MDSAP
an AO's Success Story

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What is MDSAP?

- Program allows to conduct a single audit for the following regulatory authorities:
- Australia (TGA)
- Brazil (ANVISA)
- Canada (HC)
- Japan (MHLW/PMDA)
- US (USFDA)

What is MDSAP?

Other RAs utilize MDSAP:

MDSAP Official Observers

- European Union (EU)
- Singapore's Health Sciences Authority (HSA)
- United Kingdom (MHRA)
- The World Health Organization's (WHO)

MDSAP Affiliate Members

- Argentina
- Israel
- Kenya
- Republic of Korea
- Mexico (COFEPRIS)
- Taiwan (TFDA)
- South Africa
- Malaysia

	Affiliate member	Official observer
Engages with MDSAP	X	X
Observes & Contributes to MDSAP activities, projects, work groups		X
DOES NOT participate in decision making of MDSAP	X	X
Observe MDSAP assessments and participate as Assessor		X
Annual MDSAP forum (OPEN)	X	X
Annual MDSAP forum (CLOSED)		X
Meetings, TCs (Open to RAC and Observers)		X
Meetings, TCs (Closed – RAC only)		
List of Participating manufacturers	X	X
Access to MDSAP audit reports / certificates	X Request through manufacturer	X Access via MDSAP IT portal

MDSAP Overview

- MDSAP is based on *ISO 13485*, with additional guidance on specific RA needs. MDSAP incorporates an assessment program to oversee the compliance of AOs and ensures appropriate competency and training of RA assessors.
- These requirements include, but are not limited to:
- IMDRF/MDSAP WG/N6 – Regulatory Authority Assessor Competence and Training Requirements
- IMDRF MDSAP WG/N3 – Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
- IMDRF MDSAP WG/N4 – Competence and Training Requirements for Auditing Organizations
- IMDRF MDSAP WG/N11 - MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization.

MDSAP Overview

- Audit results in standardized MDSAP Audit Report ensuring the reporting requirements of all participating RAs are effectively documented.
- After the audit an MDSAP certificate is issued. Certificate is used by RAs and can be verified via MDSAP AO.
- Not all MDSAP RAs consider MDSAP audit reports and certificates an alternative to the inspection and assessment requirements for combination products.

MDSAP Benefits to RAs

MDSAP Aims to:

- Ensure Regulatory oversight of QMS while minimising regulatory burden on industry
- Promote more efficient and flexible use of regulatory resources
- Promote globally greater alignment of regulatory approaches and technical requirements
- Promote consistency, predictability, and transparency of regulatory programs by:
  - standardizing the practices and procedures
  - Leveraging requirements and procedures for conformity assessment, and
  - standardizing the practices and procedures
- Each MDSAP RA uses the program in a different way and may also add additional requirements. MDSAP RAs remain the authority for marketing authorization within their jurisdictions.

What improved with MDSAP for AOs?

More work was outsourced from the RA inspectors to AOs – **more business**, more entry points to do business with manufacturers

- Previous to MDSAP, 3rd parties did: CMDCAS audits, JPAL audits (only can be performed by Japanese auditors), factory inspections (e.g. for INMETRO Brazil)
- Other activities (now in MDSAP scope) were done by government inspectors (e.g. US FDA routine inspections, Brazil GMP inspections)

What improved with MDSAP for AOs?

- ISO 13485 implies that CB auditors should know and enforce **regulatory requirements** applicable for the certified organization's target markets (e.g. to audit clauses 4.1.1, 4.1.3.e, 4.1.4, 4.2.1.e, 4.2.3, 8.2.3, 8.3.3…).
- With MDSAP, the auditors' competence in the various regulatory frameworks (first just the 5 MDSAP member countries, then also for observers and affiliates as well) improved, not only for MDSAP but for standalone ISO 13485 audits as well

What improved with MDSAP for AOs?

- The immediate and highly construtive **work relationship** with the other **AOs and MDSAP RAC** members (AU TGA, BR ANVISA, Health Canada, JP PMDA+MHLW, US FDA) now serves as a template for other regulators (e.g. between EU NBs and designating authorities and other EU NCAs)
- MDSAP documents were more **transparent** from day 1 than many other regulatory documentation, including EU at the time.

What improved with MDSAP for AOs?

- **Standardized concepts** that can also be used in other schemes (that don't define these as clearly or at all):
  - (Practical) **Critical suppliers** definition
  - Critical suppliers to include in-country representation like AU Sponsor
  - **Significant changes**
  - Raising awareness to standard contents (e.g. **Disclosure of residual risks** in ISO 14971) or other GMP practices (e.g. **pest control** from Brasil requirements)
- The **MDSAP audit approach** engrained a logical audit flow and process linkages to strengthen the efficiency of medical audits

What improved with MDSAP for AOs?

- Improved **contractual terms** that help the AO (also with combined audit), for example:
  - Clients cannot object to audit team composition unless there's a conflict of interest - which makes it easier to bring **trainees** to audits

MDSAP Benefits to AOs - Summary

Experience:

- Clear expectations of RAC members regarding the program
- Great communication (e.g. Global MDSAP website)
- Growing acknowledgement (of the MDSAP program by regional regulators)
- RAC adapts to change (based on input from AOs and Industry)

Benefits:

- Alignment with Industry Best Practices for predictability and harmonization
- Transparency and Compliance to National Regulatory Authority Requirements
- Strengthens QMS and Ensures Compliance across markets
- Cost, resource and Time savings instead of multiple audits covering multiple jurisdictions