Table of Contents

1. Purpose/Policy

To describe the process for initiating, receiving, resolving and maintaining records of complaints and other customer feedback relating to the quality of the Medical Device Single Audit Program (MDSAP) work products, processes and services at the Regulatory Authority(s), an Auditing Organization(s), or at a Medical Device Manufacturer. Complaints can provide valuable feedback on the effectiveness of an organization and can be used to improve the MDSAP with the customer in mind.

2. Scope

This procedure applies to the MDSAP Team's work products, processes, services.

This document should be used in concert with other pertinent MDSAP regulatory policies and/or procedures already implemented, including MDSAP P0003: MDSAP Roles and Responsibilities, MDSAP QMS P0005: Management Responsibility and Management Review Procedure and MDSAP QMS P0009: Nonconformity and Corrective Action Procedure.

3. Definitions/Acronyms

Complaint: Expression of dissatisfaction made to an organization related to its product or service or the complaints-handling process itself, where a response or resolution is explicitly expected. (ISO 9000:2015)

- Complaints are also objections, errors, or nonconformities involving work

quality, or failures to provide service or other requests of the customer including timeliness.

Correction: Action to eliminate a detected nonconformity. (ISO 9000:2015)

Corrective Action: Action to eliminate the cause of a detected nonconformity and to prevent recurrence. (ISO 9000:2015).

Escalation: The process by which MDSAP can escalate a complaint or other feedback to the Regulatory Authority Council (RAC) for final determination when necessary.

Feedback: Customer satisfaction and opinion, comments and expression of interest in a product, a service, or a complaint-handling process (ISO 9000:2015)

Whistleblower: A person or entity making a protected disclosure about improper or illegal activities is commonly referred to as a *whistleblower*. Whistleblowers may be a Regulatory Authority employee, contractors, customers, general public or an employee of an Auditing Organization or medical device manufacturer. The whistleblower's role is as a reporting party. They are not, investigators or finders of fact, nor do they determine the appropriate corrective or remedial action that may be warranted.

4. Authorities/Responsibilities

MDSAP Regulatory Authority Council (RAC) is responsible for:

- Utilizing the Management Review Report and the Concern Resolution Report (CRR) Log, conducting at a minimum, an annual review and analysis of trends and recurrences of Nonconformities, complaints and recommending appropriate remedial action.
- On escalation by the Corrective Actions Administrator, providing final authority of the disposition of all complaints, corrective actions and other issues arising from customer feedback.

Corrective Actions Administrator is responsible for:

- Managing the complaint handling process.
- Monitoring the progress of the complaint or customer feedback.
- Ensuring implementation of the complaints and other feedback procedure and for facilitating process changes when necessary.
- Collaborating with MDSAP QMS Site Representatives and other stakeholders on the evaluation of the complaint or feedback and the determination of what (if any) process or product changes are needed.
- Reviewing the completed records to determine if the action taken is adequately completed or if further follow up action or escalation to the RAC is needed.

- Notify the final corrective action and disposition of the complaint to all entities involved in this process.

NOTE: The Corrective Actions Administrator may be the MDSAP QMS Management Representative, a MDSAP QMS Site Representative, or other designee.

MDSAP Team Members

- Recording complaints and/or other feedback received on the CRR Log.

Regulatory Authority Corrective Action (RA/CA) Contact is responsible for:

- Reviewing the nonconformity, complaint or customer feedback to determine if the issue should be raised to a corrective action or closed with a correction and referred back to the Corrective Actions Administrator. If a corrective action is required, the RA/CA Contact will assign the nonconformity to a Corrective Action Assignee within their organization. Each Regulatory Authority must designate an RA/CA contact.

5. Procedures

A complaint or customer feedback may be submitted in written format, electronically (preferred method), by telephone, or in person through the Regulatory Authorities channels of communication listed below:

Australia (TGA)
Address: Medical Device Single Audit Program (MDSAP), Medical Devices Authorisations Branch, Therapeutic Goods Administration (TGA), Department of Health and Aged Care, PO Box 100, Woden ACT 2606 Australia
Phone: +61 1800 141 144
Electronic contact: MDSAP@tga.gov.au

Brazil (ANVISA)
Address: Setor de Indústria e Abastecimento (SIA) Trecho 5, Área Especial 57 / Lote 200 Brasília (DF) – Brazil. POSTAL CODE: 71205-050
Phone: 0800 642 9782 (Portuguese only)
Electronic contact: MDSAP.atendimento@anvisa.gov.br.

Canada (HC)
Address: Quality Systems Section, Medical Devices Directorate, Holland Cross, Tower A – 5th floor, 11 Holland Avenue, AL 3002A,Ottawa ON K1A 0K9
Electronic contact: qs.mdb@hc-sc.gc.ca

Japan (PMDA)
Address**:** Office of Compliance and Manufacturing Quality for Medical Devices, Division of Registered Certification Body Assessment
Shin-kasumigaseki Bldg. 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
Phone: 81-3-3506-9590
Electronic contact: MDSAP@pmda.go.jp

USA (FDA)
Address: Center for Devices and Radiological Health, (CDRH) Office of Product Evaluation and Quality/Office of Regulatory Programs
Medical Device Single Audit Program, (MDSAP) –WO-Bld.66, RM1457, 10903 New Hampshire Avenue – MD 20993-0002 – USA
Phone: 301-796-5500 main desk - ask to connect with a member of the MDSAP team
Electronic contact: MDSAP@fda.hhs.gov

Receiving Complaints and/or Customer Feedback

The MDSAP team member that received the complaint or feedback shall document it in the CRR Log.

If the complainant requests that their personal data is to be kept confidential, the MDSAP team member that received the complaint is responsible for the confidentiality and the complainant data shall not be filled into the CRR Log. In such case the form should be marked as “confidential” in the correspondent field. Any communication with the complainant, if necessary, must be done through the MDSAP team member that has the complainant data.

A complainant is considered anonymous when the personal information of the complainant is not supplied. In such case the form should be marked as “anonymous” in the correspondent field.

The CRR Log must include, at a minimum:

- The name and affiliation of the complainant (if not confidential or anonymous);
- The name of the individual logging the complaint;
- The date the complaint was received; and
- The nature of the complaint.

Processing Complaints

If the MDSAP team member that received the complaint identifies that a known

correction may be implemented, they should undertake the correction, fill the CRR Log with the information collected from the complainant and the corrections made and notify the Corrective Action Administrator.

If a correction is not known, or the cause and corrective action cannot be determined by the person receiving the complaint, submission of the complaint is still made by entering as much as possible information on the CRR Log and forward to the Corrective Action Administrator.
Corrective Action Administrator will assign the complaint to the appropriate Regulatory Authority Corrective Action (RA/CA) Contact.

The Regulatory Authority Corrective Action (RA/CA) Contact will evaluate if there is sufficient evidence to justify an investigation. If necessary, the Regulatory Authority Corrective Action (RA/CA) Contact can request additional information to the complainant.

If the evidence is not sufficient to perform an investigation and to start a corrective action, the Regulatory Authority Corrective Action (RA/CA) Contact should justify it in the CRR Log and close the Complaint, forwarding it to Corrective Action Administrator that is responsible for final revision and disposition.

If the Regulatory Authority Corrective Action (RA/CA) Contact decides that an investigation is justified, he/she will designate a Corrective Action Assignee.

The Corrective Action Assignee will assess (risk analysis according to MDSAP QMS P0004 Risk Management Procedure) the complaint to determine any adverse impact / hazard associated on the quality of MDSAP products, processes, and / or services. If it is determined that the complaint has an adverse impact, the information should be added on the CRR Log and Corrective Actions should be opened in accordance with MDSAP QMS P0009 Nonconformity and Corrective Action Procedure and recorded on the CRR Log.

Communication between MDSAP stakeholders

As part of the complaints process, Auditing Organizations and Medical Device Manufacturers are informed if there is a complaint against them, noting the complainant can request that their personal data is to be kept confidential.

If the complaint is related to the Medical Device Manufacturer, the respective Auditing Organization should be informed to help to perform the investigation. In this case, and depending on the type of complaint, the investigation could be conducted by requesting documents or records directly from the manufacturer, during a routine or special audit, or by an investigation by the RAs.

If the complaint is related to an Auditing Organization, it should be forwarded to the Assessment Program Manager to evaluate if a special assessment is needed or if the complaint can be investigated requesting additional documents to the Auditing Organization or the investigation can be done during a surveillance/re-recognition assessment.

When a complaint comes from a whistleblower reporting illegal activities all MDSAP Regulatory Authorities Assessment Program Managers should be notified to take the appropriate regulatory actions. The responsible Assessment Program Manager should also advise their RAC representative/s and the RAC Secretariat.

The Corrective Actions Administrator will:

- monitor the progress of the complaint or customer feedback.
- escalate any complaints unable to be resolved by MDSAP Regulatory Authority team members to the RAC. At a minimum, all complaints that have not been resolved within 6 months of receipt of the complaint, need to be escalated for RAC review.

Closing Complaints

- When the corrective action has been completed, the conclusion should also be recorded in the CRR Log.
- RA/CA Contact and Corrective Action Administrator will then review the completed record to determine if the action taken is effective, efficient and satisfactorily completed or if further follow-up action is needed.
- If follow-up action is needed, a follow-up date shall be determined and documented.
- MDSAP Corrective Actions Administrator will need to subsequently ensure follow-up is completed, satisfactory and documented in the CRR Log.
- Only when the corrective action has been successfully completed, would the complaint be considered closed out.
- Corrective Actions Administrator will then notify the final corrective action and disposition of the complaint to all entities involved in this process, and
- Internal audits, and eventually MDSAP management reviews, system tracking and trending will determine if changes resulting from complaints were proper, effective, timely and successful.

Feedback

Customer feedback other than complaints may be considered “continuous improvement” suggestions.

- Customer feedback may include but is not limited to:
    - Suggestions for process changes that will improve efficiency or quality;

  - Ideas for new services;
  - Comments on recognition of high-quality work products or services.
- Document customer feedback by completing the CRR Log and notify to the Corrective Action Administrator for review.
- The Corrective Actions Administrator maintains records of customer feedback. Customer feedback is included and evaluated as part of the MDSAP Management Review process.
- Activities associated with Customer Feedback should be documented on the CRR Log, and
- The Corrective Actions Administrator will monitor the progress of the customer feedback.

6. Forms

Concern Resolution Report Log

7. Reference Documents

MDSAP QMS P0009 Nonconformity and Corrective Action Procedure

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown
002	2015-12-30	Changes throughout the document were made to comply with the QMS plan. Page 2: a paragraph on Whistleblower was added. Page 3 Section Procedure a listing on address and email for each MDSAP was added.	MDSAP QMS team
003	2016-01-14	Section 6 -Forms: page 7, 3 forms were made obsolete QMS F0006.1 (NCR), QMS F0009.1 (CAPR) and QMS F0011.1 (CF). Replaced with QMS F0013.1 Concern and Resolution Form.	MDSAP QMS team
004	2016-10-20	Revisions made throughout the document to reflect the ISO 9001:2015 revisions	Liliane Brown, Patricia Serpa

VERSION No.	VERSION Date	Description of Change	Author Name/Project Manager
005	2019-01-11	Concern and Resolution Form was replaced with Concern Resolution Report Form throughout the document. Contact information of Australia (branch's name) was changed. Contact information of Japan was added in section 5.Added note to the authorities/responsibilities of Corrective Action Administrator in section 4. Adjusted formatting	Hiromi Kumada/Kimberly Lewandowski-Walker
006	2024-01-18	Periodic review Adjusted formatting Updated Regulatory Authority contact information in section 5 Concern Resolution Report Form changed to Concern Resolution Report Log	Hiromi Kumada
007	2025-03-31	Reviewed to refer to Management Review procedure and identify a defined point to escalate unresolved complaints received.	Dimity Herden – RAC Secretariat

Version Approval 007

Approved: Signature on file Date: 2025/04/01

CHAIR, MDSAP RAC