Understanding “Product” in FDA’s QSR

FDA device regulations make a distinction among components, manufacturing material, and finished devices. Often, these distinctions are difficult to understand and, initially, seem counter intuitive. For example, at first glance the phrase “manufacturing material” seems to describe the material that you use to manufacture the device. As explained below, it has a completely different meaning.

This article addresses four defined terms in QSR that can be confusing. They are:

- Product
- Component
- Manufacturing material
- Finished device

The terms come from FDA’s Quality System Regulation (QSR) – the Quality Management System (QMS) required for manufacturers who market medical device in the US. Before issuing the final version, FDA issued a draft regulation and solicited public comment. As part of the final regulation package, FDA addressed many of the comments, explained their thinking, and provided background information. The preamble can help you understand the regulations and provides valuable insight into FDA’s intentions.

Start with the definitions in 21 CFR §820.3.

Product
The first term to look at is “product”, since it the most comprehensive. According to 21 CFR §820.3(r), “*Product* means components, manufacturing materials, in-process devices, finished devices, and returned devices.” QSR does not define “in-process devices” or “returned devices”, by we can infer the meaning from the regulations.

Returned Device
A “returned device”, we infer is a device the manufacturer released for distribution, shipped to a customer, and sent back to the manufacturer for any reason. The manufacturer must analyze returned product as part of Corrective and Preventive Action (820.100(a)).

In-process Device
Similarly, we can infer a definition for an “in-process device”. An “in-process device” is not yet a finished device, but is far enough in the production process that it is subject to “in-process” acceptance activities (see 820.80(c)).

Component
QSR defines a component in 21 CFR §820.3(c) and tells us, “*Component* means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.”

A component is any intended part of the device when you are ready to release it for distribution.

This definition contrasts with manufacturing material, defined in 21 CFR §820.3(p), telling us that, "*Manufacturing material* means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer."

Manufacturing material is a residue or impurity that you don't intend to include in the finished device. You need it to make the device, but you don't want it in the finished device.

To see the contrast between a component and manufacturing material, consider printed circuit boards. Your manufacturing process has a resistor soldered at a certain location on a printed circuit board (PCB). The resistor, the PCB, and the solder are all components; you intend them for the finished device. To make a satisfactory solder joint you need solder flux. This is a contaminant that you remove before you ship the device.

The solder is a component, but the solder flux is manufacturing material!

In paragraph 29 of the preamble, FDA says, "[A concomitant constituent, or a byproduct constituent refers] to those materials or substances that naturally occur as a part of the material or during the manufacturing process which are intended to be removed or reduced in the finished device. … FDA notes that cleaning agents, mold release agents, lubricating oils, latex proteins, and sterilant residues are just some examples of manufacturing materials."

If you intend to include it in the device, it is a component; otherwise it is manufacturing material.

QSR is very specific about the requirements for components.

- The Device Master Record (DMR) includes component specifications (21 CFR §820.50(a))
- For purchased components you need Purchasing Data (21 CFR §820.50(b)) approved in the document control system (21 CFR §820.40).
- For all components you need acceptance activities and records (21 CFR §820.80).

QSR also has specific requirements for manufacturing material. In 21 CFR §820.70(h) we learn, "Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented."

Some manufacturing material may have an adverse effect, and needs removal. This leads to a cleaning process (820.70(e)) that may lead to process validation (820.75).

Finished Device

The FDA defines a finished device, in 21 CFR §820.3(l), as "*Finished device* means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized."

The preamble gives us insight about FDA's expectations. "[A]ll devices that are capable of functioning, including those devices that could be used even though they are not yet in their final form, are 'finished devices'. For example, devices that have been manufactured or assembled, and need only to be sterilized, polished, inspected and tested, or packaged or labeled by a purchaser/manufacturer are clearly not components, but are now in a condition in which they could be used, therefore meeting the definition of 'finished device'."

FDA affirms the issues by stating in the preamble, "The distinction between 'components' and 'finished devices' was not intended to permit manufacturers to manufacture devices without complying with [QSR] by claiming that other functions, such as sterilization, incoming inspection (where sold for subsequent minor polishing, sterilization, or packaging), or insertion of software, will take place. The public would not be adequately protected in such cases if a manufacturer could claim that a device was not a 'finished' device subject to [QSR] because it was not in its 'final' form.

Conclusion

The term "product" is a broad term that includes five varieties of parts and material that you might encounter is in your QSR system. Understanding these terms and being able to identify the corresponding QSR requirements can help you improve the effectiveness of your system.