



# MDSAP

Medical Device Single Audit Program

## Procedure

MDSAP P0039.001

# MDSAP Industry Group Terms of Reference

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# Preface

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**Kimberly Lewandowski-Walker, MDSAP Regulatory Authority Council Chair**

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# 1. Introduction

This document sets out the roles and responsibilities of the Medical Device Single Audit Program (MDSAP) Industry Group and provides clarification on the group's purpose, roles, responsibilities, operations, tenure and obligations in accordance with agreed terms with the MDSAP Regulatory Authority Council, henceforth referred to as the "RAC".

The goal of establishing the MDSAP Industry Group is to obtain formal industry feedback to improve MDSAP operations, processes and global adoption. Timely and recurring collaboration between the RAC and MDSAP Industry Group is viewed as essential to support the program's vision for a strong, reliable and transparent program that maintains trust and confidence by all MDSAP stakeholders.

Recognizing that Auditing Organizations play a critical role in the effective implementation and overall success of MDSAP, the MDSAP Industry Group may engage with Auditing Organizations to inform discussions and support program improvement.

## 2. Role of the MDSAP Industry Group

The role of the MDSAP Industry Group, henceforth referred to as "Industry Group," is to assist or provide suggestions to the RAC to continue to build, enhance and ensure a strong program that benefits all stakeholders. The Industry Group provides strategic and operational input and well-informed feedback/insight to the RAC on:

- the general operation of the program
- the challenges experienced by manufacturers and other industry stakeholders
- opportunities for improvement to reduce regulatory burden, streamline processes and ultimately increase MDSAP adoption

The Industry Group does not hold decision-making authority or provide oversight over the MDSAP or the RAC.

## 3. Membership

### 3.1 General membership of the MDSAP Industry Group and Group Composition

Each RAC Member is responsible for selecting up to a maximum of three (3) trade associations from their jurisdiction. Industry Group representatives shall provide a diversity of perspectives and industry. The nominated associations should represent manufacturers of various sizes, including small and medium-sized enterprises, and manufacturers that market a variety of device types within the RAC member jurisdictions. The Industry Group may also collaborate with trade associations in MDSAP Observer and Affiliate jurisdictions as appropriate.

In selecting trade associations for the Industry Group, RAC Members should consider whether candidates have sufficient resources, experience and expertise to fulfil the responsibilities of membership. Membership in global industry groups such as Global Diagnostic Imaging, Healthcare ICT and Radiation Therapy Trade Association (DITTA) or the Global Medical Technology Alliance (GMTA) is not mandatory; however, to ensure consistent and effective participation as part of the Industry Group, preference should be given to associations that are active in MDSAP and engage with other international medical device harmonization programs/efforts.

Each trade association selected by RAC Members will provide one representative to serve on the Industry Group to ensure its efficient and effective operation. Industry Group members should support the Chair and Vice Chair in upholding timely, efficient, and transparent communication. Industry Group members should participate in voting when necessary. These functions will facilitate the effective participation of industry associations within the Industry Group, fostering alignment and operational efficiency.

## 3.2 Leadership of the MDSAP Industry Group

The Industry Group shall have a Chair and Vice Chair from the same jurisdictions as the MDSAP RAC Chair and MDSAP RAC Vice Chair, respectively. Chair and Vice Chair will rotate every two years to coincide with the rotation of the MDSAP RAC Chair and Vice Chair.

In jurisdictions with multiple representative Associations, the positions of Chair and Vice Chair shall be assigned on a rotational or joint basis, unless an Association declines the role, in which case the next Association in sequence will assume the responsibility.

The Industry Group Chair and Vice Chair shall both serve as the primary contacts for the MDSAP RAC Secretariat (henceforth, referred to as the “RAC Secretariat”) for all MDSAP-related matters. The Chair and Vice Chair are responsible for convening meetings, setting agendas, and ensuring timely circulation of Meeting Minutes to support the effective operation of the Industry Group.

## 3.3 Publicly available information regarding the Industry Group

The trade associations participating in the Industry Group will be listed publicly on the MDSAP website, <https://www.mdsap.global>.

# 4. MDSAP Industry Group Meeting Types

## 4.1 Internal meetings

The Industry Group should meet internally at least twice per year and when needed on an ad-hoc basis. All trade associations that are members of the Industry Group will be invited to attend the meetings. Reasonable efforts will be made to schedule meetings in advance at a time that accommodates all participating trade associations. In the event of the Chair’s unavailability, the Vice Chair should chair these meetings.

## 4.2 Bilateral Meetings with the MDSAP RAC

The MDSAP RAC will meet with the Industry Group once per year. This meeting may be virtual or coincide with the annual MDSAP Forum and may include in-person or virtual Industry Group attendees. If substantive topic(s) arise that warrant discussion, the RAC may permit an additional ad hoc virtual or in-person meeting. Any in-person meeting may be scheduled to coincide with either the March or September RAC meetings.

# 5. Responsibilities and Operation of the MDSAP Industry Group

The following list may be amended in agreement between the RAC and the Industry Group.

1. Operation of Industry Group Meetings
  - a. Pre-scheduled Industry Group Bilateral Meetings with the RAC
    - i. RAC Secretariat shall:
      1. Provide the confirmed dates of the annual MDSAP Forum to the Industry Group
      2. Schedule and distribute invitations to the RAC-Industry Group bilateral meeting during the yearly MDSAP Forum
      3. Provide, when available, the Open Session MDSAP Forum agenda
      4. Draft Meeting Minutes for review by the RAC and Industry Group
      5. Incorporate feedback/edits into the Meeting Minutes and finalize the Meeting Minutes document
    - ii. RAC shall:
      1. Review and approve agenda topics
      2. Review and provide feedback on Meeting Minutes
      3. Provide support to the MDSAP Chair and Secretariat, as needed, during MDSAP RAC and Industry Group Meetings
    - iii. MDSAP Industry Group shall:
      1. Provide the RAC Secretariat with a draft agenda within the timeframe discussed in the Agenda Setting section below prior to meeting with the RAC
      2. Along with the agenda, the Industry Group will also provide the RAC Secretariat with the names, titles and organizations of Industry Group representatives that will meet with the RAC. The Industry Group will designate virtual or in-person meeting participation to the RAC for each representative
      3. Review and provide feedback on Meeting Minutes to the RAC Secretariat

b. Ad-Hoc Industry Group Meeting with the RAC

i. Industry Group shall:

1. Submit meeting requests to the RAC Secretariat at least 60 calendar days in advance of a requested meeting
2. Include proposed topic(s), rationale and desired outcome

ii. RAC Secretariat shall:

1. Upon receipt, submit to the RAC, in writing, the Industry Group ad-hoc meeting request and agenda topic(s). The Secretariat will request a RAC meeting decision to communicate with the Industry Group within 30 calendar days of the ad-hoc meeting request
2. Coordinate scheduling of the ad-hoc meeting and distribute meeting invitations/agenda to the RAC, Industry Group and any other invited guests/speakers

iii. RAC shall:

1. Approve/deny ad-hoc meeting request
2. Review and approve agenda topics
3. Review and provide feedback on Meeting Minutes
4. Provide support to the MDSAP Chair and Secretariat, as needed, during MDSAP RAC and Industry Group Meetings

c. Agenda Setting

i. Industry Group shall:

1. Provide a draft agenda to the RAC Secretariat at least 60 calendar days in advance prior to meeting with the RAC
2. Along with the agenda, the Industry Group will also provide the RAC Secretariat with the names, titles and organizations of Industry Group representatives that are planned to meet with the RAC. The Industry Group will also designate virtual or in-person meeting participation for each representative

ii. RAC Secretariat shall:

1. Solicit feedback from the RAC on the draft agenda, including any additional items proposed by the RAC at least 30 calendar days prior to meeting. Agenda review will only be initiated following RAC approval to meet with the Industry Group
2. Distribute the final agenda and any referenced documents at least 10 calendar days before the event

iii. Agenda topics may include:

1. Discussion regarding upcoming forum topics and speakers
2. Identification of emerging MDSAP regulatory topics for which guidance from the MDSAP RAC or training would be beneficial

3. Observations across jurisdictions of implementation challenges and successes with current MDSAP operations
4. Providing feedback on draft documents, training material and other materials developed specifically for industry stakeholders
5. Identifying opportunities for regulatory guidance or other improvements for the MDSAP website
6. Potential opportunities for projects that industry could undertake that contribute positively and constructively to the MDSAP and the priorities and/or strategic goals of the MDSAP RAC
7. Discussion regarding the results of any previous surveys or plans for future proposed surveys.

d. Meeting Minutes

i. The RAC Secretariat shall:

1. Draft Meeting Minutes and coordinate review of the draft with the Industry Group and RAC.
2. Incorporate necessary feedback/edits to the draft Meeting Minutes and provide to the MDSAP RAC for final approval
3. Provide a record of the meeting, including agreed action items and progress on prior action items to the Industry Group and RAC
4. The targeted goal for distribution of the Meeting Minutes for review will be 30 calendar days after the scheduled meeting date

The RAC and Industry Group will review the Meeting Minutes concurrently and will be provided 30 calendar days to request correction/modification to the Meeting Minutes before the document is finalized.

## 6. Document History and Approval

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME /PROJECT MANAGER
001	2026-05-26	Initial Release	Kimberly Lewandowski-Walker, FDA

Version Approval 001

Approved: SIGNATURE ON FILE  
CHAIR, MDSAP RAC

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

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

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