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1. Purpose/Policy

The purpose of this document is to define the roles and responsibilities of Regulatory Authority (RA) observers to the Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC) and the MDSAP Pilot Subject Matter Expert (SME) Group(s).

2. Scope

This document applies to the World Health Organization (WHO) and non-participating regulatory authorities wishing to observe and contribute to the development, implementation, maintenance, and expansion of the Medical Device Single Audit Program (MDSAP).

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: 2013

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: 2013

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 16/2013 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 Model:
http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM390382.pdf

Medical Device Single Audit Program Regulatory Authority Council (RAC): The RAC consists of representatives from all participating regulatory authorities and provides direction, oversight, and resources to support the MDSAP development, implementation, maintenance, and expansion.
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Observer to the MDSAP RAC (RAC Observer): A member of the World Health Organization (WHO) or a non-participating regulatory authority who observes and/or contributes to RAC activities.

Observer to the MDSAP Pilot Subject Matter Expert (SME) Group (SME Work Group Observer): A member of the World Health Organization (WHO) or a non-participating regulatory authority who observes and/or contributes to MDSAP Pilot Subject Matter Expert (SME) Work Group's activities.

4. Authorities/Responsibilities

Please refer to MDSAP P0003 Regulatory Authority Council and Lead Project Managers - Authorities, Responsibilities, Governing Policy and Rules for roles, responsibilities, and authorities of the **MDSAP RAC**, **RAC Chair**, **RAC Vice Chair**, and **RAC Secretariat**.

Relative to their participation, Observers to the RAC and SME Work Groups are responsible for provision of resources required for the development,

implementation, maintenance and expansion of the MDSAP program.

Observers to the RAC and SME Work Groups will only have access to MDSAP manufacturer audit reports and outcomes or the Auditing Organization assessment reports and outcomes contained in the MDSAP Pilot repository as described in section 4.2 below. At such time when an automated repository is developed and established, certain information may be made available dependent on existing Confidentiality Agreements with all participating MDSAP Regulatory Authority members.

4.1. Observer to the MDSAP RAC (RAC Observer)

RAC Observers must consistently participate in all MDSAP RAC activities, 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.

RAC Observers do not have equal authority with respect to final RAC decisions and deliverables. RAC Observers may express suggestions, concerns, and alternatives to RAC decisions and deliverables. However, the MDSAP RAC participating regulatory authorities retain final decision authority regarding all MDSAP development, implementation, maintenance, and expansion activities.

RAC Observers will be allowed to participate in meetings, teleconferences, portions of meetings, documents exchanges, etc. that are designated “OPEN to Members and Observers.” This type of information is typically policies, procedures, work instructions, etc. that do not involve the exchange of Non-public Information (NPI).

RAC Observers will not participate in RAC meetings, teleconferences, portions of meetings, document exchanges, etc. that are designated “CLOSED – Regulatory Authority Members Only.”

4.2. Observer to the MDSAP Pilot Subject Matter Expert (SME) Group(s) (SME Work Group Observers)

Regulatory SME Work Group Observers must have a Confidentiality Agreement with all participating regulatory authorities.

SME Work Group Observers must consistently participate in all 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.

SME Work Group Observers may participate fully in MDSAP Subject Matter Expert Technical Workgroups and Deliverable Development Teams.

Upon satisfactory completion of MDSAP Assessor competence and training requirements, SME Work Group Observers may participate as observers in MDSAP assessment activities; including on-site assessments of Auditing Organizations and witnessed audits of manufacturers. Observer's participation in any Witnessed Audit is also subject to the agreement of the manufacturer to be audited.

The number of Observers per assessment event will be limited, so that the Auditing Organization that is being assessed or the manufacturer hosting an assessment through a witnessed audit will not be unduly burdened.

An SME Work Group Observer who has obtained the necessary competence and training to be an MDSAP Assessor; and represents a regulatory authority that has established Confidentiality Agreements with all MDSAP participating regulatory authorities may act as a surrogate MDSAP Assessor for on-site assessments of Auditing Organizations. At this time, MDSAP cannot reimburse a regulatory authority for surrogate Assessor activities.

Regulatory Authorities providing surrogate MDSAP Assessors will have access to Non Public Information needed to perform that assessment.

5. Procedures

N/A

6. Forms

N/A

7. Reference Documents

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

IMDRF/MDSAP WG/N6 FINAL: 2013 Regulatory Authority Assessor Competence and Training Requirements

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2014-10-07	Initial Release	Robert G. Ruff
002	2014-11-10	Section 4.2: SME Work Group Observer participation as surrogate MDSAP Assessor for assessments activities.	Robert G. Ruff
003	2015-01-08	General changes to define information access and confidentiality aspects.	Kim Trautman
004	2015-07-13	Added page 2 under “Note” - Japan’s Medical Device Primary Legislation PMD Act.	Liliane Brown
005	2019-03-08	Updated project manager Adjusted formatting	Kimberly Lewandowski-Walker/Hiromi Kumada

Version Approval 005

Approved: ON FILE Date: 2019-03-11
CHAIR, MDSAP RAC