Table of Contents

1. Purpose/Policy

To define the roles and authorities/responsibilities of each membership type within the Medical Device Single Audit Program (MDSAP), including Regulatory Authorities (RA), the Regulatory Authority Council (RAC), Official Observers and Affiliate Members. This document also defines the roles and responsibilities of Lead Project Managers and describes the basic procedures that the RAC follows when revising membership to MDSAP and/or appointing Lead Project Managers and Assessment Program Managers.

2. Scope

This procedure applies to all members of the MDSAP.

3. Definitions/Acronyms

Ad hoc Project Work Item: MDSAP work items assigned directly by the RAC without a Project Team Work Item Proposal/Approval.

Assessment Program Manager: The individual responsible for planning and execution of the Assessment Program. The Assessment Program Manager drafts the initial Assessment Program and future amendments. The Assessment Program Manager also verifies the implementation of assessment activities by the assessment team according to the Assessment Program and reviews assessment outcomes and proposes recognition decisions to the Technical Review and Recognition Committee (TRRC). (MDSAP AS P0005)

Assessor: An employee of a Regulatory Authority with the demonstrated personal attributes and competence to conduct an assessment of an Auditing Organization. (IMDRF/MDSAP WG/N6 Final: 2021 (Edition 2))

Auditing Organization (AO) Contribution Scheme: From 2025, a scheme introduced whereby recognized MDSAP Auditing Organizations contribute financially to MDSAP to ensure the ongoing sustainability, expansion, transparency and maintenance of the Program and the capability of AOs who are critical to the Program.

Lead Assessor: The individual responsible for leading the assessment team. The Lead Assessor manages an assessment team, prepares the assessment plan, conducts any assessment related meetings, and submits the formal assessment report. (IMDRF/MDSAP WG/N6 Final: 2021 (Edition 2))

Lead Project Manager: A Lead Project Manager is responsible for managing, monitoring, and reporting the progress of a project defined within an approved Project Team Work Item Proposal/Approval; or *ad hoc* project work items assigned by the RAC.

Medical Device Single Audit Program (MDSAP): MDSAP allows a single regulatory audit of a medical device manufacturer's quality management system to satisfy the needs of multiple regulatory jurisdictions. The single audit of a medical device manufacturer's quality management system will include the assessment of the quality management system processes including management responsibility, resource management, product realization, measurement, analysis and improvement, and adverse event reporting; as well as compliance with Good Manufacturing Practices (GMPs) or other applicable requirements as outlined in the MDSAP audit approach. (MDSAP AU P0002).

MDSAP Regulatory Authority Council (RAC): The RAC is the decision-making body of MDSAP and consists of representatives from regulatory authorities that are members of the RAC. The RAC provides direction, oversight, and resources to support the MDSAP development, implementation, maintenance, and expansion.

MDSAP Official Observer: The World Health Organization (WHO) or a regulatory authority that is not a member of the RAC who observes and/or contributes to RAC activities.

MDSAP Affiliate Member: A regulatory authority that is not a member of the RAC or an Official Observer, but engages in MDSAP, demonstrates understanding of MDSAP and utilizes MDSAP audit reports and/or MDSAP

certificates for evaluating compliance with applicable medical device requirements, including a manufacturer's quality management system, under the Affiliate Member's regulatory framework.

MDSAP RAC Member: A regulatory authority that is part of the RAC.

MDSAP RAC Chair: By rotation every two years, a regulatory authority senior officer providing general management oversight and support of the MDSAP RAC. The RAC Chair is responsible for establishing the RAC Secretariat to support their term of Chairmanship.

MDSAP RAC Vice Chair: a regulatory authority senior officer supporting the current RAC Chair in their activities and can substitute for the RAC Chair, should they not be able to fulfill their duties.

MDSAP Secretariat: RA staff providing direct support to the RAC Chair, Vice Chair and members.

Project Team Work Item Proposal/Approval: The mechanism for documenting proposed MDSAP work items and their approval or rejection.

Regulatory Authority (RA): A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (IMDRF/MDSAP WG/N3 Final:2016 (Edition 2)) (GHTF/SG1/N78:2012)

4. Authorities/Responsibilities

MDSAP membership criteria and authorities/responsibilities are listed in each of the sections below and are also outlined in Annex A.

4.1 MDSAP RAC

The RAC maintains authority and final approval or rejection of processes and criteria set forth under the program. The RAC also sets strategic direction and priorities for execution by the MDSAP Subject Matter Expert (SME) Team. With the exception of the acceptance or rejection of risk-benefit criteria and decisions made in support of the MDSAP risk management program, this authority may be delegated.

The RAC is responsible for:

(A) supporting the development, implementation, maintenance, and expansion of the MDSAP, including the allocation of necessary resources;

(B) monitoring and modifying as needed the MDSAP objectives, requirements, policies, and procedures;

(C) approving and rejecting MDSAP documentation (see MDSAP QMS P0002);

(D) recognizing MDSAP AOs, RAC Members, Official Observers, and Affiliate Members;

(E) establishing and discharging project teams as necessary to support the development, implementation, and maintenance of the MDSAP;

(F) allocating MDSAP work items and project priorities;

(G) appointing and renewing RAC Chair and Vice Chair;

(H) appointing and discharging Lead Project Manager(s);

(I) appointing and discharging Assessment Program Manager(s);

(J) approving final MDSAP objectives, plans, policies and procedures;

(K) overseeing MDSAP activities, in particular

- assisting in establishing the scope and milestones for project items
- ensuring timely project team progress against milestones
- preventing duplication of project team activities
- identifying and resolving problems that might delay project completion
- approving or rejecting MDSAP risk management decisions including risk-benefit criteria and decisions as necessary
- maintenance of MDSAP documented requirements (in writing or electronically) including; objectives, plans, policies, procedures, and RAC key decisions.

(L) overseeing the AO Contribution Scheme including requests, approvals and expenditure. This includes

- assessing and advising AOs the funding required for each three-year period
- reviewing and endorsing reports provided by the TGA in February and August each year, on income and expenditure
- confirming priorities for distribution of available funds
- if required, conducting an extraordinary review of the contribution amount to implement necessary adjustments within any three-year period.

(M) reviewing MDSAP objectives, policies and procedures at regular intervals and revising as necessary;

(N) providing assistance in the planning of the MDSAP meetings and approving MDSAP meeting agendas as necessary;

(O) providing, or arranging for the provision of training or other outreach activities necessary to inform about and promote the MDSAP;

(P) providing support and/or guidance to the RAC Chair on the management and resolution of any complaints, corrective actions or disputes submitted through

- MDSAP QMS P0005: Management Responsibility and Management Review Procedure. This includes
  - via the Management Review Report provided to the RAC at least annually, reviewing and analyzing trends and recurrences of Nonconformities, complaints and recommending appropriate remedial action
  - as necessary, providing final authority on the disposition of any escalated complaints, corrective actions and other issues arising from feedback
- MDSAP QMS P0011: Complaints and/or Customer Feedback Procedure
- MDSAP QMS P0009: Nonconformity and Corrective Action Procedure
- MDSAP Procedure P0031 - Differing Professional Opinion and Dispute Resolution MDSAP

(Q) undertaking any other initiatives that contribute to achieving MDSAP goals and objectives.

Each regulatory authority on the RAC utilizes MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer's quality management system, under the RAC Member's regulatory framework.

All RAC Members have full access to the MDSAP IT Portal.

4.1.1. RAC Chair

The RAC Chair will provide general management oversight and support of:

(1) all work related to the development, implementation, maintenance, and expansion of the MDSAP; and,

(2) the RAC.

This includes:

(A) Ensuring that the RAC effectively meets* to execute its tasks, proposing an agenda for the RAC meetings, chairing the meetings and achieving consensus;

*meetings may be face-to-face or via electronic communication systems or a combination of both

(B) resolving all disputes regarding MDSAP decisions or actions presented by MDSAP RAC Members, Official Observers, or Affiliate Members, or persons outside the MDSAP (with the assistance of the RAC as needed);

(C) representing the MDSAP in *ad hoc* consultations with external parties concerning MDSAP activities;

(D) assuring MDSAP project team work item requests are documented and communicated to the assigned Lead Project Manager;

(E) the provision of secretariat services and planning support to the MDSAP for the duration of their term as RAC Chair, either via an outside contract or through assignment of one or more of their staff. Certain tasks of the Secretariat may be delegated to one of the RAC Members or be outsourced if agreed to by the RAC and the RAC Chair.

4.1.2. RAC Secretariat

The RAC Secretariat will:

(A) provide direct staff support to the RAC Chair, Vice Chair and members;

(B) prepare records and action items associated with all RAC meetings; obtain MDSAP project team work item requests approved during the RAC meetings, and arrange for their dissemination to RAC Members, Lead Project Managers, and others as necessary;

(C) maintain or arrange for the maintenance of a current inventory of all completed and in-process documents and MDSAP project team work items; and act as custodian of all MDSAP historical, policy and other documents that have a bearing on MDSAP operations;

(D) maintain the currency of content of the MDSAP website by advising the MDSAP Webmaster of any changes to Chair-approved procedures or documents to be housed on the site; advising of any website text to be added or edited and where required, draft new website content on behalf of

the RAC.

(E) serve as the primary focal point for receipt of all MDSAP documents for distribution to the RAC or the Lead Project Managers for review and/or final endorsement;

(F) assure an MDSAP document repository is maintained; and

(G) assemble the needed information and records for the Management Review and forwards them to the MDSAP QMS Management Representative, Lead Project Manager, and RAC.

Note: The responsibility for establishing and maintaining the document repository may be assigned to an MDSAP team member other than the RAC Secretariat.

4.1.3. RAC Vice Chair

The principal duty of the RAC Vice Chair is to support the current RAC Chair in their activities and to substitute for the RAC Chair, should they not be able to fulfill their duties.

In the event that the RAC Chair is unable to carry out their full term of duty, they should promptly notify the RAC so that the Vice Chair can act for the RAC Chair until an alternate from the regulatory authority of the RAC Chair can be designated to take over.

The Vice Chair may share the responsibility of the RAC Chair including for the provision of secretariat services.

4.2 MDSAP Official Observer

Official Observers observe and/or contribute to RAC activities while not having equal authority with respect to final RAC decisions and deliverables. MDSAP Official Observers may express suggestions, concerns, and alternatives to RAC decisions and deliverables. However, the RAC retains final decision authority regarding all MDSAP development, implementation, maintenance, and expansion activities.

Official Observers consistently participate in all RAC activities designated as “OPEN to RAC Members and Official Observers", including:

(A) Meetings and teleconferences;

(B) Review, comment, and revision of proposed MDSAP documents; and,

(C) Other activities related to RAC responsibilities defined within the MDSAP P0003 document.

Official Observers will not participate in RAC meetings, teleconferences, portions of meetings, document exchanges, etc. that are designated “CLOSED – RAC Members Only.” There may be occasions with the approval of the RAC, Official Observers may be invited to attend specific agenda items in CLOSED sessions.

Official Observers may participate in MDSAP SME Work Group activities, including:

(A) Meetings (one to two annually) and teleconferences (monthly and *ad hoc*);

(B) The development, review, comment, and revision of proposed MDSAP documents; and

(C) Other Deliverable Development Team activities as assigned.

Official Observers may participate fully in MDSAP SME Technical Workgroups and Deliverable Development Teams.

Upon satisfactory completion of MDSAP Assessor competence and training requirements (see IMDRF MDSAP N6), Official Observers may participate as observers in MDSAP assessment activities; including on-site assessments of AOs and witnessed audits of manufacturers. Official Observer’s participation in any Witnessed Audit is also subject to the agreement of the manufacturer to be audited. The number of Official Observers per assessment event will be limited, so that the AO that is being assessed or the manufacturer hosting an assessment through a witnessed audit will not be unduly burdened.

An Official Observer who has obtained the necessary competence and training to be an MDSAP Assessor (see IMDRF MDSAP N6) may act as an MDSAP Assessor for on-site assessments of AOs. MDSAP Official Observers provide at least one (1) MDSAP Assessor to participate in in-country or regional MDSAP assessments. At this time, MDSAP cannot reimburse a regulatory authority for MDSAP Assessor activities.

Official Observers utilize MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer’s quality management system, under the Official Observer’s regulatory framework.

Official Observers have access to reporting information in the MDSAP IT Portal.

4.3 MDSAP Affiliate Member

Affiliate Members engage with, but do not participate in the decision-making process of MDSAP. The RAC retains final decision authority regarding all MDSAP development, implementation, maintenance, and expansion activities.
Affiliate Members will be invited to attend sessions of the annual MDSAP Forum open to medical device industry, AOs, and the MDSAP SME Team. Affiliate Members will be allowed to participate in relevant forum sessions as “OPEN to RAC Members, Official Observers, and Affiliate Members.” These sessions do not involve the exchange of non-public information (NPI) and typically cover policies and procedures.

Affiliate Members will not be allowed to participate in meetings, teleconferences, portions of meetings, documents exchanges, etc. that are designated “OPEN to RAC Members and Official Observers” or “CLOSED – RAC Members Only.” There may be occasions with the approval of the RAC, Affiliate Members may be invited to attend specific agenda items in CLOSED sessions.

Affiliate Members utilize MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer’s quality management system, under the Affiliate Member’s regulatory framework. Affiliate Members report annually on the utilization of MDSAP audit reports and/or MDSAP certificates to the RAC. This report may be presented at the MDSAP Forum by the MDSAP Affiliate Member or the RAC.

Affiliate Members do not have access to the MDSAP IT Portal. Instead, Affiliate Members have access to a list of participating MDSAP facilities, which contains information on the manufacturer, manufacturing site, audit dates and the responsible AO. Affiliate Members can obtain MDSAP audit reports and/or MDSAP certificates by contacting participating manufacturers.

4.4 Lead Project Manager

A Lead Project Manager is responsible for managing, monitoring, and reporting on the progress of specific projects assigned by the RAC.

A Lead Project Manager has the authority to solicit and identify project team membership; assign project team tasks, deliverables, and target completion dates; chair project team meetings; and represent the RAC in the day-to-day management of the project.

Each Lead Project Manager will:

(A) support the development, implementation, maintenance, and expansion of the MDSAP;

(B) solicit project team membership and ensure an appropriate balance and breadth of project team membership amongst regulatory authorities that are members of the RAC;

(C) establish, revise, and maintain project plans as appropriate;

(D) report to the RAC on the activities and progress of their project team on a regular basis or at the request of the RAC Chair;

(E) organize and chair meetings, seeking consensus, discussing assigned tasks, and developing documents in accordance with milestones set by the RAC or project team;

(F) ensure efficient and timely completion of assigned tasks, including the use of a range of electronic means to facilitate effective communication;

(G) prepare summary reports regarding the work of their project team for dissemination on the MDSAP website;

(H) following each project team meeting, circulate to project team members, all relevant documents, actions items, and expectations for the next meeting;

(I) solicit and promote open discussion amongst all project team members during project team meetings;

(J) consult with other Lead Project Managers to avoid duplication of effort and ensure consistency between all MDSAP outputs, irrespective of originating project team; and

(K) assure all project deliverables are complete, documented, and approved by the RAC as applicable.

4.5 Assessment Program Manager

The Assessment Program Manager is responsible for planning and execution of the Assessment Program. The Assessment Program Manager:

(A) interfaces with the auditing organization

(B) drafts the initial Assessment Program and future amendments

(C) ensures the effective planning of the assessment activities listed in the Assessment Program and of follow-up activities where necessary

(D) verifies the implementation of assessment activities by the assessment team according to the Assessment Program

(E) reviews assessment outcomes and proposes recognition decisions to the TRRC; and

(F) provides an executive summary of Assessment Program activities to the RAC.

5. Criteria

5.1 MDSAP RAC Membership

To be eligible for membership to the RAC, an organization must meet the following criteria:

(A) Be a Regulatory Authority;

(B) Have been an Official Observer for at least the last two (2) consecutive years prior to the application for membership;

(C) Have participated in all MDSAP meetings designated as “OPEN to RAC Members, Official Observers, and Affiliate Members” for the last two (2) consecutive years;

(D) Have sufficient capacity to Chair the RAC and provide the Secretariat for a period of two years (with all MDSAP communications being in English);

(E) Have a Confidentiality Agreement with all regularity authorities that are members of the RAC;

(F) Have sufficient capacity, resources, and competencies to carry out RAC responsibilities including participating and leading assessments of AOs (see also IMDRF MDSAP N6). A RAC Member should be able to devote at least 2 full time employees and associated travel expenses to support MDSAP assessments and

(G) Commit to the objectives of MDSAP demonstrated by use of MDSAP within their regulatory framework without need for changes to the MDSAP audit approach.

(H) Commit to providing an update on the utilization of MDSAP at annual MDSAP Forums.

5.2 MDSAP Official Observer Membership

To be eligible for Official Observer membership, an organization must meet the below criteria:

(A) Be the World Health Organization or a Regulatory Authority;

(B) Have been an Affiliate Member for at least the last three (3) consecutive years prior to the application for Official Observer;

(C) If a Regulatory Authority, have current systems established for assessing a medical device manufacturer's quality management system;

(D) Demonstrate a perceived contribution or value to MDSAP;

(E) If a Regulatory Authority, operate a mature or maturing system for medical device regulation which should include:

- Established laws and regulations for medical devices building substantially on intentionally harmonized principles such as those of GHTF and IMDRF
- Proper competencies for effective implementation and enforcement of the established laws and regulation
- A system for conformity assessment of devices building on internationally harmonized guidance documents such as those of GHTF and IMDRF
- Sufficient resources and regulatory expertise to perform its duties

(F) Agree to confidentiality requirements

- For entities granted an Official Observer status *before* November 1, 2022 (i.e., WHO, European Union,[1] and United Kingdom): In the absence of a Confidentiality Agreement with the members of the RAC, the Official Observer agrees to keep discussions, information shared, and outcomes of MDSAP activities and meetings confidential to the extent permitted by applicable laws and regulations.

- For entities granted an Official Observers status *after* November 1, 2022: Official Observers must have a Confidentiality Agreement with all regulatory authorities that are members of the RAC;

[1] Regarding the European Union: Individuals from Member States may participate and serve as representatives of the European Union without their own confidentiality agreements with the members of the RAC.

(G) Demonstrate capacity to contribute resources and expertise to the objectives of MDSAP by participation in MDSAP forums for the last three (3) consecutive years;

(H) Provide a recognized commitment to the objectives of MDSAP demonstrated by use of MDSAP within regulatory framework;

(I) Commit to fulfill training, information, and meeting obligations; and

(J) Commit to providing an update on the utilization of MDSAP at annual MDSAP Forums.

5.3 MDSAP Affiliate Membership

To be eligible for Affiliate Membership, an organization must meet the below criteria:

(A) Be a Regulatory Authority;

(B) Demonstrate an understanding of MDSAP and plan to utilize MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer's quality management system, under the regulatory framework;

(C) Commit to fulfill training, information, and meeting obligations; and

(D) Commit to providing an annual report to the RAC on the utilization of MDSAP audit reports and/or MDSAP certificates.

(E) Commit to promote MDSAP and advocate adoption and use to non MDSAP members.

5.4 MDSAP Lead Project Manager

To be eligible for a MDSAP Lead Project Manager role, an individual must be appointed by the RAC and possess expertise and qualification that demonstrate the ability to successfully complete and manage assigned projects/duties.

5.5 MDSAP Assessment Program Manager

To be eligible for an MDSAP Assessment Program Manager role, an individual must be appointed by the RAC and possess expertise and qualification that demonstrate the ability to successfully plan and execute an Assessment Program.

6. Procedures

6.1 RAC Structure

The RAC will consist of two representatives from each regulatory authority that is a member of the RAC. Each RAC Member will assure the necessary representation is maintained.

Chairmanship of the RAC will rotate between each of the regulatory authorities that are members of the RAC. The term of office will last two years.

The RAC will be chaired by the RAC Chair or the Vice Chair if the Chair cannot fulfill their duties.

The RAC Chair and Vice Chair will be from different regulatory authorities.

The Vice Chair will assume the responsibility of the current RAC Chair at the completion of the current RAC Chair's term of service.

6.2 RAC Decision Making

Decisions of the RAC can only be taken when at least one representative from each RAC Member participates in the decision making process.

The RAC will operate by consensus.

6.3 Granting/Terminating Membership

An organization desiring to participate in MDSAP as an Affiliate Member, Official Observer, or RAC Member must submit the appropriate application to the RAC. Official Observer and Affiliate Member applicants must also provide a presentation to the RAC, in support of their application. After review, and presentations by Official Observer and Affiliate Member applicants, the RAC will provide a decision on the application or may ask additional questions as needed. Membership is only granted with unanimous agreement of existing RAC Members.

Memberships may be terminated by voluntary withdrawal or by exclusion. Any RAC Member, Official Observer, or Affiliate Member may withdraw from participation and remove themselves of their roles and responsibilities. The RAC may exclude an Official Observer or Affiliate Member if the organization has continuously failed to comply with its roles and responsibilities (see section 4 of this document) or if its actions or behavior impairs the proper functioning or reputation of MDSAP. Exclusion requires unanimous agreement of existing RAC Members. The voluntary withdrawal or exclusion of an Official Observer, Affiliate Member, or RAC Member shall become effective on the date of the decision taken by the Official Observer, Affiliate Member, or RAC, as applicable. Re-application for membership is permissible.

6.4 Creation/Termination of Project Teams

Project teams may be formed at any time by the RAC for a project identified as necessary to support the development, implementation, maintenance or expansion of MDSAP. Typically a project is initiated by the generation and approval by the RAC of a Project Team Work Item Proposal/Approval Form. Any RAC Member may submit a Project Work Item Proposal/Approval Form to the RAC for consideration. The RAC may modify approved Project Team Work Item Proposal/Approvals or authorize *ad hoc* project work items as necessary.

The approved Project Team Work Item Proposal/Approval will be assigned to a Lead Project Manager identified by the RAC. Upon approval and receipt of a Project Team Work Item Proposal/Approval, the Lead Project Manager is authorized to initiate the project. If the Project Team Work Item Proposal/Approval was “Approved with Comments” by the RAC, the Lead Project Team Manager must consider all comments when planning and implementing project development activities.

The size and overall composition of each project team is determined by the Lead Project Manager and will include representation from each RAC Member.

Participation in project team meetings by entities outside the participating regulatory authorities requires permission granted by the Lead Project Manager or may be dictated by the RAC.

Issues that cannot be resolved by a project team will be raised to the RAC Chair.

The RAC may discharge a project team from further responsibility, redefine the project team’s original goals and objectives, charge the project team with a new task, and/or appoint a new Lead Project Manager as necessary.

6.5 Appointment of Lead Project Managers

Lead Project Managers are appointed by the RAC to a term necessary for the completion of the project objectives. The appointment of a Lead Project Manager will be documented on the Project Team Work Item Proposal /Approval or by some other means. The RAC can relieve a Lead Project Manager from further responsibility and appoint a new Lead Project Manager based on the needs of the project team to accomplish its objectives effectively and within reasonable time expectations; or for other reasons (e.g. attrition).

Appointment of a Lead Project Manager should be based on the following considerations:

(A) possession of group and project management skills;

(B) possession of technical expertise and/or regulatory experience (of the regulatory authority they represent) relevant to the task assigned to the project team;

(C) the ability of the individual to devote adequate time and attention to the assigned task;

(D) diversity in relation to the regulatory authorities represented by other Lead Project Managers; and

(E) other considerations (e.g., the capacity of the candidate's Regulatory Authority to support such an activity that requires continuity).

Should a Lead Project Manager be unable to fulfill their term, they should promptly notify the RAC Chair who in turn will inform the RAC. The RAC Chair or their designee will then consult within the RAC and appoint a replacement, either on an interim or permanent basis.

Lead Project Managers may be supported by Project Managers and Project Support Specialists assigned by the Lead Project Manager. Project Manager and Project Support Specialist roles and responsibilities will be established by the Lead Project Manager as they will be project specific. For example, Project Manager and Project Support Specialist roles may be defined in a project plan or other project specific document.

6.6 Nomination of MDSAP Project Team Members

The Lead Project Manager will provide the approved Project Team Work Item Proposal/Approval (or other document describing the project) to, and solicit recommendations for project team membership from, all participating Regulatory Authorities.

Nominations for project team members are made by RAC Members.

Lead Project Managers are encouraged to look for the following qualities when assessing nominations for project team membership:

(A) expertise in the subject matter of the project;

(B) ability to participate in most meetings related to project team activities;

(C) ability to represent effectively the interests of the candidate's Regulatory Authority;

(D) willingness to accept project tasks and produce deliverables within target timeframes, whenever possible;

(E) ability to report effectively on project team meetings; and

(F) ability to solicit and consolidate comments and positions of the candidate's regulatory authority on project team activities and deliverables.

In exceptional cases, the Lead Project Manager or RAC may authorize an individual, with appropriate knowledge and expertise, to participate in a project team meeting as a substitute for a project team member; or, to provide specific expertise not anticipated when establishing the original project team.

6.7 Appointment of Assessment Program Managers

Assessment Program Managers are appointed by the RAC. Any member of the RAC may nominate an individual for the role of Assessment Program Manager. The appointment of an Assessment Program Project Manager will be documented. The RAC can relieve an Assessment Program Manager from further responsibility and appoint a new Assessment Program Manager based on the needs of the program to accomplish the objectives of MDSAP effectively; or for other reasons (e.g. attrition).

Appointment of an Assessment Program Manager should be based on the following considerations:

(A) possession of group and project management skills;

(B) possession of technical expertise and/or regulatory experience (of the regulatory authority they represent) relevant to responsibilities of an Assessment Program Manager;

(C) the ability of the individual to devote adequate time and attention to the role of Assessment Program Manager;

(D) diversity in relation to the regulatory authorities who have previously served as Assessment Program Managers; and

(E) other considerations (e.g., the capacity of the candidate's Regulatory Authority to support such an activity that requires continuity).

Should an Assessment Program Manager be unable to fulfill their duties, they should promptly notify the RAC Chair who in turn will inform the RAC. The RAC Chair or their designee will then consult within the RAC and appoint a replacement, either on an interim or permanent basis.

7 Forms

MDSAP F0003.1 MDSAP PTWI Proposal/Approval

MDSAP F0003.2 MDSAP Affiliate Membership Application Form

MDSAP F0003.3 MDSAP Official Observer Application Form

MDSAP F0003.4 MDSAP RAC Member Application Form

8 Reference Documents

MDSAP Functional Statement, MDSAP P0001

IMDRF/MDSAP WG/N6 FINAL:2021 (Edition 2) Regulatory Authority Assessor Competence and Training Requirements

9 Annex A- MDSAP Membership Criteria and Roles

	RAC Member	Official Observer	Affiliate Member
Criteria	• Must be a Regulatory Authority • Must have been an Official Observer for at least the last two (2) consecutive years prior to the application for membership • Must have participated in all MDSAP meetings designated as “OPEN to RAC Members, Official Observers, and Affiliate Members" for the last two (2) consecutive years • Must have sufficient capacity to Chair the RAC and provide the Secretariat for a period of two years (note that MDSAP communications are all in English) • Must have a Confidentiality Agreement with all RAC Members. • Must have sufficient capacity, resources and competencies to carry out RAC responsibilities including participating and leading assessments of AOs	• Must be the World Health Organization or a Regulatory Authority • Must have been an Affiliate Member for at least the last three (3) consecutive years prior to the application for Official Observer • Regulatory Authority should have current system for assessing medical device manufacturer’s quality management system • Perceived contribution or value to MDSAP • Regulatory Authority should operate a mature or maturing system for medical device regulation which should include: ○ Established laws and regulations for medical devices building substantially on internationally harmonized principles such as those of GHTF and IMDRF	• Must be a Regulatory Authority • A demonstrated understanding of MDSAP and plan to utilize MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a medical device manufacturer’s quality management system, under the regulatory framework • Commitment to fulfill training, information, and meeting obligations • Commitment to providing an annual report on utilization of MDSAP reports and/or MDSAP certificates to RAC • Commitment to promote MDSAP and advocate adoption and use to non MDSAP members

	• Recognized commitment to the objectives of MDSAP demonstrated by use of MDSAP within regulatory framework without need for changes to the MDSAP audit approach • Commitment to providing an update on the utilization of MDSAP at annual MDSAP Forums	○ Proper competencies for effective implementation and enforcement of the established laws and regulation ○ A system for conformity assessment of devices building on internationally harmonized guidance documents such as those of GHTF and IMDRF ○ Sufficient resources and regulatory expertise to perform its duties • Must have a Confidentiality Agreement with all RAC Members • Demonstrated capacity to contribute resources and expertise to the objectives of MDSAP • Recognized commitment to the objectives of MDSAP demonstrated by use of MDSAP within regulatory framework	

		• Commitment to fulfill training, information, and meeting obligations • Commitment to providing an update on the utilization of MDSAP at annual MDSAP Forums	

Roles	• Responsible for development, implementation, maintenance, and expansion of MDSAP including:
	  ○ Approval and rejection of all MDSAP documentation
	  ○ Recognition of AOs, official observers, and affiliate members
	  ○ Overseeing of all MDSAP activities
	  ○ Planning and executing MDSAP meetings and trainings
	• Assumes the chair of the RAC on a rotating basis
	• Utilizes MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer's quality
		• Observes and/or contributes to RAC activities while not having do not have equal authority with respect to final RAC decisions and deliverables. Does not participate in the decision making process of MDSAP, but may express suggestions, concerns, and alternatives to RAC decisions and deliverables
		• Reviews, comments, and revises proposed MDSAP documents
		• Consistently participates in any SME work group activities
		• Provides at least one (1) Assessor to participate in in-country or regional MDSAP assessments
			• Engages with, but does not participate in the decision-making process of MDSAP in MDSAP
			• Invited to attend annual MDSAP Forum open to medical device industry, AOs, and MDSAP Subject Matter Expert (SME) Team
			• Participates in forum sessions designated as "OPEN to RAC Members, Official Observers, and Affiliate Members"
			• Does not participate in meetings designated as "OPEN to RAC Members and Official Observers" or "CLOSED- RAC Members Only" unless invited by RAC for specific agenda item
			• Utilizes MDSAP audit reports and/or MDSAP certificates

	management system, under the RAC Member's regulatory framework • Has full access to the MDSAP IT Portal.	• May participate in on-site assessments or witnessed audits of AOs after completion of MDSAP Assessor competence and training requirements • Consistently participates in meetings designated as "OPEN to RAC Members and Official Observers" • Does not participate in meetings designated as "CLOSED- RAC Members Only" unless invited by RAC for specific agenda item • Utilizes MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer's quality management system, under the Official Observer's regulatory framework • Has access to reporting information in the MDSAP IT Portal	for evaluating compliance with applicable medical device requirements, including a manufacturer's quality management system, under the Affiliate Member's regulatory framework • Does not have access to the MDSAP IT Portal; instead have access to a list of participating MDSAP facilities and contact manufacturers for MDSAP audit reports and/or MDSAP certificates
Procedure	• Application file for RAC Membership submitted to RAC	• Application file for Official Observer Membership submitted to RAC	• Application file for Affiliate Membership submitted to RAC

	• Application reviewed by the RAC • RAC members will be accepted with the unanimous agreement of existing RAC members	• Application reviewed by the RAC • Official Observers will be accepted with unanimous agreement of existing RAC members	• Application reviewed by the RAC • Affiliate members will be accepted with unanimous agreement of existing RAC members

10 Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2012-10-19	Initial Release	Robert Ruff
002	2013-08-01	Revised Header and history table to reflect the approve template layout. Page 2; Section 3-Definition: Regulatory Authority definition was added as described in document (IMDRF WG (PD2)/N3R5) (GHTF/SG1 /N78:2012)	Liliane Brown -1
003	2019-03-08	Updated project manager Adjusted formatting	Kimberly Lewandowski-Walker/Hiromi Kumada
004	2023-01-05	Added mechanism for RAs to become RAC members if certain conditions are met Included all roles and responsibilities in one document (instead of three separate documents) Changed RAC chair time period from three years to two years Renamed “REPS” to generic IT platform given upcoming changes Added roles and responsibilities table as Annex A	RAC
005	2024-05-14	Updated to add requirement for Official Observers and Affiliate Member applicants to provide a presentation to the RAC.	RAC
006	2025-03-31	Updated to add additional information on Chair, Secretariat and RAC responsibilities in relation to MDSAP QMS P0011, MDSAP QMS P0009, MDSAP P0031 procedures, AO contributions and the MDSAP website.	RAC

Version 006
Approval

Approved: Signature on file Date: 25/04/01

CHAIR, MDSAP RAC