MEDTECH INSIGHT
CITELINE COMMERCIAL

08 Jul 2019 | **Analysis**

Compliance Corner: How A Firm Handles Nonconforming Products Can Make Or Break Its FDA Inspection, Investigator Says

by Shawn M. Schmitt

US FDA investigator and medical device specialist Thomas Peter says workers at device companies often fail to identify nonconforming products and don't adequately document troubles when they're discovered. Using quality audits is one way to nip this problem in the bud, he explains.

An investigator for the US Food and Drug Administration says workers at device firms often fail to identify nonconforming products and don't adequately document problems when they're found.

"What we're seeing during inspections – and it's especially true when we get out to the manufacturing floor and start talking to your operators and observing their work practices – is that they're not recognizing instances of nonconforming products, and they're not documenting the activities that they take when they encounter it," said Thomas Peter of Division 1 within the Office of Medical Devices and Radiological Health Operations (*OMDRHO*), within the FDA's Office of Regulatory Affairs (ORA).

This is commonly discovered, he said, when investigators look at a company's sterile packaging operations.

> *"We ask [workers], 'How do you document that occurrence?' – and all we hear are crickets." – Thomas Peter*

"We'll go to the production process and begin watching what your operators are doing. They're going to be performing typically a visual inspection after packaging, and we'll see them periodically opening up packaging and repackaging it," Peter, who is also a medical device specialist for the agency, said at MedCon 2019 in Cincinnati, OH.

"And then when we ask them, 'What are you doing?' That's when we learn that there was debris on the product, or there was debris within the packaging, or maybe there was a void on the seal of that package," he said. "And then we ask them, 'How do you document that occurrence?' – and all we hear are crickets. So there's no documentation that these issues are occurring."

Investigators also routinely notice similar issues when reviewing a firm's final cleaning operations, which are especially important for implantable devices.

"We've heard from operators who say that during a product inspection process they'll see residue or debris on product after the final cleaning operation, and they just manually wipe it off so they can go to the next step," Peter said.

"That's a huge red flag for final cleaning, especially because – more often than not – that's going to be a process that requires validation. It cannot be visually verified," he said. When that happens, investigators will "typically go down the path of looking at validation, and typically – unfortunately – we find lots of problems there. Or worse yet, we discover that the process wasn't validated at all."

> *"When you're doing a quality audit, don't confine yourself to a conference room. Get out to the floor; talk to your operators." – Thomas Peter*

Peter noted that device-makers also fall down when documenting the reason for scrapping product.

"Often, when we're doing a DHR [device history record] review during an inspection, nowhere in that DHR will we see a reason for scrapping out the product. We don't know what spec was not met. We don't know if there was a cosmetic defect or something dimensionally out of specification, or a functional test, maybe," he said. "So, we don't know, and when we ask companies, they're not able to explain any of that to us, which is an even bigger issue."

Quality Audits Can Help

If a firm is conducting adequate internal quality audits, then it will likely discover whether mistakes have been made when handling nonconforming product.

"These are pretty basic things that should be picked up during your quality audits," Peter said. "When you're doing a quality audit, don't confine yourself to a conference room. Get out to the floor; talk to your operators. Ask them, 'What are some of the common issues you see here, and what do you do in those situations?' And maybe most importantly, 'How do you document those activities?'

"I think the responses you will get will be pretty enlightening."