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Title: MDSAP Affiliate Members Roles and Responsibilities Policy	Project Manager: Neil Mafnas, USFDA	

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1. Purpose/Policy

The purpose of this document is to define the roles and responsibilities of Regulatory Authority (RA) Affiliate Members to the Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC).

2. Scope

This document applies to regulatory authorities not currently participating as an MDSAP Observer or MDSAP RAC member but wish to engage in MDSAP and to utilize MDSAP audit reports for evaluating a medical device manufacturer's quality management system.

3. Definitions/Acronyms

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(Ed 2)

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(Ed 2)

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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 specific to a participating regulatory authority. MDSAP P0003

Note: Other applicable requirements specific to a participating authority include for example:

- Australia's TG(MD) Regs Schedule 1
- Brazil's RDC 665/2022 requirements
- Canada's Part 1 of the Canadian Medical Devices Regulations
- Japan's Medical Device Primary Legislation PMD Act
- United States' 21 CFR 803, 807, etc.

For the complete description of all the applicable requirements see MDSAP AU P0002 Audit Approach:

<https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-audit-procedures-and-forms>

Medical Device Single Audit Program Regulatory Authority Council (RAC): The RAC consists of representatives from all participating regulatory authorities (Australia, Brazil, Canada, Japan, United States) and provides direction, oversight, and resources to support the MDSAP development, implementation, maintenance, and expansion. MDSAP P0003

MDSAP Observer: A member of the World Health Organization (WHO) or a non-participating regulatory authority who observes and/or contributes to RAC activities. MDSAP P0030.

MDSAP Affiliate Member: A non-participating MDSAP Observer or non-participating MDSAP RAC regulatory authority that wants to engage in MDSAP, demonstrates understanding of MDSAP and utilize MDSAP audit reports and/or MDSAP certificates for evaluating a medical device manufacturer's quality management system.

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4. Roles/Responsibilities

Please refer to MDSAP P0003 "Regulatory Authority Council and Lead Project Managers - Authorities, Responsibilities, Governing Policy and Rules" and MDSAP P0030 "MDSAP Observer Roles and Responsibilities Policy."

4.1 Statement of Intent

Regulatory authorities interested in becoming an MDSAP Affiliate Member shall complete the MDSAP Affiliate Member application form and submit it to the RAC. The application to the RAC will describe their interest in utilizing MDSAP audit reports and/or MDSAP certificates as part of their evaluation of a medical device manufacturer's quality management system. The application will also describe the regulator's current system for assessing medical device manufacturer's quality management system, how the regulatory authority will utilize MDSAP audit reports and/or MDSAP certificates and provide a commitment from the regulatory authority to fulfill the training, information, and meeting obligations as an MDSAP Affiliate Member. The RAC will officially recognize MDSAP Affiliate Member applicants after they have adequately demonstrated understanding and utilization of the program.

4.2 Training

MDSAP Affiliate Members shall demonstrate an understanding of MDSAP by completing the on-line training materials and staying up to date on MDSAP policy documents: <https://www.fda.gov/training-and-continuing-education/cdrh-learn>

4.3 Reporting and maintaining the MDSAP Affiliate membership

MDSAP Affiliate Members shall report annually the utilization of MDSAP report and/or MDSAP certificates to the RAC, which may be presented at the MDSAP Forum by the MDSAP Affiliate Member or the RAC.

4.4 Information Exchange and Meetings

MDSAP Affiliate Members will be given access to an extract of the MDSAP master email lists, which includes weekly status reports that will contain information on the manufacturer, manufacturing site, audit dates and the recognized auditing organization (AOs). MDSAP Affiliate Members can obtain MDSAP audit reports and/or MDSAP certificates by contacting participating manufacturers. MDSAP Affiliate Members will not have access to the MDSAP database on the Regulatory Exchange Platform – (REPs) secure IT web portal.

MDSAP Affiliate Members will be invited to attend sessions of the annual MDSAP Forum open to medical device industry, AOs, and the MDSAP Subject Matter Expert (SME) Team. MDSAP Affiliate Members will be allowed to participate in relevant forum sessions as "OPEN to Members, Observers, and Affiliates." These sessions do not involve the exchange of non-public information (NPI) and typically cover policies and procedures.

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MDSAP Affiliate Members will not be allowed to participate in meetings, teleconferences, portions of meetings, documents exchanges, etc. that are designated “OPEN to Members and Observers” or “CLOSED – Regulatory Authority Members Only.” MDSAP RAC participating regulatory authorities retain final decision authority regarding all MDSAP development, implementation, maintenance, and expansion activities.

5. Termination of Affiliate Membership:

The MDSAP Affiliate Membership shall terminate by voluntary withdrawal or by exclusion. Any Affiliate Member may withdraw from participation as an MDSAP Affiliate Member and remove themselves of the roles and responsibilities of an MDSAP Affiliate Member.

The RAC may exclude an MDSAP Affiliate Member if the Affiliate Member has continuously failed to comply with its roles and responsibilities as an Affiliate Member or if its actions or behavior impairs the proper functioning or reputation of MDSAP.

The voluntary withdrawal or exclusion of an Affiliate Membership shall become effective on the date of the decision taken by the Affiliate Member or RAC, respectively. Re-application for membership is permissible.

6. Forms

MDSAP F0035.001 MDSAP Affiliate Membership Application Form

7. Reference Documents

MDSAP P0003 Regulatory Authority Council and Lead Project Managers - Authorities, Responsibilities, Governing Policy and Rules

MDSAP P0030 MDSAP Observer Roles and Responsibilities Policy

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

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8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2019-05-14	Initial Release	Ryan Hoshi
002	2022-06-21	Updated to reflect the current regulatory references and guidance documents	Hiromi Kumada

Version 002
Approval

Approved: ON FILE Date: 2022-06-21
CHAIR, MDSAP RAC