

# How to derive the scope of Quality Management System



# Table of contents

**01** Introduction

**02** What is the scope

**03** How we can define the scope

**04** Main factors of the scope

**05** ISO Standards

**06** Internal audit

**07** Quality manual design

**08** Procedure manual design

**09** Conclusion



# Announcement

Isolocity is the quality management system that drives itself. To stay updated, follow us on



# Introduction

The scope of a quality management system is one of the most important aspects to consider while implementing it.

It helps in deciding what needs to be **included** and **excluded** from the quality management system.

The scope is defined by identifying the products, services and processes that are covered by the QMS for achieving the desired results.



# What is the scope?

The scope of the quality management system is the boundaries of your business. It is a set of activities, products and services that make up your organization.

You need to know what the scope is before you start designing a quality management system for your business because you will use this knowledge when creating policies and procedures for your system



# How can we define the scope



## Boundaries

What are our organizational boundaries? For example, does the organization operate in more than one country or state? Are there multiple facilities that make up the company?



## Product/Service

What do we produce or deliver as a product or service? Do we offer multiple products or services with different characteristics from each other (like a restaurant with different types of menu items)?



## Variation

How much variation can be expected in terms of products/services produced within a reasonable timeframe or period of time (for example, manufacturing automobiles)?

# Main factors of the scope



## Organization

- What does your company do?
- Who are its main customers?
- What are their needs?
- What kind of operations does it perform?
- How does this relate back to the overall purpose of the company?



## Quality

- Why does your organization need a QMS?
- Are there any regulatory issues that require compliance with specific standards/guidelines for example ISO 9000 series)?
- Do any customers require such control systems as a condition for doing business with them?



## **Are all requirements applicable to our organization as per the ISO standard, identifying what is not applicable?**

As you begin to gather information about the scope of your quality management system, it's important to remember that ISO has a lot of requirements. You'll need to evaluate each requirement carefully and determine its applicability to your organization. It's also important to identify what is not applicable at this time.

For example, if there are specific standards that apply only under certain conditions or in relation to particular types of products or services, those will have no relevance for your organization right now. What's more is that there may be other requirements that are not relevant because they are not practical or achievable with the resources available within your company (e.g., conducting audits).

Once you've identified which requirements are relevant and which ones aren't, you'll then want to prioritize them based on their importance for operationally effective quality management systems (i.e., QMSs).

# Should the internal audit be conducted to ensure that all aspects have been considered and covered?

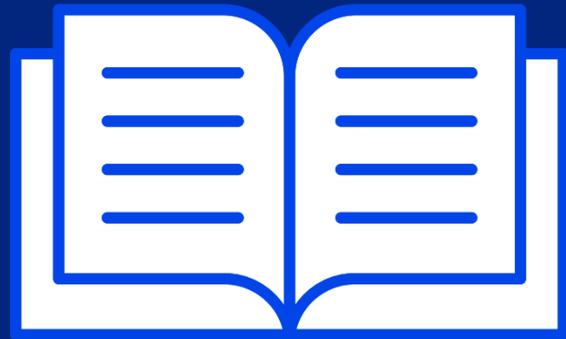
The answer is no.

A detailed internal audit is not mandatory, but it is a good practice to perform one.

The purpose of conducting an internal audit is to ensure that all aspects have been considered and covered in your quality management system (QMS), which will help you maintain compliance with your own QMS regulations and standards such as ISO 9001:2015, ISO 13485:2016 etc.,

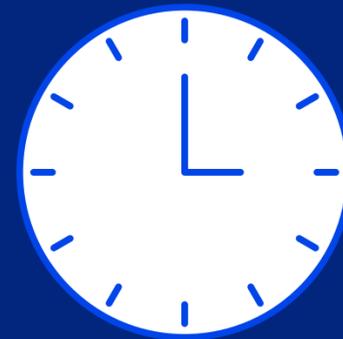


# Quality Manual Design



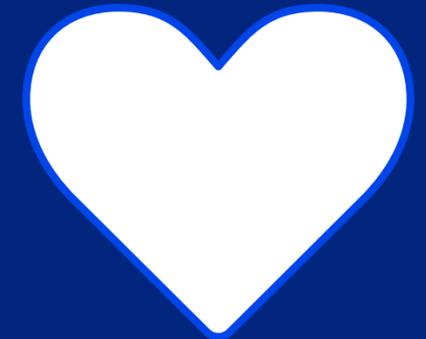
## Comprehensive

Your manual should cover all aspects of your QMS, from top to bottom. This includes procedures and records related to all areas of your operations, as well as internal audits and quality audits.



## Up to date

The manual should reflect any changes you've made since its last update—whether it's new equipment or processes, new staff members or training programs—anything that has significantly changed how you operate should be reflected there with an explanation of what was changed and why it was necessary for the company's quality improvement process



## Easy to read

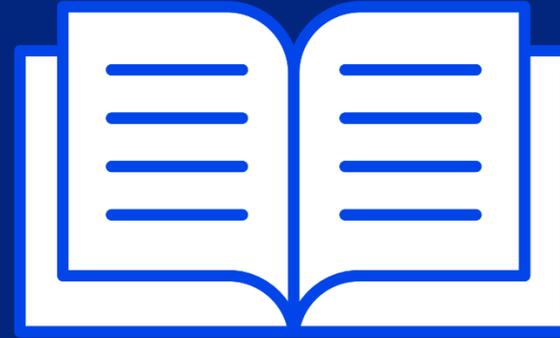
Easy to read and understand by anyone who needs access to it (employees).

# Procedure Manual Design



QMS

An explanation of the Quality Management System (QMS) and how it works, including any relevant standards and regulations that apply



Documents

A list of quality management documents, including QMS policies, procedures and work instructions (WIs)



SOP

A list of any quality-related documents that are referenced in your SOPs for easy access

# Conclusion

The scope of quality management system is a very important part of the entire process. It helps in identifying and understanding what is required to be included in the Quality Management System.

If you are looking for a specific template, we have a word doc template as well, download the same from this blog.