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Approval Sign-Off Sheet

1. Purpose/Policy

This document sets forth the policy and procedures for Medical Device Single Audit Program (MDSAP) participants to include Regulatory Authority (RA) employees, representatives of the Auditing Organizations (AOs) and manufacturers to express and resolve their *Differing Professional Opinions* (DPOs) when dispute resolution solutions cannot be agreed upon between the disputing parties. This procedure provides for:

- Short time frames for hearing DPOs so they can be resolved expeditiously
- Review of the DPO by qualified staff not directly involved in the dispute with the assistance of the RAC as needed (MDSAP P0003 - Section 4 RAC responsibilities)

The formal procedures set forth in this policy should not be invoked until the parties involved have made good faith efforts to resolve differences through informal means.

2. Scope

This policy applies to Differing Professional Opinions regarding decisions made in the context of the MDSAP, as a result of differing interpretation of scientific, regulatory, procedural, and or organizational facts.

It is not intended to address issues related to personnel or work environment situations, nor decisions pertaining to recognition.

This document applies to documents that cover the basis for MDSAP policies and related regulatory decisions including the review of material contained in submissions/applications from the Auditing Organizations or regulated industry. It also applies to the development of documents that may or may not involve review of industry submitted materials (memorandum supporting proposed compliance actions, risk assessments, other). This document should be used in concert with other pertinent MDSAP regulatory policies and/or procedures already implemented. In other words, this document pertains to activities defined by the MDSAP program.

3. Definitions/Acronyms

— The term "*Differing Professional Opinion* (DPO)" refers to any difference of opinion that may influence MDSAP policies, procedures, or outcomes.

Note: In order for a dispute to be eligible for resolution under this procedure, it must be consequential to a decision. A dispute is consequential to a decision if taking one position on an issue would lead to a different decision than taking another position.

— A "significant negative impact" on the MDSAP program will cause program vision, policy and objectives to be compromised.

4. Authorities/Responsibilities

MDSAP Participant in Decision Making

- File a DPO when your MDSAP action or inaction is likely to have significant negative effect on the program and existing mechanisms for resolving disputes have been exhausted
- Prepare any additional material that will assist in dispute resolution or panel consideration of the Ad Hoc DPO Review Panel (all comments, emails, draft documents, precedent setting documents, etc.)
- Be aware of any timelines as they may pertain to any regulatory/MDSAP decisions
- Record outcome of contested decision and/or action in the minutes of the monthly teleconference

RAC Chairperson

- RAC Chairperson designate the Ad Hoc panel
- Confirms receipt of DPO to the submitter
- Notify the requestor if the DPO package was incomplete
- Notifies the interested parties of the decision and / or action

RAC

- Decides if the request is complete/sufficient to support the case, justifiable

and worthy
- Notify the RAC Chair if request information is insufficient
- Confirms or revises the contested decision and / or action
- Issue a written decision and rationale for that decision on the DPO within 15 business days of receipt of recommendation from the ad hoc panel

Add Hoc DPO Review Panel
- Review all information submitted in the DPO
- Make a written recommendation to the RAC within 30 calendar days of receipt

5. Procedures

Background

MDSAP's decision-making process ensures that regulatory actions and policy decisions consider an array of perspectives and concerns. In the free and open discussion of MDSAP issues within a regulatory environment, differing professional views are expected. Individual MDSAP participants are strongly encouraged to discuss their differing views and resolve any differences through discussion with all participants including the RAC. In most cases, the decision may be altered to reach a greater consensus.

The process to make a decision is complex and may involve team leaders, project managers, (TGA, ANVISA, Health Canada, FDA, and PMDA/MHLW) RA participants, including the RAC members/Chairperson and other subject matter experts. In such cases, each MDSAP participant will document their individual views, and the documentation travels with the decision information (package) as it moves through the process – MDSAP chain-of-command.

It is important that individual views and significant controversies or differences of opinions, and their resolution, be documented in an official administrative file. This will provide a historical perspective/precedent for the MDSAP participant and the RAC to consider during the process. It is important that this policy defines the roles and responsibilities of the MDSAP participants including the RAC in documenting views and findings and resolutions of disputes.

This procedure describes a formal process by which all participants can ensure that their views are heard.

Policy

It is the policy of MDSAP to maintain a working environment that encourages all

participants/project teams to make known their professional judgments even if they differ from a prevailing team view, disagree with a MDSAP or RAC decision or policy, or take issue with proposed or established practices.

If there are disagreements between a MDSAP project team(s) and eventually the RAC about a regulatory action or policy decision, the project team leader must take the differing opinions into consideration and make a decision. In all cases, the views of all participants involved in the process must be respected. Any differences of opinions need to be documented.

If a team member believes a decision is to be made, or MDSAP is failing to act in a situation that will have a significant negative impact on the program, it is MDSAP policy to ensure that this team member express a DPO and to have his or her views heard and carefully considered by the RAC.

The RAC and RAC Chairperson will be the focal point for receiving and facilitating resolution of DPOs if necessary.

Process

Any MDSAP team member/participant may initiate the formal DPO review process by preparing a written statement that includes:

- A summary of the position with which the person disagrees, whether it is a prevailing team member view, or a proposed regulatory action or policy decision, or failure to act,
- A description of the submitter's views and how they differ from the above,
- A description of the nature of the disagreement (e.g. interpretation of regulatory requirement, data, methodology, or judgment),
- An assessment of the possible significant negative consequences to the program should the submitter's position not be adopted
- A list of at least three potential candidates for the *ad hoc panel* that will be convened

Note: The statement may be brief, but if it does not include these five elements; it will not be processed as a DPO.

The statement should be clearly marked "Differing Professional Opinion" (DPO) and forwarded through the project team leader directly to the RAC Chairperson.

Within 5 business days of receipt of the DPO, the RAC should consider the DPO and determine whether the consequences of the decision/action/inaction would be likely to have a significant negative effect on the MDSAP program. If so, the DPO is registered, assessed and a decision made. In coming to a decision on whether the RAC must ensure that all other avenues for resolution MDSAP team discussion, MDSAP regulatory briefing, etc. have been exhausted

before a DPO is filed. However, where an individual believes that his or her professional opinion will not be considered by or that there is not time to exhaust other options for dispute resolution without seriously endangering the program the submitter should include in the DPO package a written request to bypass these other mechanism and move directly to a DPO.

If the RAC determines that the potential consequences of the contested decision/action will not have a significant negative impact on the MDSAP program, the DPO will not be progressed and the MDSAP project team leader who submitted the DPO will be informed in writing. The rationale for this decision should be included on the DPO request which must be filed in the MDSAP document repository

Should the RAC determine that the DPO could have the potential to impact negatively on the MSDAP program the RAC Chairperson will appoint an ad hoc DPO review panel to review the DPO. To the extent possible, the DPO panel should not include individuals who have directly participated in the decision-making process up to the time of the DPO. However, the DPO panel should include individuals with the relevant technical expertise and experience to understand the issue at hand.

As soon as the panel has been appointed and has received the necessary information they will:

- Determine whether sufficient documentation was provided by the DPO submitter to complete a detailed review and, if not request additional information.
- Review the DPO and all other relevant materials.
- Consider all sources of information before making their decision.
- Request technical assistance and additional documentation (e.g. reviews, meeting minutes, proposed policies, procedures etc.) from appropriate internal or external sources. The panel will make a written recommendation to the RAC Chairperson. If the panel is unable to reach consensus, the report should reflect the differing opinions of the panel.

  This part of the review should take no more than 30 calendar days to make a written recommendation to the RAC Chairperson.

- The RAC Chairperson will review the panel's recommendation and, in conjunction with the panel, make the decision. If the RAC is unable to reach a consensus on a DPO outcome, the RAC Chairperson has final decision authority on all DPO outcomes.

- Upon resolution of the DPO, the RAC will provide the MDSAP project team leader who submitted the DPO a written RAC decision and rationale

for that decision with 15 business days after receipt of the panel's recommendation.

- All records pertaining to DPOs will be maintained in the MDSAP document repository at each site until the MDSAP Portal has been created.

The email addresses for each Regulatory Authority is as follows:

- Australia: MDSAP@tga.gov.au.
- Brazil: MDSAP@anvisa.gov.br
- Canada: qs.mdb@hc-sc.gc.ca
- Japan: MDSAP@pmda.go.jp
- USA: MDSAP@fda.hhs.gov

6. Forms

MDSAP F0031.1 Differing Professional Opinions Template
MDSAP F0031.2 Flowchart – Attachment 1 (see page 8)

7. Reference Documents

MDSAP P0003 - MDSAP Roles and Responsibilities

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2015-08-20	Initial Release	Liliane Brown
002	2015-10-01	Overall change made by the "team" lead by FH to fit better the purpose of the process. Although procedure was approved and signed off on 2015-08-20 version 001 had not been posted.	Liliane Brown and Frederic Hamelin
003	2019-03-08	Updated project manager Adjusted formatting throughout the document Updated email address for Japan Corrected minor errors on section 6 and 7	Kimberly Lewandowski-Walker/Hiromi Kumada
004	2022-11-22	Updated email address for Health Canada in section 5	Hiromi Kumada
005	2023-01-05	Updated reference document in section 7	Hiromi Kumada

Version Approval 005

Approved: ON FILE _____ Date: 2023-01-05

CHAIR, MDSAP RAC

Attachment 1

MDSAP F0031.2.001 DPO Process Flowchart