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Determining Requirements Related to Products

Both ISO 9001:2008 and ISO 13485:2003 have specific expectations of the organization to determine product requirements. Both standards have the same requirements. This is one of those cases where both standards agree, *i.e.*, ISO 13485 does not have additional or changed requirements specific to medical devices.

The product requirements fall into four broad categories. In summary, they are:

- required and customer stated;
- required and not customer stated;
- statutory and regulatory; and
- required and supplier stated.

The first, required and customer stated, are often in a contract between you and the customer. Typically, there is a drawing, specification document, or some other method enumerates the requirements. An example is a dimension on a drawing; the supplier might specify 3 ± 0.1 inches.

The second, required and not customer stated, are the product expectations that the customer has not explicitly included. An example is electrical safety. If your product plugs into the wall, the customer may assume you have an adequate electrical safety program in place. They may even assume you have a safety mark such as UL or CSA.

The third, statutory and regulatory, relates to legal requirements. Often a design must follow specific codes. In the EU, product directives establish Essential Requirements and may require the CE Mark. In the US, the FDA may need to clear or approve a device. The electrical safety example above is interesting because, in some justifications, a safety mark is a legal requirement. This illustrates that a requirement may not fall neatly into only one category; they are not necessarily mutually exclusive.

The fourth, required and supplier stated, are often the things that distinguish your product. This could include color schemes and logos; certain panel layouts, or other design features that distinguish your product.

These requirements relate to the product, so they should be included as part of the design and development input in 7.3.2.