

SAMPLE PAGES

FOR

ISO 9001:2015

POCKET GUIDE

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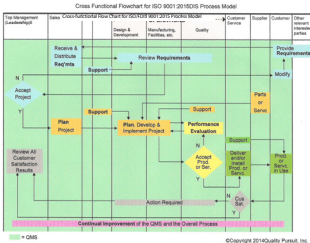
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CLAUSE 4.1

UNDERSTANDING THE ORGANIZATION AND ITS CONTEXT

As we begin our discussion about the requirements of the standard, we are introduced to the concept of organizational context. The



The initial requirement asks for identification of all issues that enhance or impede optimum achievement of targeted outcomes of the QMS. The origins of the issues contributing to the organization's context may be internal or external. Furthermore, the issues themselves, may be well defined or substantially subjective. For example, a well-defined external issue may be attainment of FDA approval for a new pharmaceutical product. On the other hand, a subjective internal issue may be the level of teamwork within and among groups in your organization. It is your job to capture, follow and review those internal and external issues that affect achievement of defined success. With this knowledge, you are better prepared to make improvements to your organization. (4.1)

Context of the organization

Management's Role - The creation of the quality management system, in accordance with the requirements, is in the hands of management. They must allow those who understand your company the best to work with people who understand the standard very well in an effort to create a suitable, adequate and effective ISO 9001:2015 compliant quality management system. Any auditor assessing the above requirement may initiate a dialog about the context of your organization while seeking to understand issues that may affect the QMS. From your position of knowledge there should be little concern that an external auditor would disagree with your view of the context of your organization.

Each Employee's Role – During the creation of the quality management system, some of you may be called upon as subject matter experts. Make your best effort to capture sufficient process detail so that the results from everyone implementing the process are as much alike as possible.



CLAUSE 4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

Keeping in mind the 4.1 discussion above, it can be seen that “interested parties” are part of the context of your organization. An understanding of the interested parties that affect your QMS is required. It is further required that your organization:

- be familiar with the requirements of these interested parties that impact the QMS.

Context of the organization

- maintain an awareness of the interested parties and respond to changes of their relevant requirements. (4.2)

There are many organizations that can be considered as possible interested parties. Here is a partial list of possible interested parties in no particular order of importance or otherwise: customers, suppliers, employees, stockholders, competitors, regulators, neighbors, governments and special interest groups. Your organization's goals may be affected by needs of interested parties or by your reluctance to recognize them. Analyze the needs thoroughly and respond appropriately.

Management's Role - For the interested parties that have hard requirements for your organization, like customers and regulators, you have no choice except to be completely responsive. For others with whom you have a give and take relationship, you must carefully consider the consequence of your responses. Strive to maintain a cooperative environment with all interested parties.

Typically, an auditor will question only obvious exclusions from your list of interested parties.

Each Employee's Role – Clearly, employees will always be an included interested party. As employees, you should seek, through your representatives, the conditions that support optimum performance of the group. Temper your requests by seeking only the true needs of the group. Strive to maintain a cooperative environment.

DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

When determining the scope of your QMS there are three questions that should be considered. (1) To what does my

organization's QMS apply? (2) Where is the QMS to be used? (3) Can any of the requirements of the ISO 9001:2015 standard be documented as non-applicable?

Some of the possible “whats” and “wheres” are listed below:

- products
- services
- locations
- departments
- etc.

The inclusion of products and/or services is an obvious requirement. Your organization's understanding of internal/external issues and needs of relevant interested parties (see 4.1 and 4.2 respectively) are also required inputs when developing the QMS scope statement. The following discussion applies to question (3) above:

Exclusions of requirements of the ISO 9001:2015 standard are allowed if no applicability exists. For example, consider

