

# How the TGA uses MDSAP

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# Process

- Approval for supply in AU; three stage process
  - EU styled Conformity Assessment (CA)
  - Submission of Manufacturer's Evidence
  - Marketing Authorisation – ARTG inclusion (MA)
- CA has both product and QMS components
  - MDSAP is to provide evidence of a Manufacturer's QMS for regulatory purposes
  - Manufacturer = Name on labelling

# Conformity Assessment

- AU Regulations require that some products must have TGA CA certifications for product and QMS
  - Incorporate medicinal substances
  - Incorporate animal material in the design or production process
  - Incorporate material of a microbial or recombinant origin in the design or production process
  - Class IV IVDs (Blood testing, Disease screening)
- Some of these are loosely referred to as “combination” products












# Manufacturer's Evidence and Marketing Authorisation

- The Australian Sponsor submits
  - Manufacturer's QMS Certification
  - Where relevant, Product Design Certification
- Is a pre-requisite for marketing authorisation
- MA allows the TGA to make the final decision as evidence may come from many sources;
  - EU Notified Bodies
  - Other Comparable Overseas Regulators (MDSAP)
  - Manufacturers or Critical Suppliers

# MDSAP use for TGA CA

TGA Issued CA Certification	MDSAP Use by TGA
<p>For Schedule 3 Part 1 for Regulation 4.1 devices;</p> <ul style="list-style-type: none"><li>- Incorporating a medicine</li><li>- Animal, microbial, recombinant origin</li><li>- “combination” products</li><li>- Class IV IVDs</li></ul>	<p>Audit Reports for Manufacturers &amp; Critical Suppliers used to abridge TGA’s QMS compliance verification audits for initial/ surveillance/ recertification.</p> <p><b>Additional information / audit likely</b> required by TGA within the 5 year CA Certification cycle</p>
<p>For all other currently issued TGA QMS Certifications for the CA procedures</p>	<p>Eligible to replace TGA issued QMS Certifications for the CA procedures</p>

# Evidence for AU CA Procedures

Devices	TGA CA QMS	EU CA QMS	MDSAP QMS
Regulation 4.1 Devices		 Eligible to abridge	 Eligible to abridge
Other currently issued TGA Certificates for QMS			
Other not requiring or without CE Certification			
All Others			

# Evidence

- Initial and Recertification Audits
  - Full audits cover all aspects of the QMS and Regulatory Requirements
- Surveillance Audits
  - Elements covered over 2 audits in a cycle.
- May require the TGA to review a number of audit reports for a cycle to determine a understanding of the extent of QMS compliance.

# MDSAP use for MA

AU Marketing Authorisation	Use by TGA
Products that <b>must</b> be selected for an “Application audit” prior to MA (Regulation 5.3)	MDSAP Certifications initially accepted as Manufacturer’s evidence. Audit Reports may be used to review QMS compliance prior to MA
Any other products that <b>may</b> be selected for an “Application audit” prior to MA	QMS Certifications initially accepted
Other products for which there is no EU QMS Certification	QMS Certifications initially accepted



# MDSAP for Post-Market

Post-Market Surveillance	Use by TGA
TGA Issued CA Certificates	Audit Reports and status of certification used for monitoring continuing QMS compliance
Adverse Event / Recall follow-up	Audit Reports used for monitoring continuing QMS compliance and implementation of corrective action plans

# Post-Market

- 5-Day Notices
  - Grade 5 or more than 2 Grade 4s
  - Fraudulent Activity
  - Public Health Threat
- Reviewed by Device Vigilance and Monitoring Section for action or referral
  - Adverse Event Investigation
  - Recall Action
  - Suspension / Cancellation of the ARTG inclusion
  - Enforcement actions

# Comparable Overseas Regulator Guidance



Australian Government

Department of Health

Therapeutic Goods Administration

Use of market authorisation evidence  
from comparable overseas regulators /  
assessment bodies for medical devices

For abridgement of TGA conformity assessments and as  
supporting information for applications for ARTG inclusion

# Other uses

- To promote regulatory convergence
  - Format and content of Audit Report
  - Consistent requirements for 3<sup>rd</sup> parties operating on behalf of the participating RAs
  - Sharing of resources and information with Regulatory Authorities

# Contact / Questions

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