OUTCOME STATEMENT
2025 Medical Device Single Audit Program Forum
16-20 June 2025
Amsterdam, The Netherlands

The 2025 Medical Device Single Audit Program (MDSAP) Forum was held in-person in Amsterdam, the Netherlands from 16 to 20 June 2025. Australia's Therapeutic Goods Administration (TGA) and Health Canada co-chaired the Forum on behalf of the MDSAP Regulatory Authority Council (RAC).

Approximately 115 in-person and 75 virtual attendees participated in the two public days of the Forum. Approximately 70 attendees participated in-person across various agenda topics during the Closed Agenda days for the remainer of the week. Attendees at the 2025 Forum included MDSAP Regulatory Authorities (RAs), Official Observers and Affiliates, European Union (EU) Member States (Competent Authorities), MDSAP Auditing Organisations (AOs), EU Notified Bodies (NBs) and Industry representatives.

Overview of Forum and Agenda

The MDSAP holds an annual forum to provide a platform for MDSAP stakeholders to engage on the current operation and performance of the MDSAP and advance work on enhancement activities. This is also a regular event where Observers and MDSAP AOs receive face-to-face training.

The 2024 and 2025 Forums were held in Europe to help support harmonization efforts and understanding amongst EU Competent Authorities about the MDSAP.

Feedback from participants of the Forum agreed on the ongoing value of the opportunity to engage in discussions, and that continued industry involvement in the annual MDSAP Forum be encouraged to understand the views of manufacturers and facilitate the advancement of the program.

Public (Open Agenda) Sessions

The MDSAP Open Agenda sessions took place on 17 and 18 June 2025 and included all stakeholder groups.

Introduced by the MDSAP RAC Chair, the European Commission (EC), the EU Notified Body Coordination Group (NBCG-Med) and the Global Medical Technology Alliance, the agenda included MDSAP RA presentations on the operation MDSAP, recent performance data and the strategic direction. Observers, EU Member States and Affiliates were also given opportunity to present on the benefits, challenges and opportunities of MDSAP participation in their jurisdictions and answered questions.

The contributions of all presenters and participants to these sessions was invaluable for informing the direction of the program, including where opportunities for improvements and further projects might lie.

Performance data

At the Open Session, information was provided to participants on overall performance of the MDSAP. The MDSAP RAC is working towards providing more detailed performance information on its website in 2026. A summary of the data reported at the June Forum included:

- Number of MDSAP Audits conducted – 31,426 (January 2018-May 2025)
- Number of AOs authorized and recognized to conduct MDSAP Audits – 15
- Number of countries where MDSAP Audits occurred – 82
- Number of Active Facilities participating in MDSAP – 7357 (an increase from 7060 in 2024)

MDSAP Enhancement Program

In 2023, the MDSAP RAC agreed to a number of possible enhancements to consolidate MDSAP operations to support future growth and performance. These enhancements included:

- Increasing capacity
- Improving timeliness
- Monitoring performance
- Rapid identification, escalation and resolution of issues
- Enhancing quality
- Increased engagement
- Reporting on performance

Forum participants were updated on the status of priority projects underway in these focus areas and provided feedback on how to further refine this work. Major milestones for projects announced at the Forum included:

- **Remote and Hybrid Auditing Pilot Program** – Post completion of a successful pilot, a procedure has been implemented to allow for remote and hybrid audits to support work and provide opportunities to increase capacity.
- **AO Prioritization Criteria and re-opening of AO applications** – Applications for new AOs would reopen 1 July 2025, supported by priority selection criteria to maximize the benefits that new AOs bring and minimize impact on resources.
- **Independent MDSAP Public Website** – A new independent website and branding – MDSAP.global were formally launched at the 2025 MDSAP Forum.
- **AO Financial Contribution Scheme** – A new AO financial contribution scheme commenced to ensure the ongoing sustainability, expansion, transparency and maintenance of the MDSAP.

- **Non-conformity (NC) Writing Improvement** – A project was completed to improve the quality of NC writing, with an updated procedure and form published, and AO training completed. Assessors are to evaluate successful implementation of the new criteria for writing NCs. The focus of this working group will now shift to identify ways to streamline and improve how audit reports are documented.

Training (Closed Sessions)

The closed sessions provided attendees with opportunities to participate and contribute to training, discussion and knowledge sharing. These sessions included EU Member States to offer them with an opportunity to learn more about the MDSAP operation and share the European experience.

The MDSAP RAs work closely with MDSAP AOs to determine those items prioritized for training and discussions, along with items to include in the Technical Meeting scheduled for December 2025.

MDSAP RAC Meetings

The MDSAP RAC met formally, and also with all Official Observers and EU Member States to reflect on the knowledge shared during the first three days of the Forum and agree to next steps. Actions agreed to in these meetings are monitored through RAC processes.

The RAC also engaged with those Affiliate members who attended to discuss use of the program in their jurisdiction. This engagement provided opportunity to learn more about their audit operations and how others may benefit from similar approaches. All Affiliates have opportunities to meet with the RAC on request either at the forum, or virtually at another mutually agreed occasion.

The RAC also agreed to give Observers and Affiliates more time to discuss program use, observations and share feedback in future Open Agenda days.