Quality Policy, Quality Objectives and Key Performance Indicators

Background

ISO 13485:2016 requires manufacturer to establish a quality policy (clause 5.3) and measurable quality objectives (clause 5.4.1). Usually the quality objectives are followed-up by key performance indicators (KPI's) which monitor the quality management system (QMS) processes (clause 8.2.5) and product (8.2.6). Management review (clause 5.6) is conducted to evaluate quality policy, quality objectives and KPI's to determine if the QMS is adequate, suitable and effective.

Many companies struggle to balance the efforts spent on the above. Unfortunately it can be seen that non-value adding statements and documents are generated for the sake of passing QMS audits. Especially small companies with just a few employees and small management teams would like to reduce the workload to a useful level.

Purpose

This document was written to provide a pragmatic approach to fulfill requirements from ISO 13485:2016. Although it delivers a straight-forward way to reduce efforts to a minimum, the solution provided still requires top management to stay committed to maintain an effective QMS.

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Quality Policy, Quality Objectives and Key Performance Indicators

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1. Quality Policy

As a rather small economic operator within the medical device industry we are

- Aiming to develop, manufacture and distribute state-of-the-art medical devices improving patients' health,
- Committed to comply with requirements and to maintain the effectiveness of the quality management system,
- Continue to keep and expand our market shares.

2. Quality Objectives

Increasing competition on the market, difficult resource situation and an incredible complexity of international regulation and bureaucracy are forcing us to keep focus on the core contents of our quality policy. The following quality objectives are therefore established:

Quality objective	The objective will be considered achieved, when…
Sustain the marketed products on the market to keep track with the state-of-the-art.	All articles can be successfully kept on the market throughout the year.
Maintain existing certification to EU 2017/745 (MDR), ISO 13485:2016 and MDSAP (Australia, Canada and US)	The certificates can be successfully maintained without causing business interruptions throughout the year.
Achieve MDSAP certification for Brazil enabling market entry.	Brazil was added the MDSAP until the end of the year.

Quality Policy, Quality Objectives and Key Performance Indicators

Quality policy and quality objectives are supplemented by key performance indicators (KPI's) as per SOP Data Analysis which monitor the quality management system (QMS) processes and product. The KPI's (see Appendix A: Key Performance Indicators (KPI's)) will guide us to achieving the quality objectives.

Approvals

As required by ISO 13485:2016, we will review Quality Policy and Quality Objectives at least annually as per SOP Management Review for continuing suitability.

General Manager: _____

Quality Management Representative: _____

3. References

- SOP Management Review
- SOP Data Analysis

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Appendix A: Key Performance Indicators (KPI's)

The following KPI's are established and will be evaluated in management review:

KPI	Thresholds	Relevant section of the QMS	Remark
Feedback	PMS reports and PSUR are maintained and updated as per SOP PMS	8.1, 8.2.1, 8.4	-
Complaint handling	Complaint rate will not increase versus previous year	8.2.2	25ppm in 2023
Reporting to regulatory authorities	Zero late reports to authorities	4.1.1, 8.2.3	-
External audits	No interruption to certification	4.1.1	-
Internal audits	Conduct all internal audits as planned	4.1.1, 8.2.4	-
Monitoring and measurement of processes (8.2.5)	100% software validation completeness	4.1, 7.5	93% in 2023
	Median change request closure time < 30 days	4.2	35.2 days in 2023
	Conduct >80% of planned maintenances as planned	6.3	85% in 2023
	Conduct pest control as planned	6.4	-
	Continue supplier development to achieve >80% A suppliers	7.4	79% in 2023
	Conduct >90% of planned calibrations as planned	7.6	88% in 2023
Risk Management	Review each risk management file once a year	7.1	-
Monitoring and measurement of products	Review state-of-the-art at least once a year	7.3	
	Reject rate in incoming inspection will not increase versus previous year	7.4.3	12% in 2023
	100% process validation completeness (IQ, OQ, PQ)	7.5	93% in 2023
	80% first pass rate in final inspection	8.2.6	78% in 2023
	Zero use-on-concession	8.3	2 in 2023
CAPA	CAPA effectiveness >80% during initial effectiveness check	8.5	86% in 2023

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KPI	Thresholds	Relevant section of the QMS	Remark
Applicable new or revised regulatory requirements	Review of list of standard and regulations every 6 months	4.1.1, 5.2, 7.2	-
	Implement Brazilian MDSAP requirements into QMS in Q1/2024	4.1.1	-
Resources and management commitment	Implement job descriptions for at least 60% of all employees	5, 6.1, 6.2	20% in 2023

The KPI's are deemed adequate as quality policy and quality objectives are supported. Each key element of the QMS is monitored with at least one KPI.