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Compliance Corner: 5 Key Steps To Reassessing Management Reviews At Your Firm

by [Shawn M. Schmitt](#)

Abbott Laboratories' quality VP, Monica Wilkins, outlines five steps that device-makers should take when reevaluating their management review process to make sure they get the most out of the meetings.

Medical device manufacturers that want to get the most out of management reviews should periodically reassess their process for conducting the meetings to make sure critical information doesn't slip through the cracks.

"It's never an easy task to reevaluate management review. But it's always needed because you need to have fresh eyes on your data, because you could be missing important things when the whole process simply becomes too routine," said Monica Wilkins, divisional VP of medical, quality and strategic support for device-maker Abbott Laboratories.

At a [Case for Quality](#) Metrics Workshop in Cincinnati hosted by the Medical Device Innovation Consortium ([MDIC](#)) and Xavier University, Wilkins outlined five steps that companies should take when reassessing management reviews to get the most out of the meetings.

Specifically, manufacturers should:

1. Put together a cross-functional team. "If your firm wants to reassess its management review function, one of the things you need to do first is form a cross-functional team and be inclusive, not exclusive. What I mean by that is, include people and groups that perhaps you wouldn't think of including before who might say, 'Hey, I see this data out there. Maybe you should look at it this way instead,'" Wilkins said.

"A cross-functional team could be set up to include sub-teams. It just depends on what you're

trying to achieve, how complex you want to make it, or how important is it that you take a good look at what you have and whether you're using all the right data.

"So, having that cross-functional team can help you formulate a good plan for moving forward with management reviews, and begins the step of ownership of the meetings themselves."

2. Identify all available data sources and systems. "This is a challenge. I've actually walked entire facilities to understand all of the lab equipment and manufacturing equipment and where it is, where all of the testing is performed, and where all of the data goes," Wilkins said. "You'd be surprised: Sometimes you'll find someone who says, 'I didn't know we had that spreadsheet over there. I didn't know we were collecting that type of data.'"

"So, if you're going to do a good reassessment exercise, go through and verify your systems, whether they're software applications, automated systems or paper records. That's where your cross-functional team can help.

"You'll probably be surprised by the systems you find people using. You'll be surprised by some of the automated systems, and you'll be surprised that things you thought were automated aren't – and you may even find that you still have paper records. Even big companies will have some paper records."

3. Define datasets and processes. "There's so much data and all kinds are valuable. So, it's important to determine what subset is valuable to you," Wilkins said. "What data do you want to bring in? It may vary from what you've been doing in the past, and if it does, how do you make it relational, meaning that you don't lose continuity?"

"Then, of course, you have to establish metrics. You'll probably keep some of the ones you have established and you may come up with new ones. More important, do you have metrics that are specific to an area? And do you have metrics that are more global that gives you a bigger picture?"

"Firms also have to be agile. A management review should be flexible, and there will be data coming in that's not planned. So, what do you set up in the process to ensure that unplanned data is coming in, and that that's well presented and dissected, and that it's meaningful?"

"Then, after your cross-functional team achieves most of this – and it is a lot of work – go back in and redefine the process. There's a lot of elements to redefining the process, including deciding who is required to attend management reviews and the frequency of the meetings. It's also important to determine the owners of datasets and consider the periodic reevaluation of those datasets."

4. Involve top management. "If executive management is disinterested – if they don't buy into

your data or if they're just doing management reviews as a checkmark – you're not going to get the discussion that's needed," Wilkins said.

"When you are reassessing or recalibrating the data in your management review process, how much are you engaging executive management? Do you go and ask what they would like to see? What they find to be not useful? What they recommend should also be brought to the meeting? What would make it easier for them to connect the dots? Because if you're not doing that and you're just presenting, then guess what? Some people will be disinterested, or they may look at all of the information and say, 'OK, I get it,' put it down, and not ask questions.

"It's also vitally important to request feedback and recommendations from executive management, and to make sure you get their endorsement of the process."

5. Communicate. "If executive management does not deliver clear messages, then your work may not always reach the right level. Communication from top leaders is key," Wilkins said.

"But communication also starts with your own work groups and with your own team, and it goes all the way up. All management levels should communicate with their functional groups. And there has to be a process for disseminating information. Who does it go to? Who do you share it with?

"Then, the larger you get, you have to think about, who did I leave out, who was important? Because a lot of the data is reviewed by critical teams, and they're making monthly reviews and decisions at those points before it even gets to management review."

From the editors of The Gray Sheet

More Management Review Advice

In two other Compliance Corner articles, Monica Wilkins names seven reasons why device-makers screw-up management reviews, and five things that should be discussed at the meetings.

You can check out those articles [here](#) and [here](#).