TGA – Australian Sponsor guidance**
  https://www.tga.gov.au/australian-sponsor-guidance
- **Hopestone Capital & Consulting** — hopestonecapital.com

IMPORTANT

Product-specific Australian requirements and current TGA guidance govern.
Confirm classification, evidence, labeling, and submission obligations before execution.