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Medtech Tips: First-Rate Problem Statement Key To Failure Investigations, Cardinal Health Quality VP Says

by Shawn M. Schmitt

A clear, succinct problem statement is the backbone of a winning device failure investigation, Karl Vahey says. He notes that a well-developed statement is also useful to have on hand when regulators conduct a facility audit and review corrective and preventive action (CAPA) activities.

When a medical device manufacturer is trying to figure out what went wrong with a troublesome product, launching a failure investigation is a must. But a firm can find itself in hot water quickly if it kicks off the investigation with a weak or incorrect problem statement, one quality expert says.

"If you don't have an accurate problem statement, you're going to be going after the wrong thing and ultimately implement a corrective action that is not applicable to the problem that you have," said Karl Vahey, VP of Operations Quality for device giant *Cardinal Health Inc.*

When that happens, "you just address the symptoms instead of diving deep enough" to find the root cause, he added.

Vahey said a good problem statement is a concise yet complete definition of a problem that should answer:

- What is the product or process involved?
- Where was the issue discovered?
- When was the issue discovered?

- Who discovered it?
- Why is it a problem?
- How was the issue discovered?

The statement should also determine the scope of the problem (e.g., plant, division, facility, shift, machine, product code), and include measurable and objective evidence.

"Albert Einstein once said, 'The formulation of a problem is the most essential part of problem-solving.' So, if you don't start off right, you're almost certainly going down the wrong path," Vahey said. "You must define the problem and quantify it."

> ***"A clear and succinct problem statement is essential for a good executive summary that you can provide to a regulator," Cardinal Health's Karl Vahey says.***

He noted that a well-developed problem statement is also useful to have on hand when regulators conduct a facility audit and review corrective and preventive action (CAPA) activities.

"A clear and succinct problem statement is essential for a good [CAPA] executive summary that you can provide to a regulator," Vahey said. "You have to remember that for these investigators or auditors that are coming into your plant, this is the first time they're seeing a CAPA that maybe you've spent a lot of time working on. And that's not the best time to have a confused auditor or a confused investigator."

Comments from Vahey came at FDAnews' 12th Annual FDA Inspections Summit in Bethesda, Md.

From the editors of The Gray Sheet