

Regulatory Requirement	Document Section
ISO 13485:2016 Section 5.6	All

Summary

This SOP describes how the surveillance of the quality management system shall be conducted to ensure ongoing adequacy, suitability and efficacy of organizational processes. The organization regularly conducts a Management Review to document the assessment of QMS surveillance outputs and overall compliance with regulatory requirements.

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

General Considerations

1.1. Management Review Input

The organization can use varying key performance indicators (KPIs) to measure processes. At minimum, the following data must be collected as input for the Management Review:

- **Status of Measures of Previous Management Reviews**
Input: which measures have been implemented as planned.
Management shall evaluate the effectiveness and efficacy of previous measures.
- **Audits Results**
Input: findings and measures from internal audits, audits by authorities and Notified Bodies, supplier audits conducted by the organization.
- **Status of Corrective and Preventive Actions (CAPA)**
Input: summary of nonconformities found and respective actions taken.
- **Status of Feedback Management and Complaint Handling**
Input: summary of feedback and complaints received and actions taken in response.
- **Status of Risk Management**
Input: summary of actions taken as part of risk management, e.g. risk mitigation, updates of the risk management report, results from post-market surveillance, etc.
- **Status of Incident Reporting**
Input: potential incidents that were assessed, incidents that were reported, summary of coordination with supervisory authorities, actions taken as a result.

- **Status of Applicable Regulation**

Input: published and/or anticipated updates of relevant regulation, including expected implications for the QM system.

- **Changes to the Quality Management System**

Input: implemented and/or anticipated changes that impact the QM system (and which, ideally, are assessed as part of the Change Evaluation List - for instance, changes to the organizational structure, infrastructure, processes or customer requirements).

- **Other Key Performance Indicators (KPIs)**

Typically, every processes should be assigned an indicator that allows the assessment of process effectiveness, unless there is a valid explanation for why no KPI is reasonably applicable (see ISO 13485:2016, para. 4.1.3). KPI results become management review input.

1.2. Management Review Output

At minimum, the Management Review Report shall provide an assessment of the adequacy, suitability and efficacy of the QM system to comply with regulatory requirements. Additionally, process impact on product safety shall be critically reviewed.

As part of this process, the Management also reviews the organization's quality policy, quality objectives and the status of key performance indicators (KPIs).

Based on findings during the Management Review, the Management may define further measures such as the revision of single processes, product changes or the (re-)allocation of resources.

1.3. Review Period

The organization shall conduct a Management Review (at least) once per year. Ideally, the review is conducted before an external audit (e.g. by a Notified Body) and no sooner than audit reports from internal auditing are available.

Process Steps

2.1 Setting Up Process Key Performance Indicators

At the beginning of every review period, Management together with the QMO defines key performance indicators (KPIs) for the QMS processes of the company. The quality objectives are reviewed for continued adequacy.

The results of this process step are communicated to all relevant members of the organization (e.g. process owners).

Participants	Management, QMO
Input	Quality Policy, Quality Objectives
Output	Process KPIs

2.2 Data Collection and Analysis

Every process owner is responsible to track the KPI of their process during the review period and to keep records as required by the process.

At the end of a review period, the QMO collects data input from process owners and analyzes the KPI data against pre-defined criteria in preparation for the Management Review. The QMO may undertake further investigation to identify nonconformities and to provide a preliminary assessment of the adequacy, suitability and efficacy of the QM system.

Participants	QMO, Process Owners
Input	KPI records
Output	Completed data analysis

2.3 Management Review Report

Management and QMO together discuss the reported input and completed data analysis. The Management is responsible to evaluate the results against the pre-defined criteria and formulate an assessment of the adequacy, suitability and efficacy of the QM system. Where necessary, the Management defines measures for improvement. The results of the Management Review are documented in the Management Review Report.

Where necessary, the Management sets up new or revised process KPIs as well as quality objectives for the next review period. This is communicated again to all relevant members of the organization.

Participants	Management, QMO
Input	Completed data analysis
Output	Management Review Report, new or revised KPIs and strategic goals, planned measures

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