



TGA - Use of MDSAP



TGA Use of MDSAP



MDSAP is used for both pre-market and post market CA certification decisions and also to support Marketing Authorisation.

- Over 400 medical devices have been included on the ARTG using MDSAP certificates as evidence.
- Over 130 TGA audits have been postponed or cancelled.
- Approximately 70% of manufacturer's holding a TGA CA certificate have entered the MDSAP.
- Over 3500 MDSAP participating sites are now audited against TGA regulatory requirements.



- MDSAP Audit Reports can be provided as a form of evidence to demonstrate a manufacturer's QMS meets requirements (for all conformity assessment routes and device classes).
- QMS assessment may be abridged IF the MDSAP audit report contains sufficient evidence of compliance. The TGA will initially perform a desktop assessment of the QMS instead of an on-site audit.

If gaps are identified, the TGA options include:

- request AO to provide specific information if missing from the audit report, or
- directly request information from the Sponsor (Manufacturer), or
- request the AO to audit specific content (at a special audit or at the next scheduled audit), or
- if options above are not suitable, perform a TGA on-site audit.

Gaps identified in the MDSAP audit process or report content will be relayed back to the AO to drive continuous improvement.

Examples of gaps identified in the MDSAP audit reports:

- Site may not have been physically assessed under MDSAP (for example, the report only contained evidence of supplier controls for a critical supplier performing all steps of manufacture).
- There may not be a report available in the Regulatory Exchange Platform (REPS). Some reports are not available 12 months after the audit.
- TGA regulatory requirements not covered in audit scope – incorrectly excluded by the AO.
- Specific products are not covered (for example, the AO has sampled products outside of the TGA DE/CA certificate device category scope).

Examples of gaps identified in the MDSAP audit reports:

- Critical processes not covered (for example, sterilisation, validation and Reg 4.1 requirements)
- Poor audit report quality (for example, objective evidence not available in the narrative).
- Timing of the MDSAP audit pre-dates the applicable change (for example, a new sterilisation supplier that was added after the last audit).
- MDSAP Report provided was a surveillance audit and did not include full audit model scope.



See '[Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices \(including IVDs\)](#)' for detailed guidance.



Australian Government
Department of Health
Therapeutic Goods Administration

Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)

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

Version 1.3, July 2019

TGA Health Safety
Regulation



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM