OUTCOME STATEMENT
2026 Medical Device Single Audit Program Forum
15-19 June 2026
Kyoto, Japan

The 2026 Medical Device Single Audit Program (MDSAP) Forum was held in person in Kyoto, Japan from 15 to 19 June 2026. This was the first MDSAP Forum held in the Asia-Pacific region. The United States Food and Drug Administration (USFDA) served as chair for the Forum. Japan's Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) facilitated and led the Open Session agenda on behalf of the MDSAP Regulatory Authority Council (RAC).

Approximately 130 in-person attendees and 90 virtual attendees participated in the two Open Session days of the Forum. Approximately 90 attendees participated in-person during the Closed Session days for the remainder of the week. Attendees at the 2026 Forum included MDSAP Regulatory Authorities (RAs), Official Observers, Affiliates, MDSAP Auditing Organisations (AOs), Notified Bodies (NBs), and non-RAC member RAs from the Asia Pacific Region and beyond. The MDSAP Industry Group and other industry representatives were also present at the Forum and participated in the Open Session days.

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 MDSAP and advance work on enhancement activities. The Forum also provides a unique opportunity to provide regulators and AOs with face-to-face training.

The 2024 and 2025 Forums were held in Europe to support harmonization efforts and facilitate a deeper understanding of MDSAP operations by EU Member States and Competent Authorities. The 2026 Forum in Japan held a similar purpose but focused on program outreach and training for the Asia Pacific RAs, including non-MDSAP regulatory authorities from the region.

Feedback from Forum participants remains a valuable tool for RAC members to manage strategic priorities, focus operational efforts, and gather input on process improvements.

Public (Open Sessions)

The MDSAP Open Sessions took place on 16 and 17 June 2026 and included all registered stakeholder groups. Opening remarks were provided by MHLW, PMDA, the MDSAP Chair, and the MDSAP Industry Group Chair representative.

2025 MDSAP Annual Report

The MDSAP Chair provided the first presentation of the Open Session, highlighting the newly published 2025 MDSAP Annual Report. The presentation communicated activities accomplished against the five Strategic Focus Areas currently being progressed by the MDSAP RAC, which are: 1) Increasing Capacity; 2) Timeliness and Monitoring; 3) Issue Escalation and Resolution; 4) Enhancing Quality; and 5) Increasing Engagement.

A summary of 2025 performance data reported at the 2026 Forum included:

- Number of MDSAP Audits conducted in 2025 – 5,657
- Number of participating MDSAP manufacturers – over 7,600 in 84 jurisdictions
- Percentages of audit reports submitted in 2025 by target goals: 55% submitted in 90 days; 79% of audit reports submitted within 120 days.

MDSAP Project Updates

The following projects were presented to participants during Open Session days of the 2026 Forum.

Medical Device Organization (MDO) Pilot

ANVISA provided a background and update on the MDO Pilot Project. Forum participants were informed that preliminary results from 10 months of the Pilot (August 2025 – May 2026) are being evaluated, along with the input received from AOs in the MDO survey. Experience, lessons learned and feedback will inform the RAC's decisions regarding the next steps for the MDO Pilot. AOs also presented their "lessons learned" from participating in the MDO Pilot.

MDSAP-EU Medical Device Regulation (MDR) Update and Mapping

EU Member State and Notified Body Coordination Group representatives provided key updates on their five ongoing work items: 1) Witnessed Audits; 2) Mapping; 3) Single MDSAP-MDR-IVDR report; 4) Audit Approach Input; and 5) AO Assessments. Presenters indicated that initial experience provided valuable insight, but additional experience is needed. Also, additional observed audits by EU competent authorities would help accelerate the progress of their work items.

Republic of Korea's Ministry of Food and Drug Safety (MFDS) MDSAP and KGMP Combined Audits

MFDS presented on its experience with combined audits that included MDSAP and KGMP requirements. A comparison between both regulatory frameworks was presented, as well as manufacturer's requirements for applying for a combined MDSAP-KPMG audit. MFDS indicated that KGMP and MDSAP audit cycles were aligned and that audit report submission for combined audits was extended to 45 days. MFDS also indicated that approximately 2 extra man days were needed to cover KGMP requirements for these combined audits.

Regulatory Authority Updates

During the Open Sessions, non-MDSAP and MDSAP RA members presented regulatory updates to Forum participants. Representatives from Egypt's EDA, India's CDSCO, Indonesia's MoH, Thailand's FDA, Vietnam's VIMDA, and the Southeast Asia Regulatory Network (SEARN) provided an overview of their regulatory frameworks and perspectives on MDSAP.

MDSAP Affiliate Members and Official Observers also provided regulatory and MDSAP utilization updates. The following affiliates participated in-person or remotely to share updates: Argentina's ANMAT; Israel's MoH; Kenya's PPB; Malaysia's MDA; Mexico's COFEPRIS; Republic of Korea's MFDS; South Africa's SAHPRA; and Taiwan FDA. Observers that presented at the Forum included the European Commission, Singapore's HSA, UK's MHRA, and the WHO.

Industry Updates & Presentations
The new MDSAP Industry Group (IG) presented to Forum participants on their role and purpose in supporting MDSAP. The IG indicated that it would provide suggestions from Industry to the RAC and MDSAP more broadly to build, enhance and strengthen the program. The Chair and Secretariat of the IG for 2026-2027 aligns with the RAC Chair and Secretariat. For the next two years, the U.S. trade association, AdvaMed, will chair the IG with ABIMED of Brazil serving as Vice Chair.

Becton Dickinson (BD) also provided an industry presentation on the company's MDSAP journey. They discussed their history with the program dating back to 2017, when the first BD site joined MDSAP, to present day with dozens of participating sites. Insightful information was also provided on the criteria for a site joining the program and how the AO was selected. Lastly, BD covered their preparation for an MDSAP audit for the legal manufacturer and a MDO.

Closed Session
This year, the MDSAP Closed Sessions featured separate "tracks" for the 2026 Forum. Multiple tracks ran simultaneously and each targeted specific stakeholders. Tracks were implemented to make best use of time and offer participants opportunities to obtain training, provide feedback or discuss MDSAP projects in more detail.

MDSAP Overview Training

TGA provided in-person and virtual MDSAP training to the APAC and SEARN representatives on the first day of the Closed Session. The session covered in-depth information on MDSAP membership and the operation and management of the program. AOs also attended the training to address questions on the scheduling and performance of MDSAP audits and other criteria they must comply with under the program.

MDSAP Case Workshop

Participants separated into groups to consider an example of an MDSAP nonconformity that was anonymized for the workshop. The aim was to discuss and demonstrate expectations for drafting high quality nonconformity language based on new MDSAP criteria. Regulators were also able to clarify the regulatory significance and potential postmarket strategies to address nonconformities of varying degrees.

MDSAP RAC Meetings

The MDSAP RAC held separate meetings with APAC RAs, SEARN, Affiliate Members and Official Observers to discuss experiences with MDSAP, options for improvement, clarifications; as well as the Forum content, structure, and experience. These meetings included a question and answer portion and provided an opportunity for the RAC to obtain feedback for organizing and planning the 2027 MDSAP Forum.


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