SOP Feedback Management and Customer Complaints

Summary

This SOP describes how to respond to feedback and complaints.

Process Owner	*<enter role of process owner>*
Key Performance Indicators	*<enter KPIs to be tracked for the Management Review>*

Regulatory requirements:

Regulation 2017/745 (MDR)	Art. 83-88 (Post-market surveillance, trend analysis and vigilance)
ISO 13485:2016	8.2.1 / 8.2.2
IEC 62304:2006	6.2.1

General Considerations

In this section, provide general information about how you intend to set up your company's feedback management system.

Consider sub-sections that describe more specifically:

- Customer support availability (typically e.g. 9am - 5pm CET Mon - Fri)
- Customer support ticket system (if applicable, consider GDPR requirements for sensitive data)
- Contact channels: describe the primary way to contact your customer support (e.g. support email address).
- Think about the most commonly used contact channels for your product and organization. Also consider channels independent from internet connection. Ideally, inquiries should be responded to in the same way of communication as they were received by.
- Feedback prioritization (*optional*, e.g. high - medium - low)

Feedback Classification

All feedback is classified into one of the following categories. If the Operations team is not sure how to classify a ticket, it consults the QMO.

Feedback Category	Feedback Description
Support Inquiry	Any request for help that can be resolved by providing the user with (usability) information.
Change Request	Any request to add, modify or remove product functionalities.
Customer Complaint	Any complaint that can be related to our products or organization and which is not classified as an "issue with potential negative influence on patient health".
Issue with potential negative influence on the state of health	Any customer complaint related to:problem with the medical device that could cause or may have caused or did in fact cause a death or serious deterioration in the state of health.problem with the medical device that significantly impaired the performance criteria of the device (based e.g. on the information given in the intended use, user manual or marketing material).

> Add more categories as required by your organization. For example: positive feedback (praise), data privacy inquiries, differentiate product complaints <> customer complaints (not product related), etc.

Serious Deterioration of the State of Health
A serious deterioration of the state of health includes at least one of the following:life-threatening illness,permanent impairment of a body function or permanent damage to a body structure,a condition which requires medical or surgical intervention to prevent one of the above,any indirect harm as a consequence of an incorrect diagnostic result when used within manufacturer's instructions for use.

Process Steps

1. Documentation of Feedback

The Operations team receives feedback through a contact channel, which automatically opens a respective ticket in our system (see general considerations above). Based on the input, the Operations team then documents at minimum the following information in the ticket:

- Date of feedback
- Description of the issue (e.g. software version, runtime environment, if available: screenshots / images)
- Affected users, contact details and customer locations
- Steps to reproduce the problem

Participants	Operations team
Input	Received feedback / complaint
Output	Structured documentation of feedback in ticket system

2. Evaluation of Feedback

The Operations team classifies the feedback according to the categories outlined in the general considerations of this process. Depending on the feedback category it takes respective actions:

Support Inquiry:

The Operations team actively supports the customer / user in solving the issue by answering questions or providing additional user training.

Change Request:

The feedback ticket is forwarded to the Product team to decide over implementation and potentially initiate the change management process.

Customer Complaint:

- If the customer complaint constitutes a persistent problem related to a medical device that cannot be resolved by providing user information or training (e.g. software bugs), it is forwarded to the Product team to initiate the problem resolution process.
- If the customer complaint is related to an organizational issue (e.g. sales and marketing efforts), the Operations team involves other teams of the organization where necessary to provide the customer / user with a satisfactory response.
- If the customer complaint may constitute a systematic issue, the feedback is additionally forwarded to the Quality Management Officer (QMO) to initiate the process for corrective and preventive actions (CAPA).

Issue with a Potential Negative Impact on the State of Health:

All issues with a potential negative impact on the state of health must be reported immediately, but no later than on the same day, to the Person Responsible for Regulatory Compliance (PRRC) to initiate the SOP Vigilance.

All product-related feedback shall be checked for a potential impact on:

- product requirements for the respective device;
- the post-market surveillance for the respective device, including trend analysis (see Art. 83 and 88 MDR);
- the device risk management file.

Participants	Operations team
Input	Documented feedback

Output	Classified feedback and decision on actions

3. Validation of Actions

The Operations team proactively receives updates regarding the status of actions per ticket from other teams.

Once the actions are considered completed (e.g. for change requests: decision to implement a feature or not is made), the Operations team informs the customer / user and validates if the actions taken are satisfying. If so, the validation is documented in the ticket and the ticket is closed. If not, this process is re-initiated.

If a customer / user does not respond, validation is tried at least a second time before the ticket is closed.

Participants	Operations team
Input	Implemented actions
Output	Validation of actions, ticket is closed

> Optionally, depending on the features that your ticket system provides, consider adding a process step to assign each ticket a status (open, pending input, closed).
