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'Program Alignment' Turns 1: FDA Wants To Train Investigators On Innovative Tech As Part Of Its Inspection Scheme – But Will It Be A Cakewalk?

by Shawn M. Schmitt

At the one-year anniversary of "program alignment" – US FDA's ambitious reorganization of its inspectional body – the agency is pushing hard to train its investigators on an array of medtech products. In that spirit, FDA has asked manufacturers to willingly open their doors to its investigators so they can learn more about the type of devices the firms are making, says Blake Bevill, a program division director for program alignment. Industry group AdvaMed and health-care organization Medical Alley Association are also getting in on the action by helping investigators learn about an array of topics, including software, electrical engineering, validation and design.

After a full year of growing pains for US FDA's "program alignment" inspectional reorganization, it appears to be gaining its sea legs. And now the agency has reached out to device-makers and industry groups to help educate investigators about hot topics such as software, electrical engineering, validation, design, and more.

Launched on May 15, 2017, program alignment was the most sweeping change to FDA's inspectional approach in agency history. Under the scheme, inspections performed by FDA's Office of Regulatory Affairs (ORA) – the office that conducts all of the agency's field activities – are structured along commodity-specific product lines to make audits more predictable and consistent for investigators and manufacturers. (Also see "*'Program Alignment' Snaps Together: What's Next For US FDA's Inspection Scheme*" - Medtech Insight, 9 Nov, 2017.)

Program alignment restructured FDA's five regional offices into seven specialized programs,

including one for devices. Situated under the umbrella of the Office of Medical Products and Tobacco Operations (OMPTO), the Office of Medical Devices and Radiological Health Operations (*OMDRHO*) has *three divisions*: northeast (Div. 1), central/southern (Div. 2), and western (Div. 3). The divisions encompass all 20 former district offices.

"It's our one-year anniversary [for program alignment, and] keeping a commodity-based focus ... has really worked out well. It's allowed us to streamline a lot of operations and focus in a number of [product] areas," said Joe Matrisciano, program division director (PDD) for Division 1.

"Our interaction with [FDA's Center for Devices and Radiological Health] has become more refined since program alignment began. So, I see this program as only improving from here," Matrisciano – who also serves as director for the former New England district office – said on May 4 at MedCon 2018 in Cincinnati.

UPDATED: 10 Things You Need To Know About FDA's 'Program Alignment' Inspectional Reorg

By Shawn M. Schmitt

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Now that US FDA's "program alignment" inspection paradigm is in full swing, does your device firm know where to send an FDA-483 response? How to alert the agency about a recall? Who to contact if there is a problem with an FDA investigator? If not, then check out the answers to those questions – and seven more – in this...

Read the full article here

Under program alignment, district directors retained their former district responsibilities, along with taking on the PDD role. They are the most senior FDA officials in each district, an FDA spokeswoman told *Medtech Insight* in February.

Such district director duties include coordinating staff needs within the physical locations of the district, regardless of the programmatic reporting structure, among other tasks. While division directors became program division directors when program alignment began, not all PDDs are district directors.

Investigator Training Amps Up; FDA Wants Firms To Open Their Doors

Through FDA's formal training center – the Office of Training, Education and Development (*OTED*) – investigators are undergoing intensive studies in the device arena.

"For the first time since we were program-aligned, we have a dedicated medical device training officer in the program," said Blake Bevill, program division director for Division 2.

Speaking at MedCon, Bevill noted that training officer Monica Forrest, who previously was the

"point person to train all the different programs," is now exclusively working on guiding investigators assigned to device work.

OTED offers what Bevill described as a "basic list" of courses to investigators, including education on data integrity, radiation safety, and more. "I'm sure there will be more courses developed as we have people now concentrating on devices," he said.

And the agency is busy identifying so-called "subspecialty areas" that investigators should be trained on, including materials, *in vitro* diagnostics, sterilization, electronics, computers, software, statistics and reliability engineering.

"There's just so much enhancement when you're concentrated in one program," Bevill said, noting that investigators are being introduced to "new medical device technologies and seeking to do that with the help of industry."

In that vein, FDA is asking device-makers to voluntarily open their doors to agency investigators for purely educational purposes. Investigators would be laser-focused on the type of products the firms are making and would not be there in any kind of official compliance role.

"We want to partner with [device-makers]. Of course, we'll do a compliance history check and make sure you're not in trouble with us before we do a tour," Bevill said, noting that device giants Boston Scientific and Philips – and some other smaller firms – have already welcomed investigators to their plants to learn more about their devices.

> ***"Training is very important to us. We want very high-quality investigators in your firms, using their time wisely," FDA's Blake Bevill says.***

Such industry-FDA teachings for post-market/compliance staff are a rarity. On the pre-market side, the device center – CDRH – has its *Experiential Learning Program* (ELP) that gives FDA reviewers more insight into how a product works by sending them to firms to learn about innovative technologies in an effort to bridge any knowledge gaps.

In fact, "we've started thinking about working with Lynne Rice at OCE to join the reviewers on some of those" site visits through ELP, Bevill said. Rice is director of FDA's Office of Communication and Education.

That type of collaboration "is a perfect example of what program alignment has done," Bevill said. "Now [ORA is] doing more with the device center and trying to jump in on some of that [ELP learning]."

The bottom line? "We're trying to become better through program alignment, and I think we are," he said. "You're going to see a lot of changes. You're going to see the expertise develop more and more."

Nevertheless, while program alignment is crawling, making it walk will take some time, Bevill cautioned.

"It takes a few years for an investigator to get good at their job and write observations. It also takes another couple of years for them to realize what is significant and what should go on an FDA-483" inspection form, he said.

"If you add all that together, training is very important to us. We want very high-quality investigators in your firms, using their time wisely. And when there are issues, we want to talk to you about those issues that are significant," Bevill said.

AdvaMed, Medical Alley Aid In Training

But device-makers aren't the only ones facilitating investigator learning. FDA is also working with industry advocacy group AdvaMed to develop web-based training modules, and is partnering with health-care advocacy group Medical Alley Association to visit a handful of manufacturers.

"With AdvaMed we are developing some software lifecycle Web training and rolling that out to all of our [investigators] in June," Bevill said.

That training will be organized into four modules and delivered by subject-matter experts in AdvaMed member companies.

"We are providing this training at the request of, and in collaboration with, ORA. We hope to use the June training as a template for future AdvaMed-sponsored training to ORA on different topics," AdvaMed spokesman Mark Brager told *Medtech Insight*.

And, Bevill said, "with Medical Alley we are developing a training event that will take place at a couple of facilities in the Minneapolis, [Minn.], area during September, where we plan to send 30 [investigators]."

At that event – "a two-day roadshow" for "show-and-tell," Bevill described – investigators will gain advanced insights into subspecialty areas such as combination device-drug products,

software, electrical engineering, validation and design.

"In keeping with the original charge of program alignment, we want to develop the world's best medical device inspectional workforce, and we will be looking to do more new medical device technology training development with industry in the future," Bevill said, noting that FDA plans to reach out to "other industry groups, academia and regulated firms" to help.

From the editors of The Gray Sheet