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Are Your Suppliers Keeping A Sharp Eye On Critical-To-Quality Attributes? You Should Know, FDA Investigators Say

by

Too many device firms don't make sure that suppliers of critical components are adhering to specified quality requirements, say two FDA investigators. Further, knowing which supplied components are critical to the quality of devices is something that every manufacturer should be aware of and keep tight control over, they advise.

Device-makers are ultimately responsible for the quality of components they buy. Manufacturers may get assurances from suppliers that they will adhere to specified quality requirements, but if the vendor doesn't honor its pledge, the device firm remains accountable.

That's the message from two FDA investigators, who urge companies to identify supplied parts that are most essential to the manufacturing of their device so they can exercise appropriate control over component makers.

"Critical-to-quality [CTQ] attributes need to be monitored by either your supplier or by your own firm. A lot of times what we hear from firms is, 'Well, we gave the supplier our specifications, so they must be monitoring all [CTQ] attributes for the component," said Ben Dastoli, an investigator in FDA's Cincinnati district office.

But manufacturers shouldn't make that assumption. "It’s a company's responsibility to make sure

that [CTQ] attributes are being monitored either by the firm itself or its supplier," Dastoli said at the recent MedCon medical device conference in Cincinnati.

> ***At some companies, "suppliers weren't ensuring the quality of their parts and the firms didn't even know why the parts were being used. That's just a big 'wow' moment," says Phil Pontikos, FDA's national device expert.***

A CTQ is anything that directly or indirectly links to quality; for example, one critical-to-quality characteristic for a battery component would be that the battery's seals are welded correctly so it does not leak when inside a finished device. (Related: *(Also see "FDA: Don't Wait On 'Case For Quality'; 'Build Bridges' To Better-Than-Baseline Practices Now" - Medtech Insight, 1 Apr, 2015.).)*

Phil Pontikos, FDA's national device expert and an investigator, says he will sometimes ask company employees during an inspection why a particular critical component is used for a product only to see "blank stares" from the workers.

"They say, 'We don't even know why we're using this or that,'" Pontikos said. "In fact, in some cases I've seen where a component is listed as being critical to device quality, but the firm assumes the supplier is monitoring that component's quality attributes."

That's because manufacturers might receive a Certificate of Analysis or Certificate of Compliance along with incoming parts, giving them a false sense of security by assuming that supplied parts are of good quality when they are not. (Related: *(Also see "Pay Close Attention To Equipment Calibration Certificates, FDA Says" - Medtech Insight, 1 Jun, 2010.).)*

"In such instances, the suppliers weren't ensuring the quality of their parts and the firms didn't even know why the parts were being used. That's just a big 'wow' moment," Pontikos said at MedCon.

"That's definitely why this is an area we focus on during an inspection."

Are Manufacturing Processes Validated?

Device firms should also double-check that components they buy are made under validated manufacturing processes, the investigators say.

"If a component were in my product, I would want to know what processes were going into making it, and I would want to know if that supplier is using validated processes," Dastoli said. "This is common. I find this problem during nearly every inspection I perform."

He added: "It's your responsibility to know if a process has to be validated. So look at the validation. Find out if the supplier is monitoring manufacturing and quality parameters. If not, then maybe you need more control on your end."

FDA gives manufacturers the flexibility to determine the type and extent of control to have over vendors.

"It's always a balance – how much control the suppliers have and how much you have. But, remember, it is your responsibility to understand that balance," Dastoli said. "I've seen a lot of internal quality audits where they don't even cover this."

Pontikos agreed. "The supplier's really an extension of you. So if they've got these processes and you're heavily relying on them to do particular activities, you're going to have to put appropriate controls in place."

He also reminded firms to make sure they are notified when suppliers make changes to manufacturing processes.

"Ultimately what you're really trying to establish through this whole process is to know the variation that may occur in your product. You need to know how to detect it and how to overcome any variation that's out there," Pontikos said.