SOP Sales

Regulatory Requirement	Document Section
Medical Device Regulation Article 7	All
ISO 13485:2016 7.2	All

Summary

This SOP describes how we offer and sell our medical devices, including trial and research projects. With this SOP we want to make sure that we only offer medical devices and services we develop, and that we sell medical devices/services that comply with regulatory requirements.

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

1. General Considerations

1.1 Marketing Material

On the basis of its technical documentation, the Sales team compiles the product Marketing Material. The Marketing Material refers to all claims regarding the functionality, usability and performance of the medical device. It has to be reviewed and approved by the PRRC and QMO prior to use. The Sales team is responsible for keeping it up to date.

1.2 Company Product Portfolio

The organisation's product portfolio, in the scope of sales and marketing, is defined as all products and services that are released for sales following the software development and product certification and registration process.

1.3 Special Requirements for Client-Facing Roles

Following national provisions for the German market, every person working in client-facing roles must obtain training as a Medical Device Consultant.

Optionally, the following provisions may be added:

- *Specification of a CRM tool and how it should be used.*
- *Specification on how to store and manage customer-related information. For example, use one Google Drive folder for all information related to the same customer.*

2. Process Overview

2.1 Compilation of Marketing Material for Medical Device

On the basis of its technical documentation, the Sales team is responsible for compiling the product Marketing Material and for keeping it up to date. Both PRRC and QMO must approve the Marketing Material prior to use to ensure that:

- The information is compliant with regulatory requirements for the country in which the Marketing Material is used.
- The information is consistent with other relevant documents of the technical documentation, in particular the device's intended use, risk management, clinical evaluation and user manual.

Whenever the technical documentation is updated following the change management process, the Marketing Material must be reviewed for necessary changes.

Participants	Sales team
Input	New released medical device
Output	Released marketing material

2.2 Marketing of Medical Device

Before a marketing event (e.g. presentation to a customer, conference or other external event), event-specific, product-related claims must be checked for compliance against the Marketing Material. The responsible employee therefore obtains approval from the leader of the Sales team or the QMO. Approval must be given in written form (electronic communication is sufficient), documented and archived.

Participants	Any employee
Input	Draft of specific marketing material (e.g. presentation, flyer, posters, etc.)
Output	Approved specific marketing material,Documented approval

Optional:

Add process step(s) for lead management: how to generate, qualify and contract B2B leads. How to exchange and where to store customer information. Define customer information: also include informal meetings, phone calls, etc.? What information must be documented at minimum? Are NDAs required and if so, when?

2.3 Compilation of Customer Contract / Offer

Note: this applies for B2B-customers only and must be customised to your company setting

In case of a **portfolio-based request:**

The Sales team evaluates the organisation's capacities to carry out the customer project (e.g. capacities of service provision, product delivery and maintenance, et.c). Confirmation by the Management may be requested. If deemed sufficient, the Sales team compiles an offer / contract. If not deemed sufficient, the project is terminated and no offer / contract is extended.

Any offer / contract is submitted to the customer in written form (e-mail is sufficient) and is documented in <specify tool here>. Differences between the customer request and the contract / offer should be pointed out specifically.

In case of a **non-portfolio, new medical device request**:

If the customer requests a medical device (feature) which is not part of the existing portfolio, the Sales team consults with the Management if new development efforts should be taken into consideration. If not, the project is terminated and no offer / contract is extended.

If new development efforts are deemed acceptable, the Sales team requests instructions from the development team and the QMO on how new customer requirements should be collected.

The Sales team compiles a customised offer / contract that must be approved by Management and the QMO. Approval must be documented. The offer / contract is submitted to the customer in written form (e-mail is sufficient) and is documented in <specify tool here>. Differences between the customer request and the contract / offer should be pointed out specifically.

Participants	Sales team
Input	Customer request
Output	Submitted and documented standard or individual offer

2.4 Closing Customer Contract and Key Account Management

Once the customer accepts the contract / offer, a signed copy is stored on <specify tool here>. The Sales team appoints a responsible person to serve as the main point of contact. This person is communicated to the customer. The deployment process is initiated.

Participants	Sales team
Input	Submitted standard or customised offer / contract
Output	Deployment process initiated

2.5 Handling Feedback

The Sales team proactively reaches out to customers to obtain feedback. All customer feedback is handled following the organisation's feedback management

process.

The vigilance process must immediately be initiated for any customer complaint related to:

- a 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**.
- a 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).

A *serious deterioration in state of health* results in at least one of the following:

- life-threatening illness or injury
- permanent impairment of a body structure or a body function
- hospitalisation or prolongation of patient hospitalisation or a condition which requires medical or surgical intervention to prevent any of the above
- chronic disease
- any indirect harm as a consequence of an incorrect diagnostic result when used within manufacturer's instructions for use

Participants	Sales team
Input	Running customer project
Output	Initiated feedback management or vigilance process