Regulatory Requirement	Document Section
MDD Annex I and X	All
MDR Annex XIV	All
MEDDEV 2.7/1, rev. 4	All

Summary

This SOP describes the development of medical devices in accordance with regulatory requirements of Annex I and X (MDD) and Annex XIV (MDR) regarding medical device clinical performance. It ensures the level of demonstrated safety and risk-benefit ratio that is required for our medical devices both for initial certification and for continued safe use in the market.

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

Process Steps

1.1 Clinical Evaluation Plan

The clinical evaluation is initiated following a Management decision to place a new or updated medical device on the market. The organization follows this process both for initial market placement and for continuous updates during the marketing phase.

The initial clinical evaluation is planned as part of the Clinical Evaluation Plan. During the marketing phase, this plan is continuously updated as part of the Post-Market Clinical Follow-Up.

External partners can be involved in both conducting the initial clinical evaluation and the post-market clinical follow-up in order to ensure higher clinical expertise during the process and lower the risk of regulatory nonconformity. In this case, different external partners should be evaluated with regard to sufficient experience (see MEDDEV 2.7/1 rev. 4 section 6.2). The Head of the Medical Team serves as the point of contact to provide all relevant information to the partner.

> NOTE: if your organization maintains a purchasing process, the selection of an external partner for the clinical evaluation should be subject to supplier evaluation.

Participants	Medical Team

Input	Initial release: decision on new device, preliminary product specifications (intended use, risk assessment, available preclinical data, information on equivalent devices, etc.)
Output	Initial release: completed Clinical Evaluation Plan

1.2 Clinical Evaluation Report

Relevant data is collected and analyzed as part of writing the Clinical Evaluation Report to evaluate the device's clinical performance. At minimum, the clinical evaluation must take account of:

- Intended use (incl. user and patient population, use environment, device features)
- Data to support equivalence with other devices (if applicable)
- Discussion of state of the art technology
- Discussion of the selected categories of clinical data, the quality of clinical data and its sufficiency to support an overall balanced risk-benefit ratio of the device and compliance with the General Safety Performance Requirements (MDR) / Essential Requirements (MDD).

In the course of data collection and analysis, new risks may be identified and are documented accordingly as updates to the risk management file.

> NOTE: where a Notified Body is involved in the conformity assessment of the device and the Medical team identifies remaining uncertainty with regard to the sufficiency of the clinical data, the Notified Body can be contacted to discuss additional measures (e.g., as part of the post-market clinical follow-up) that ensure product conformity and approval.

Participants	Medical Team
Input	Product specifications
Output	Completed Clinical Evaluation ReportIf necessary: updated risk file

1.3 Post-Market Clinical Follow-Up (PMCF)

Following the initial clinical evaluation, the organization plans the post-market clinical follow-up for the medical device, ensuring its continuous safety and sufficient performance during the marketing phase. The PMCF serves as input to regularly update the clinical evaluation.

The Medical team is responsible to compile and implement a Post-Marketing Clinical Follow-Up Plan, including at minimum:

- Methodology for data collection and justification for selected methods

- Consideration of new data related to the risk management file, the claims discussed in the Clinical Evaluation Report or applicable regulations
- Specification of the PMCFP period (no longer than one year), including a time plan for PMCF activities and the next update of the clinical evaluation

The CAPA process must be initiated if new information collected as part of the PMCF activities indicates that a balanced risk-benefit ratio and the safety of the device is in question.

All PMCF activities conducted per PMCF period are documented in a Post-Market Clinical Follow-Up Report.

Participants	Medical team
Input	Clinical Evaluation Report New clinical data during the marketing phase
Output	Completed Post-Market Clinical Follow-Up Plan and ReportIf necessary: PMCF measures (e.g., CAPA, updated risk file, etc.)