

 Responsible Office/Division	Document No.: MDSAP QMS P0011.005	Page: 1 of 8
	Version Date: 2019-01-11	Effective Date: 2019-01-15
Title: MDSAP QMS Complaint and / or Customer Feedback Procedure		Project Manager: Hiromi Kumada, PMDA

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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 Medical Device Single Audit Program with the customer in mind.

2. Scope

This procedure applies to the MDSAP Team's work products, processes, services, and the MDSAP Quality Management System.

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).

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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:

- Reviewing and analyzing trends and recurrences of Nonconformities, complaints and recommending appropriate remedial action.
- Providing final authority of the disposition of all complaints and other issues arising from customer feedback.

Corrective Actions Administrator is responsible for:

- Populate the complaint database with information from the MDSAP QMS F0013.1 Concern Resolution Report Form.
- Monitor 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 forms to determine if the action taken is adequately completed or if further follow up action is needed. If acceptable the Corrective Actions Administrator signs off on the form.
- 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 MDSAP QMS F0013.1 Concern Resolution Report Form.

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

- Review 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 his/her organization. Each Regulatory Authority must designate an RA/CA contact.

5. Procedures

A complaint or customer feedback may be submitted in written format, electronically, 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 Branch, Therapeutic Goods Administration (TGA), Department of Health, PO Box 100, Woden ACT 2606 Australia

Phone: 61 2 6221 6876

Electronic contact: MDSAP@tga.gov.au

Brazil (ANVISA)

Address: Coordenação de Inspeção e Fiscalização de Produtos – ANVISA. SIA Trecho 5, Área Especial 57, Bloco B – Térreo CEP 71205-050 – Brasília – DF - Brazil

Phone: 0800 642 9782 (Portuguese only)

Electronic contact: <http://portal.anvisa.gov.br/fale-conosco> (form in Portuguese only) or through the e-mail MDSAP.atendimento@anvisa.gov.br.

Canada (HC)

Address: Quality Systems Section, Medical Devices Bureau, 2934 Baseline Road Tower B, Address Locator: 3403A , Ottawa, Ontario, K1A 0K

Phone: 613-957-4786

Electronic contact: QS MDB HC@hc-sc.gc.ca,

Japan (PMDA)

Address: Office of Standards and Compliance 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

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USA (FDA)

Address: Center for Devices and Radiological Health, (CDRH) Office of Compliance, (OC)
Medical Device Single Audit Program, (MDSAP) –WO-Bld.66, 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 MDSAP@fda.hhs.gov

Receiving Complaints and/or Customer Feedback

The MDSAP team member that received the complaint or feedback shall document it on the MDSAP QMS F0013.1 Concern Resolution Report Form.

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 MDSAP QMS F0013.1 Concern Resolution Report Form. 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 Concern Resolution Report Form 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, he/she should undertake the correction, fill the Concern Resolution Report Form with the information collected from the complainant and the corrections made and forward it to 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

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still made by entering as much as possible information on the Concern Resolution Report Form and forward to the Corrective Action Administrator. Corrective Action Administrator will populate the Complaint database with information from the Concern Resolution Report Form and 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 Concern Resolution Report Form 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 Actions 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 Concern Resolution Report Form and Corrective Actions should be opened in accordance with MDSAP QMS P0009 Nonconformity and Corrective Action Procedure and recorded on the same Concern Resolution Report Form.

Communication between MDSAP stakeholders

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 RA's.

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 should be notified to take the appropriate

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regulatory actions.

The Corrective Actions Administrator will monitor the progress of the complaint or customer feedback.

Closing Complaints

- When the corrective action has been completed, the conclusion should also be recorded in the Concern Resolution Report Form. The form is submitted to the RA/CA Contact and Corrective Action Administrator electronically.
- RA/CA Contact and Corrective Action Administrator will then review the completed form to determine if the action taken is effective, efficient and satisfactorily completed or if further follow-up action is needed. If satisfactorily completed the RA/CA Contact and Corrective Action Administrator signs off on the form and close the complaint.
- 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 system.
- 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 MDSAP QMS F0013.1 Concern Resolution Report Form and forward to the Corrective Action Administrator for entry into the database.
- The Corrective Actions Administrator maintains records of customer feedback. Customer feedback is included and evaluated in the MDSAP management review process.
- Activities associated with Customer Feedback should be documented on the

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- MDSAP QMS F0013.1 Concern Resolution Report Form, and
- The Corrective Actions Administrator will monitor the progress of the customer feedback.

6. Forms

MDSAP QMS F0013.1 Concern Resolution Report Form

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
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

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Approval

Approved: ON FILE
CHAIR, MDSAP RAC

Date: 2019-01-11