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QUOTED. June 14, 2018. Phil Pontikos.

by

US FDA is concerned about the large number of recalls initiated by device-makers and is urging firms to take a close look at their quality systems to determine why troublesome products make it to market in the first place. See what the agency's national device expert, Phil Pontikos, said about it here.

"From our perspective, what we see is that firms can identify the cause – or causes – of a failure, and then engage in CAPA [corrective and preventive action] activities. But firms also need to ask themselves a big question: 'Why did the quality system that we put in place fail us so we couldn't figure [the problem] out before we released it?'" –Phil Pontikos, national device expert, US FDA

- Find out more:*As Device Recalls Hit The Stratosphere, FDA Asks Firms To Keep A Sharp Eye On Quality Systems*

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