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 Applicable Regulations.

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 Applicable Regulations.

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

2. Actions Based on Applicable Regulation

If a new or revised applicable regulation is brought to their attention, the QMO updates the List of Applicable Regulations. Where necessary, updates 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.

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 relevant section of the Management Review Report, it is evaluated if updates to applicable regulations have been implemented effectively.

Participants	QMO
Input	New or revised regulation
Output	List of regulatory requirements (updated), Communication to relevant members of the organization