Regulatory Requirement	Document Section
ISO 13485:2016 Sections 5.6.2 and 7.3.3	All

Summary

This SOP describes how the organization identifies changes to regulation applicable either to the organization as a manufacturer or its products in the market. This process shall ensure that changes are identified early enough and required changes are implemented in a timely manner so that regulatory compliance is guaranteed at all times.

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

Process Steps

1. Regulatory Input / Review

The QMO is responsible to gather all available regulatory information that is potentially relevant for the organization and its medical device(s) based on respective documentation provided by the Product Manager(s). Input may entail statutory laws, regulations and guidance documents. The QMO analyzes the applicability of relevant regulations and documents his assessment in a List of Regulatory Requirements.

Relevant input channels may include, but are not limited to: * Newsletter of ISO / IEC * (For Germany) Beuth newsletter * FDA newsletter * EU website on harmonized norms * Consultancy newsletters (Johner, Open Regulatory, . . .)

Every relevant regulation is reviewed at least once per year, every time before a new medical device is placed on the market or as specified by the List of Regulatory Requirements.

Participants	QMO
Input	Medical device specification (technical documentation), Available regulatory requirements
Output	List of Regulatory Requirements

2. Changes Based on Applicable Regulation

If a new or revised applicable regulation is brought to their attention, the QMO conducts a gap analysis to assess if:

- changes to the organization;

- changes to the quality management system;
- changes to any of the medical devices;

are necessary in order to stay compliant with the updated regulatory requirements. The completed gap analysis is saved to the QMS records for audit purposes. The QMO also updates the List of Regulatory Requirements accordingly.

Changes to medical devices are implemented according to the change management process. Where updates to the organization's quality management system processes are necessary, the QMO implements those directly or delegates implementation to the respective process owners.

Participants	QMO, Process owners
Input	New or revised regulation
Output	Gap analysis of new or revised applicable regulation, List of Regulatory Requirements (updated)

3. Communication and Evaluation of Changes

The QMO communicates new or revised regulation to relevant members of the organization (e.g. process owners or product managers). Management is informed of new or revised regulation at least annually as part of the Management Review. As part of the Management Review, it is also evaluated if updates to applicable regulations have been implemented effectively.

Participants	QMO, Management
Input	Implemented changes based on new or revised regulation
Output	Communication to relevant members of the organization, Management Review Report: evaluation of implemented regulatory updates