Supply Chain Roles in ISO 13485:2016

ISO 13485:2016, clause 4.1.1 requires the organization to document the roles it has in the medical device supply chain. In an accompanying note, the roles could include manufacturer, authorized representative, importer, or distributor.

Clause 0.1 provides background information. Jurisdictions have regulatory requirements for the application of the quality management system in various supply chain roles. To accommodate these roles the standard expects the organization to:

- identify any roles under each jurisdiction's regulatory system
- identify the regulatory requirements that apply to those activities
- incorporate the regulatory requirements into the quality management system

ISO 13485:2016 and ISO 9000:2015 provide definitions of the various roles.

> *Supplier* means an organization that provides a product or a service [ISO 9000:2015, 3.2.5]
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> *External supplier* means a provider that is not part of the organization [ISO 9000:2015, 3.2.6]
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> *Manufacturer* means a natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s) [ISO 13485:2016, 3.10]
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> *Authorized representative* means a natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation [ISO 13485:2016, 3.2]
>
> *Importer* means a natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed [ISO 13485:2016, 3.7]
>
> *Distributor* means a natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user [3.5]

The EU Medical Device Regulation

The European Union intends to publish medical device regulations (MDR) that will supersede the existing medical device directive. This new regulation includes definitions of roles and the corresponding regulatory requirements. Consequently, it provides an example of the type of problem companies will encounter identifying and documenting the roles.

Unfortunately, the definitions in the MDR are not the same as the definitions in ISO 13485:2016. Each medical device manufacturer needs to determine the roles that they take on under the MDR as well as the roles of any companies that provide services such as an authorized representative or a distributor.

Recommendation

To conform to ISO 13485:2016, a company will first need to make a list of all the jurisdictions in which it does business. Then determine which roles the company has in each of these jurisdictions. With this information available, the company should be able to determine the regulatory requirements for each of these roles recognizing that they will not be the same in each jurisdiction.

With the regulatory information, the company needs to include each requirement in the quality management system (QMS). One effective approach is a traceability matrix in which each requirement from each jurisdiction maps to a standard operating procedure by name, number, revision level, and paragraph. This method will help ensure all the regulatory requirements are included in the QMS. In addition, the matrix will be valuable to evaluate SOP updates, since the information could help prevent inadvertent changes causing the company to be out of compliance.