US Medical Device Reporting: **Who Is Responsible?**

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When various companies are involved in the manufacture and export of medical devices to the United States (US), it is not always easy to understand the reporting responsibilities under the US Medical Device Reporting regulation. A new rule has been published to help companies better understand the requirements. This article discusses the new rule, ways to determine responsibilities and suggestions for compliance.

Plain language regulation

The United States (US) Medical Device Reporting (MDR) regulation specified in 21 Code of Federal Regulations Part 803, requires deaths, serious injuries and certain malfunctions related to medical devices to be reported to the US Food and Drug Administration (FDA). On 28 February 2005, a Direct Final Rule on the MDR regulation was published in the US Federal Register.[1] Unless significant adverse comments are received leading to its withdrawal, it will become effective on 13 July 2005. Readers should be aware of this so that they can obtain a copy of the Rule, maintain it in their files, and begin to refer to this version of the regulation once the Rule becomes effective.

The new Rule does not change the existing MDR requirements. Its primary purpose is to ensure that the MDR regulation is written in plain language so that it is easier to understand. This action is being taken in accordance with a Presidential Memorandum on Plain Language issued on 1 June 1998, under the Clinton Administration, which directed the US Federal Government to use plain language in government writing and provided guidance on how to do this.

Therefore, the newly written regulation attempts to use commonly understood words, "you" and other pronouns, the active voice and short sentences. For example, the current title of Section 803.50, Individual adverse event reports; manufacturers, in the new rule becomes, If I am a manufacturer, what reporting requirements apply to me?

The attempt to issue regulations in clear and easy to understand language is laudable. These regulations need to be understood not just by those whose native language is English, but companies located in various parts of the world manufacturing or marketing medical devices sold in the US.

Identifying the manufacturer

The types of business arrangements among companies involved with marketing medical devices can sometimes lead to uncertainties in determining regulatory responsibilities. For example, if one European company purchases a medical device from another European company that manufacturers the device, and the first company sells the device to a company located in the US that imports it into the US and markets the device under its own name, are either or both European companies responsible for complying with the MDR regulation? Some may believe that, in this example, only the US company is responsible for complying with the MDR regulation; however, the MDR regulation applies to all three companies.

To understand why this is so, it is necessary to recognise that the MDR regulation applies to manufacturers and to understand the US regulatory definition of "manufacturer." The definition is presented in Table I. That is, under US regulations, a manufacturer is any person who manufactures the device regardless of whether or not that person markets the device under his own name. This →

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differs from the definition under the European Directives, whereby the manufacturer is the person who places a product on the market under his own name regardless of whether or not that person actually manufactures the product. Under US regulations, a manufacturer is also a person who initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications.

Therefore, in the US, the MDR applies to the company that actually manufacturers a medical device and the company that is responsible for initiating the specifications for a device, which is manufactured by another company. However, these responsibilities may be shared as long as certain actions are taken to ensure full compliance with the regulation.

Regulatory responsibilities

Before discussing methods of complying with the MDR regulation, it should be mentioned that importers and user facilities are responsible for submitting certain types of reports to FDA and/or the manufacturer. In addition, distributors are responsible for maintaining certain types of files. Although a discussion of these responsibilities is beyond the scope of this article, an analysis of actions that companies should take to ensure full compliance with the MDR regulation should be based on a knowledge and understanding of these additional requirements.

In the example presented above, the US company is in contact with the user, is responsible for managing complaints and is responsible for identifying any complaint that could represent an MDR event. In addition, the company must ensure that complaints and MDR events are properly investigated in a timely fashion. This responsibility is also shared by the European company from which the device was purchased and the company that manufactures the device. This means that, depending on their agreement, the US company or the European company from which it purchased the device, should provide copies of complaints and MDR events to the company that manufactures the device so that appropriate investigations are conducted by persons with the requisite technical knowledge and capability.

Before providing an example of how companies can fulfill the requirements under the MDR regulation, it is important to note that companies should interpret their responsibilities based on the regulation itself and their own circumstances. That is, they should not act based solely on the example provided in this article. However, in situations similar to the example provided above, FDA has found it acceptable that if a written agreement specifies that the US-based company will be responsible for submitting MDR reports to FDA, the European-based companies do not need to submit an MDR report for the same event.

Table I: Definition of manufacturer in US 21 CFR Part 803, Medical Device Reporting.

Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles or processes a device by chemical, physical, biological or other procedure. The term includes any person who

(1) Repackages or otherwise changes the container, wrapper or labelling of a device in furtherance of the distribution of the device from the original place of manufacture

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications

(3) Manufactures components or accessories, which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or

(4) Is the US agent* of a foreign manufacturer.

*All MDR requirements concerning the US agent or US designated agent have been stayed indefinitely. Current requirements for US agents are in 21 CFR Part 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices.

Ensuring full compliance

The types of business arrangement and the number and role of companies involved in the design, manufacture and sale of medical devices vary significantly. When medical devices are designed and manufactured by companies outside the US for export into the US, these relationships can become even more complex and regulatory responsibilities must be defined. To ensure full compliance with US MDR regulations, the regulatory responsibilities of all parties involved in the management of complaints and MDR events, including the reporting of these events to FDA, should be clearly described in standard operating procedures (SOPs), which are maintained by the parties.

Furthermore, it is advisable that companies establish an SOP for managing MDR events that is separate from procedures to manage events under other jurisdictions. For example, companies sometimes combine in one SOP the management of MDR events and the management of European Medical Device Vigilance reports. This practice too often results in a confusing procedure that is difficult to understand and follow and leads to inadequate compliance.

In addition to developing relevant SOPs, it is important that any duties and responsibilities for the management of complaints and MDR events are included in commercial agreements, or that these agreements refer to established SOPs.

Reference

1. US Federal Register of 28 February 2005 (70 FR 9516), downloadable from www.fda.gov/OHRMS/DOCKETS/98fr/05-3829.pdf or www.gpoaccess.gov/fr/index.html mdt

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