



**MDSAP**

Medical Device Single Audit Program

**Medical Device  
Single Audit  
Program**

**Regulatory  
Authority Council  
Report - 2025**



## Preface

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**Tracey Duffy, Chair, MDSAP Regulatory Authority Council – 2024 and 2025**

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# 1. Introduction

Established in 2013, the Medical Device Single Audit Program (MDSAP) represents a significant advancement in the regulatory landscape for medical devices, allowing manufacturers to streamline their compliance efforts while ensuring adherence to essential quality standards.

The 2025 MDSAP Regulatory Authority Council (RAC) Report outlines recent program performance and key enhancement activities. From 2025, the RAC intends to publish annual reports to keep stakeholders and prospective participants informed about program operations and ongoing improvements.

## 1.1 About MDSAP

MDSAP streamlines quality management system (QMS) related audits for medical device manufacturers by enabling a single audit, conducted by an MDSAP recognized auditing organization (AO), to meet the regulatory requirements of the Australia, Brazil, Canada, Japan and the United States. The regulatory authorities (RAs) from these jurisdictions form the program's governing body, the MDSAP RAC.

Following completion of the [MDSAP pilot program](#) in 2017, program participation has grown steadily, reaching over 7,600 manufacturers across 84 jurisdictions as of December 2025—an increase of about 13% from 2023 to 2025. Audit volumes have risen similarly, from 4,781 in 2022 to 5,567 in 2025 (around 16.5%). Most participating manufacturers (62%) are located in the United States (34.6%), China (13.6%), Germany (7.7%) and Canada (6.1%).<sup>1</sup>

Further information on the program's history, benefits and participation process is available on the [MDSAP website](#).

## 2. Our focus areas

In 2023, the MDSAP RAC launched a program of enhancements to strengthen capacity, performance, oversight and transparency. The work aims to increase operational transparency, demonstrate program value, communicate effectiveness and continuous improvement, build confidence in program maturity, and support performance reporting with RA Subject Matter Experts (SMEs) and AOs.

In 2025, RAs delivered several key elements of this strategy, laying the foundation to streamline the program and expand audit capacity. Section 2 outlines these achievements and ongoing initiatives.

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<sup>1</sup> Regulatory Exchange Platform – secure (REPs) – Data as at May 2025. REPs is an IT data portal that facilitates the exchange of information between participating MDSAP RAs and AOs.

## 2.1 Increasing capacity

### 2.1.1 Expanding the number of Auditing Organizations

In 2025, the MDSAP RAC resumed accepting applications to recognize new AOs in order to support ongoing program growth. A limited number of applications were selected for assessment and potential recognition, supported by prioritization criteria to help select candidates and manage resource demands. Further information on the AO application reopening and criteria is available [here](#).

Applications closed on 29 September 2025. On 28 January 2026, the RAC reviewed the candidates and identified which applicants would be selected for assessment. On 10 February 2026, the MDSAP Secretariat notified KIWA and mdc medical device certification GmbH that their applications were selected to move to the initial assessment stage by the MDSAP RAC.

### 2.1.2 Remote and Hybrid Audit program

During the COVID-19 pandemic, MDSAP RAs identified criteria and developed a procedure for AOs to be able to conduct remote audits. This procedure was developed to maintain medical device supply and maintain manufacturer certification cycles. In 2020, 55% of audits were conducted remotely and 58% of audits performed in 2021 were at least partly remote.

In 2023, the RAC launched an 18month Remote and Hybrid Auditing Pilot to assess whether these models could permanently expand audit capacity. The pilot confirmed remote/hybrid audit effectiveness, and full implementation went into effect in March 2025.

As travel restrictions eased, remote and hybrid audit rates have reduced in recent years—11% in 2023, 22% in 2024 and 24% in 2025.

More information on this program is available [here](#).

### 2.1.3 Expanding RA participation

Harmonization and reliance efforts help reduce regulatory burdens and costs for manufacturers and consumers. [MDSAP's membership](#) continues to expand, with several new Affiliate Members joining in 2024–2025 and Singapore's Health Sciences Authority elevating from an Affiliate Member to an Official Observer in 2024.

MDSAP participation is expected to continue to grow. Increases in RA capacity through shared responsibilities—including AO recognition—will further strengthen the program. Information on how to participate in MDSAP is available [here](#). There are many jurisdictions that do not have MDSAP membership but can still benefit from the certifications issued under the MDSAP.

### 2.1.4 Medical Device Organization (MDO) Pilot

MDSAP eligibility currently applies only to “legal” manufacturers that market devices under their own name in at least one participating jurisdiction and meet applicable QMS or good manufacturing practices (GMP) requirements.

In response to feedback from industry and regulators, the RAC launched a pilot in August 2025 to assess extending eligibility to MDOs—such as contract manufacturers and specification developers—that meet QMS/GMP requirements but do not market devices under their own name. The pilot was launched in response to feedback from potential AO clients that wanted to participate in MDSAP, but did not meet the definition of a legal manufacturer.

The pilot will continue into 2026, with eligibility applying only under Brazilian, Japanese and US regulations. More information on this pilot is available [here](#).

## 2.1.5 AO Financial Contribution Scheme

In consultation with MDSAP AOs, the RAC introduced an AO financial contribution scheme on 1 January 2025 to support the program’s sustainability and ongoing development. Contributions are used to fund the annual forum, host and maintain the MDSAP website and training activities, with AOs and SMEs helping shape training priorities.

## 2.2 Improving timeliness and monitoring performance

### 2.2.1 Monitoring RA and AO performance

Data<sup>2</sup> show that AOs submitting audit reports within 90 days<sup>3</sup> has improved from 30% in 2023 to over 55% in 2025, with 79% completed within 120 days. Further work is ongoing to improve the timeliness of audit report submissions, noting some submission timelines may be impacted by the complexity of the manufacturer operations.

The RAC is also enhancing its oversight systems, including a new dashboard to track assessments and recognitions. The RAC has been monitoring overdue RA assessment reports. Increased monitoring and streamlining the drafting of assessment reports will address late reports and prevent future occurrence.

## 2.3 Rapid identification, escalation and resolution of issues

### 2.3.1 Strengthening governance

In 2025, the RAC updated the program’s [Complaints and Customer Feedback](#) procedure to introduce a six-month RAC escalation point and published clearer process guidance on the MDSAP website.

In line with the [MDSAP Management Responsibility and Management Review Procedure](#), the RAC also undertook two management reviews to assess the effectiveness of the MDSAP QMS, review complaint and corrective actions, track progress on scheduled procedure reviews, consider risks and internal audit outcomes and identify areas for improvement.

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<sup>2</sup> REPs – May 2025.

<sup>3</sup> ‘The AO is required to submit an audit package within 90 calendar days from the end date of the audit. More information is available [here](#).

## 2.4 Enhancing quality

### 2.4.1 Independent MDSAP Website and new branding

A key part of the MDSAP enhancement program was developing a new independent website and modernized branding. The site—[MDSAP.global](https://www.mdsap.global)—went live in May 2025 and was formally launched at the 2025 MDSAP Forum. It provides a central platform for RAs to communicate with stakeholders about program performance and improvement activities and will continue to evolve based on user feedback. The updated branding is intended to strengthen trust, confidence and recognition in MDSAP over time.

During 2025, further enhancements were made to improve the layout of [MDSAP.global](https://www.mdsap.global)—and strengthen communication of new and updated information to MDSAP stakeholders, including:

- Streamlined information in some left-hand navigation menus, reducing visual clutter and overall page length.
- Improved search engine optimization to increase visibility of the website.
- Added a mega footer to consolidate frequently used links, improving accessibility and user experience.
- Introduced pagination for MDSAP documentation listings to improve usability and make navigation more intuitive.
- Added a 'Last reviewed' field to content pages to confirm information currency.

Usage of [MDSAP.global](https://www.mdsap.global) increased significantly following launch, indicating increased awareness of the site and improved discoverability. Between May and August 2025, the site recorded approximately 24,000 page views per month; this increased to approximately 46,000 page views per month between September and December 2025.

Further enhancements are in progress and will be completed in 2026, including a redesign of the AO contact information to modernize presentation and improve usability.

### 2.4.2 Non-Conformity Writing and Audit Report Quality Improvement / Feasibility Study – EU Notified Body and MDSAP AO Combined Audit Report

In 2025, a project was completed to improve the quality of non-conformity (NC) writing. Further information on this work is available [here](#).

MDSAP RAs are currently working with AOs to identify ways to streamline and improve how audit reports are documented. Through this RA-AO collaboration, the audit report template was streamlined without impacting regulatory reporting requirements. Use of template language was also developed and implemented to improve report quality, and feedback from AOs is informing further refinements.

A project is currently underway to assess the feasibility of developing a combined MDSAP and European Union (EU) Notified Body (NB) Audit Report, in collaboration with the European Commission (EC) and EU Competent Authorities. While MDSAP does not address EU medical device regulatory requirements, many MDSAP AOs are also designated as EU NBs and are therefore able to conduct audits under both certification frameworks. If viable, the use of a common audit report template across both MDSAP and

EU regulatory schemes could reduce duplication for AOs and NBs and improve consistency for regulators.

In 2025, EU Competent Authorities observed several MDSAP Witnessed Audits to learn more about MDSAP operations. [Witnessed audits](#) allow qualified [MDSAP RA assessors](#) to verify that an AO effectively conducts their audits using the [MDSAP Audit Approach](#) and reports appropriately on the outcomes of audits. It is an essential assessment activity for building and maintaining confidence in the reliability of the third-party AO. Work is underway to schedule more opportunities for these joint activities in 2026.

## 2.5 Increased engagement

### 2.5.1 2025 MDSAP Forum and Technical Meetings

The MDSAP holds an annual forum for RAs, Official Observers, Affiliate Members, AOs, industry bodies and manufacturers to discuss program operations and enhancement work.

The 2024 and 2025 Forums—hosted by TÜV NORD CERT in Essen and BSI Group in Amsterdam, respectively—provided valuable opportunities for MDSAP RAs and EU Competent Authorities to exchange insights on MDSAP operations and alignment with the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) frameworks.

Further information is available in the [2025 Forum Outcome Statement](#).



Figure 2.5.1: 2025 MDSAP Forum - Amsterdam

In addition to annual forums, face-to-face United States-based technical meetings in December 2024 and 2025 brought together MDSAP RAs, Official Observers and recognized AOs to progress enhancement projects and provide additional training.

## 2.5.2 Strengthening industry partnerships

To support its enhancement program, the RAC is strengthening feedback collection. This was demonstrated through an industry-facilitated discussion about options for industry and/or regulator Manufacturers Surveys. Building on a smaller 2023 survey of Australian and Canadian manufacturers, an initial survey design was discussed at the 2025 Forum.

In consultation with industry, in 2025 the RAC agreed to establish a formal MDSAP Industry Group. The role of this Industry Group would be to provide strategic, operational and well-informed feedback and insights on the operation of the program, the challenges experienced by manufacturers and opportunities for improvement. The terms of reference for this group are expected to be finalized in 2026.

## 3. Future Outlook

The progress achieved in 2025 demonstrates the MDSAP RAC's commitment to strengthening the program's foundations and advancing its maturity. Enhanced capacity, clearer governance, improved audit quality and stronger engagement among regulators, AOs and industry continue to build a more transparent, efficient and trusted global audit framework.

As the program continues to grow, the RAC will remain focused on ensuring these developments deliver value to manufacturers, regulators and consumers. With ongoing collaboration and support from stakeholders, MDSAP will build on these achievements and further reinforce its role in supporting medical device safety worldwide.



**Please visit our website  
for more details.**

[www.mdsap.global](http://www.mdsap.global)

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