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Compliance Corner: FDA Investigator Sees These 4 Common Sterilization Problems When Inspecting Facilities

by Shawn M. Schmitt

Phil Pontikos, who is also the US agency's national device expert, explains how device-makers can avoid running afoul of the FDA's rules and expectations for sterilization activities.

A US Food and Drug Administration investigator says he's concerned about the large number of medical device recalls because of troubles with sterilization activities.

"There are a few problem areas in particular that investigators see when it comes to sterilization," said Phil Pontikos, who is also the agency's national device expert. "And just to put this in perspective, the amount of recalls that have to do with sterilization is in the 10% to 15% range.

"That's a pretty hefty number of recalls from year to year, and it hasn't changed a whole heck of a lot over time," he added.

At MedCon 2019 in Cincinnati, OH, Pontikos highlighted four sterilization-related mistakes manufacturers routinely make that can land them in hot water.

1. Not knowing who is ultimately responsible for sterilization. "One of the areas that we continue to see issues with is the idea of who is responsible for what in terms of the OEM [original equipment manufacturer] versus the contract sterilizer. Even our investigators have a challenge sometimes plowing through that process with firms.

"So, let me be clear: The ultimate responsibility is on you as the manufacturer of the medical device.

"In the end, it boils down to having a sterilization contract in place, defining the scope and the activities that the contract sterilizer is supposed to conduct for you, and then ultimately providing that to the FDA so we understand that scope and magnitude.

> *"Without proper environmental monitoring, you won't understand trends that occur in your facility." – Phil Pontikos*

"Of course, some contract sterilizers do more than just perform the sterilization activity for you. They may be involved in helping you determine a stability assurance level for your product, and actually validating. They may be helping you with micro studies. And they may do some consulting work for you, depending on the type of manufacturer you are.

"All of these things need to be factored in, because our investigators are going to ask: 'Are you ensuring that all of the processes that are properly monitored and were necessary, validated?'

"And don't just take a sterilizer's word for it that they're doing things the right way. Don't simply say, 'They're the experts. I rely on them to tell me if things are OK or not.' That's not the right answer."

2. Failing to conduct package-integrity testing. "As an investigator, it’s so interesting when you go to a company and you find that there’s little to no package-integrity testing being done during routine manufacturing.

"Now, we understand that these tests oftentimes are destructive tests. Your non-destructive testing of, let’s say, a visual inspection only gives you some level of assurance of that package. But in some cases, you need to do an integrity test, whether it’s the seal- or burst-strength testing of the actual package itself.

"So, why do you need to do package-integrity testing? To build up the assurance level of that package to hold that integrity of that sterile barrier. It’s a pretty significant thing that you’re trying to demonstrate. If you don’t have that objective evidence and then you find out later that your seal strength is not where it should be or you have channeling in your seal, then you have to ask yourself the question: 'When was the last time I even challenged this?'

"By simply doing the testing, you can build assurance into the process and help you better understand if the packaging is holding its integrity."

3. Not monitoring the environment. "Without proper environmental monitoring, you won't understand trends that occur in your facility. And, in fact, you may not be aware of excursions happening from failure modes caused by the No. 1 source of failure in the end process, which is a human being.

"Somebody could come into the facility and not gown properly, or not be as sanitized or as clean as they should be. They can come in and wreak havoc in your cleanrooms and your controlled environments. So, without the environmental monitoring you'd have little to no assurance of proper sterility.

"Environmental monitoring is critical for you to be able to detect any variations that can occur. And let's be honest with ourselves: They do occur, and it's mainly because of the operator. It's not the only source, but it's certainly one of the top sources."

4. Manufacturing in aging facilities with poor layouts. "We are seeing this problem in an array of FDA-regulated commodities, but it's particularly a problem for medical devices. There are some facilities that were designed 20-, 30-, 40-plus years ago. And those facilities have gone through an awful lot of changes and things have moved around, and operations have changed in those facilities. And they don't have optimum layouts.

"Without an appropriate layout and a good quality facility, it's a bigger challenge for you to do proper monitoring to ensure that your sterilization activities are acceptable."