

WHAT IS ISO 9001?

ISO 9001 is an international standard that gives requirements for an organization's **quality management system (QMS)**. It is part of a family of standards published by the International Organization for Standardization (ISO) often referred to collectively as the "ISO 9000 series" or "ISO 9000 family".

For this reason, you may sometimes hear your suppliers refer to being "ISO 9000 certified", or having an "ISO 9000-compliant QMS". This will normally mean that they are claiming to have a QMS meeting the requirements of ISO 9001, the only standard in the ISO 9000 family that can be used for the purpose of conformity assessment.

It is important to understand, however, that ISO is the body that develops and publishes the standard – ISO does not "certify" organizations, as will be explained later in this text.

The objective of ISO 9001 is to provide a set of requirements that, if effectively implemented, will provide you with confidence that your supplier can consistently provide goods and services that:



- Meet your needs and expectations
- Comply with applicable regulations

The requirements cover a wide range of topics, including your supplier's top management commitment to quality, its customer focus, adequacy of its resources, employee competence, process management (for production, service delivery and relevant administrative and support processes), quality planning, product design, review of incoming orders, purchasing, monitoring and measurement of its processes and products, calibration of measuring equipment, processes to resolve customer complaints, corrective/preventive actions and a requirement to drive continual improvement of the QMS. Last but not least, there is a requirement for your supplier to monitor customer perceptions about the quality of the goods and services it provides.



ISO 9001 does not specify requirements for the goods or services you are purchasing. That is up to you to define by making clear your own needs and expectations for the product. You might, for example, refer to product specifications, drawings, national or international product standards, supplier's catalogues, or other documents as appropriate.

WHAT DOES “CONFORMITY TO ISO 9001” MEAN?

This means that your supplier has established a systematic approach to quality management and is managing its business to ensure that your needs are clearly understood, agreed and fulfilled. A statement of conformity to ISO 9001 should not, however, be considered as a substitute for a declaration or statement of **product** conformity.



HOW DOES ISO 9001 HELP YOU IN SELECTING A SUPPLIER?

ISO 9001 provides some requirements for the purchasing process that include you as the customer. These requirements address the following topics :

- Requirements regarding the purchasing information that should be provided so that suppliers clearly understand their customers' needs
- The ways in which supplied products can be verified as meeting the requirements of the customer.

Note that whenever ISO 9001 refers to “products”, this also includes intangible products like services, or software.

You have an important role to play by specifying to your supplier what you actually want. You may need to consult with your own internal technical staff (the actual users) in this process. If you don't do this, you might find that you receive a product that meets all your stated requirements and the applicable regulatory requirements, but which is absolutely wrong for your intended application. So, first of all, you should concentrate on specifying your needs related to the intended use of the product.

To help in this task you may consider the following:

- What is the specific product (goods or service) you are buying?
- What impact does this product have on your own business?
- What are the risks to your business if you experience problems with this product?
- How can you be sure that the product you receive will actually meet your requirements?

- What do you know about the reputation and historical performance of your supplier?
- What level of confidence do you need in your supplier's ability to provide you with conforming product on a consistent basis?
- If you decide that conformity to ISO 9001 is important, (based on your assessment of the risks associated with the goods and services you are buying) how can you be sure that your supplier does have a QMS that meets ISO 9001 requirements?
- Are the goods and services you require covered by your supplier's QMS? (You may need to ask for a copy of your supplier's actual certificate or declaration of conformity to find this out!).

