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1. Purpose/Policy

To define the authorities, responsibilities, governing policy and rules of the Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC) and Lead Project Managers.

All regulatory authorities participating in the development of the MDSAP have equal say in the development, implementation, and management of the program.

2. Scope

This procedure applies to all regulatory authorities participating in the development, implementation, maintenance, and expansion of the Medical Device Single Audit Program (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.

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 specific to a participating regulatory authority.

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.

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 WG (PD2)/N3R5) (GHTF/SG1/N78:2012)

4. Authorities/Responsibilities

MDSAP RAC

The RAC maintains authority for the final approval or rejection of all MDSAP documentation describing the development, implementation, maintenance, and expansion activities of the program. 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) recognizing MDSAP participating regulatory authorities and auditing organizations;

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

(E) allocating MDSAP work items and project priorities;

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

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

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

(I) 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

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

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

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

(M) providing support and/or guidance to the RAC Chair on the resolution of any complaints or disputes; and,

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

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 Medical Device Single Audit Program; and,

(2) the Regulatory Authority Council.

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 participating regulatory authorities 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 his/her term as Chair, either via an outside contract or through assignment of one or more of his/her staff. Certain tasks of the Secretariat may be delegated to one of the participating regulatory authorities or be outsourced if agreed to by the RAC and the Chair.

RAC Secretariat

The RAC Secretariat will:

(A) provide direct staff support to the RAC 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) serving 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; and,

(E) assuring an MDSAP document repository is maintained.

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

RAC Vice Chair

The principal duty of the RAC Vice Chair is to support the current Chair in his/her activities and to substitute for the Chair, should he/she not be able to fulfill his/her duties.

In the event that the RAC Chair is unable to carry out his/her full term of duty, he/she should promptly notify the RAC so that the Vice Chair can act for him/her until an alternate from the participating regulatory authority of the RAC Chair can be designated to take over.

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

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 participating regulatory authorities;

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

(D) report to the RAC on the activities and progress of his/her 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 MDSAP 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.

5. Procedures

RAC Structure

The RAC will consist of two representatives from each participating regulatory authority. Each participating regulatory authority will assure the necessary representation is maintained.

Chairmanship of the RAC will rotate between each of the participating

regulatory authorities. The term of office, will last three years. The participating regulatory authority initially occupying the RAC Chair and subsequent rotation will be determined by the RAC upon its final constitution.

The RAC will be chaired by the RAC Chair or the Vice Chair if the Chair cannot fulfill his/her duties.

The Vice Chair will be appointed from a participating regulatory authority separate from the current Chair.

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

RAC Governing Policy and Rules

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

The RAC will operate by consensus.

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 the MDSAP. Typically a project is initiated by the generation and approval by the RAC of a Project Work Item Proposal/Approval Form. Any participating regulatory authority may submit a Project Work Item Proposal/Approval Form to the RAC for consideration. The RAC may modify approved Project 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 participating regulatory authority.

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.

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 he/she represents) 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 his/her term, he/she should promptly notify the RAC Chair who in turn will inform the RAC. The RAC Chair or his/her 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.

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 the participating regulatory authority.

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 participating 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 participating 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. Forms

MDSAP PTWI Proposal/Approval, Form MDSAP F0003.1

7. Reference Documents

MDSAP Functional Statement, MDSAP P0001

8. 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-Definitions/Acronyms: Regulatory Authority definition was added as described in document (IMDRF WG (PD2)/N3R5) (GHTF/SG1 /N78:2012)	Liliane Brown

Version Approval

Approved: Kimberly A. Trautman — Date: 1 August 2013

CHAIR, MDSAP RAC