US Importer and Distributor Requirements

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A medical device manufacturer who exports products to the United States (US) may risk success in this activity by not being aware of US importer and distributor requirements. This article discusses the requirements and actions that nonUS manufacturers should take to ensure these requirements are met.

Corrections and removals

In late 2003, a United States (US) subsidiary of a well-known multinational medical device company received a Warning Letter from the US Food and Drug Administration (FDA) relating to 11 products that it was responsible for importing into the US. The US-based company not only served as US Agent for the corporate entity located outside the US, but was responsible for the initial handling of complaints, submission of Medical Device Reports, 510(k) and Premarket Approval submissions, correction and removal reports and radiological-product reports. The company received a Warning Letter because it had failed to comply with the FDA correction and removal regulation specified in 21 CFR Part 806. This requires manufacturers and importers to report to FDA within 10 working days any correction or removal of a device to reduce a risk to health.

In this case, the company had recalled the 11 products, but apparently had not notified FDA. During an FDA investigation, these recalls were examined and considered by FDA to be Class II recalls. Under the general FDA policies on recalls in 21 CFR Part 7, Enforcement Policy, a Class II recall is one in which exposure to the product may cause temporary adverse health consequences. The correction and removals regulation, which applies to medical devices, requires that manufacturers and importers promptly report to FDA any correction or removal of a device if the correction or removal was initiated to reduce a risk to health. FDA found that the company had conducted the recalls, which met the definition of "removal" in 21 CFR 806.10 (a)(1). However, it had not submitted the required reports to FDA. In the Warning Letter, FDA requested that the company notify FDA within 15 working days from date of receipt of the letter of the steps that would be taken to correct the violation. In addition, the company was asked to describe its plans for preventing the violation from recurring.

According to FDA officials, not all US importers are aware of the corrections and removals regulation, which is a relatively new regulation compared with other US device regulations. For example, the general FDA policies in 21 CFR Part 7 are usually well understood by importers. These policies cover all products regulated by FDA except electronic products that emit radiation and are subject to 21 CFR Parts 1003 and 1004. In addition, FDA has only recently begun active enforcement of the correction and removals regulation.

For these reasons, nonUS manufacturers exporting medical devices to the US should be aware of the corrections and removals regulation and check that the US importer has procedures in place to ensure full compliance. Otherwise, failure to comply with this regulation could lead to FDA enforcement actions such as those in the Warning Letter discussed above. FDA informed the company that failure to take prompt action to correct the violations could result in FDA initiating regulatory action →

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without further notice. That action can include seizing the product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

Registration and listing

Under 21 CFR Part 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices, FDA defines "initial importer."

> An initial importer is any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage or otherwise change the container, wrapper or labelling of the device or device package.

Initial importers are subject to important requirements under this regulation including the need to register their establishment and meet the medical device listing requirements that apply to them.

Adverse event reporting

The US regulations for reporting serious adverse events are specified in 21 CFR Part 803, Medical Device Reporting (MDR). These regulations apply to importers and distributors. Under the MDR regulations, an MDR reportable event is

- an event about which user facilities become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury
- an event about which manufacturers or importers have received or become aware of information that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury
- an event in which the device has malfunctioned and the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Under the MDR regulations, "importer" is defined as any person who imports a device into the US and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labelling of the device or device package.

A "distributor" is defined as any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labelling of the device or device package.

Importers must submit MDR reports of individual adverse events to FDA within 30 days after the importer becomes aware of an MDR reportable event. A copy of this report must be submitted to the manufacturer. In contrast, importers are required to submit reports of malfunctions only to the manufacturer within 30 days after the importer becomes aware of the malfunction.

As discussed in a previous article,[1] manufacturers of finished devices, including nonUS manufacturers of finished devices sold in the US under the name of another company, are also responsible for submitting reportable events to FDA under the MDR regulations. It is also important to note that the MDR regulations hold manufacturers responsible for conducting an investigation of each event and evaluating the cause of the event. Therefore, nonUS manufacturers need to have a clear understanding of the MDR regulations and written procedures that describe how all requirements that apply to them will be fulfilled.

NonUS manufacturers should also understand how the importer intends to comply with the MDR regulations. This is critical because some nonUS manufacturers believe that only the US importer is directly responsible for submitting MDR reports. This is not the case; however, FDA has accepted the submission of an MDR report only from the importer if certain criteria are met. For example, the report includes necesary information from the manufacturer and written procedures and agreements clearly define manufacturer and importer responsibilities for meeting MDR requirements. If companies have any doubts about the arrangements that they have made with their importers regarding the submission of MDR reports, they should seek confirmation from FDA that these arrangements are acceptable or seek expert advice regarding this issue. NonUS manufacturers should also ensure that importers have procedures for ensuring that all product complaints (MDR and nonMDR events) are forwarded to the manufacturer in a timely fashion.

MDR event files

Files and records provide a critical source of evidence that importers, distributors, and manufacturers are complying with the MDR regulation. The MDR regulation also applies to user facilities; however, this aspect of the regulation will not be discussed in this article. Therefore, nonUS manufacturers should be fully aware of the requirements under 21 CFR 803.18, Files and distributor records. Under this section of the regulation, importers and manufacturers must establish and maintain MDR event files. These are written or electronic files that must contain:

- Information in the possession of the reporting entity or references to information related to the adverse event, including all documentation of the entity's deliberations and decision-making processes used to determine if a device-related death, serious injury or malfunction was or was not reportable under this part.
- Copies of all MDR forms, as required by the MDR regulation and other information related to the event that was submitted to FDA and other entities such as an importer, distributor or manufacturer.

MDR event files may also contain references to the location of relevant information such as medical records, patient files and engineering reports. ➔

Distributor event records

Under 21 CFR 803.18(d)(1), a device distributor is required to establish and maintain device complaint records that contain any incident information, including any written, electronic or oral communication received by, or generated by, the company that alleges deficiencies related to the identity (for example, labelling), quality, durability, reliability, safety, effectiveness or performance of a device. Readers should note that these complaints records are consistent with the meaning of complaints under the US Quality System Regulation as defined in 21 CFR Part 820. In addition, section 803.18(d)(1) also requires that distributors maintain information, if any, on the evaluation of these allegations in the incident record. Device incident records must be prominently identified as such and filed by device, and can be maintained in written or electronic form. Files maintained in electronic form must be backed up.

It is important that nonUS manufacturers know whether or not these records are being maintained for the specified period of time. That is, the regulation requires the distributor to retain copies of these records for a period of two years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the record.

Contractual agreements

Prudent nonUS manufacturers will understand not only the requirements that apply to them, but also those that apply to US importers and distributors. Compliance with these requirements should be thoroughly discussed so that all involved parties have the same understanding of how importer and distributor requirements will be met. Appropriate procedures should be maintained by the manufacturer, importer and distributor for the same reason. Written agreements should describe relevant roles and responsibilities to avoid any misunderstandings of US regulations as they apply to the importer and distributor and any responsibilities that may be shared with the manufacturer.

References

1. M.E. Donawa, "US Medical Device Reporting: Who Is Responsible," *Medical Device Technology*, **16,** 3, pp. 27–29 (2005). mdt

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