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15 May 2018 | **Analysis**

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

by Shawn M. Schmitt

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 updated feature article.

[Editor's note: *A version of this story was originally posted on Feb. 20, 2018. It has been updated to reflect staffing changes for "program alignment."*]

As US FDA celebrates the first anniversary of its "program alignment" inspection scheme, the agency says the massive reorganization is moving in the right direction. (See lead story below.)

But the past year hasn't always been easy for device-makers, many of which were left scratching their heads about how they should interact with the agency given that the traditional district office paradigm was dismantled.

Facility inspections performed by FDA's Office of Regulatory Affairs (ORA) under program alignment – the most sweeping change to the agency's inspectional approach in its history – are now structured along commodity-specific product lines.

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

Program alignment restructured the agency's five regional offices into seven specialized programs; the medical device program is

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housed in the Office of Medical Devices and Radiological Health Operations (OMDRHO). The OMDRHO office is split into *three divisions*, in the northeast (Div. 1), central/southern (Div. 2), and western (Div. 3) areas of the country.

Here, *Medtech Insight* rounds up some of the most pressing questions manufacturers have about interfacing with FDA under program alignment – and answers them.

By Shawn M. Schmitt

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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...

Read the full article here

1. "What was the fate of the district directors?" Although the traditional district office has gone away, district directors have not. In fact, they have an expanded role now.

"Under program alignment ... the district directors retained their ... district responsibilities and now specialize in one program as program division directors. They are also the most senior FDA official locally," agency spokeswoman Deborah Kotz told *Medtech Insight*.

"In addition to their specialized role in one of the program areas, the district director is responsible for coordinating all staff needs within the 'physical locations' of the district regardless of the programmatic reporting structure," Kotz added. "This includes space allocation, parking, storage, *et cetera*. District directors are also responsible for oversight of their location's COOP [continuity of operations], local Safety Committee, weather closures, and for ensuring all staff are safe and accounted for during an emergency."

Not all program division directors are district directors, though.

2. "Who are my program division directors?" For devices, because there are three OMDRHO divisions, there are three program division directors:

- Division 1: Joseph Matrisciano, 781- 587-7490; *Joseph.Matrisciano@fda.hhs.gov*
- Division 2: Blake Bevill, 407-475-4734; *Blake.Bevill@fda.hhs.gov*
- Division 3: Shari Shambaugh, 214-253-5215; *Shari.Shambaugh@fda.hhs.gov*

3. "Where do I send my FDA-483 response and to whom should I address it?" Before program alignment, device-makers sent responses to FDA-483 inspection observation forms to the director of their FDA district office.

Now, firms should send their responses to a general email inbox that corresponds to a manufacturer's specific program alignment division. For devices, there are three inboxes:

- Division 1: *oradevices1firmresponse@fda.hhs.gov*
- Division 2: *oradevices2firmresponse@fda.hhs.gov*
- Division 3: *oradevices3firmresponse@fda.hhs.gov*

Responses should be addressed to "Dear Program Division Director."

4. "If I send an FDA-483 response to the general email inbox, to whom should I mail the hard copy?" A firm's former district office is responsible for maintaining all hard-copy documentation. On that copy, manufacturers should write, "Attn: Chicago District Office," or whichever district office is applicable, former US FDA investigations branch director Ricki Chase says.

On the envelope, "address your hard-copy response to FDA at your old district office, and write, "Attn: Compliance." The district will have a mailroom person who will open it up and send it to file," she said.

Chase is compliance practice director for Lachman Consultant Services, a firm she joined in 2016 after spending 16 years at FDA, where she was also an investigator, medical device specialist and supervisory investigator.

"The digital copy of your 483 response that you send to one of the three general email inboxes is considered by FDA to be the original copy that goes to the agency for review," Chase said. "Quite frankly, FDA would prefer that firms not hard-copy it because the agency is trying to go to a completely digital database, but manufacturers are going to hard-copy FDA anyway to make sure they have their bases covered."

5. "If I have a question related to compliance issues I'm having, who do I call?" Firms should contact the director compliance branch (DCB) in their specific division:

- Division 1: Gina Brackett, 513-679-2700 x2167; *Gina.Brackett@fda.hhs.gov*
- Division 2: Vacant; contact program division director
- Division 3: Kelly Sheppard, 949-608-4426; *Kelly.Sheppard@fda.hhs.gov*

6. "I used to request meetings with my former district office. Now if I want a meeting, whom do I ask?" Such requests should go to the divisional DCBs.

7. "If I have a problem with an FDA investigator, who do I call?" In this situation, device-makers should contact the director investigations branch (DIB) in their division:

- Division 1: Arduino Frankovic, 718-589-7490; *Arduino.Frankovic@fda.hhs.gov*
- Division 2: Kathleen Sinninger, DIB 407-475-4715; *Kathleen.Sinninger@fda.hhs.gov*
- Division 3: Eric Anderson, 510-337-6752; *Eric.Anderson@fda.hhs.gov*

Those DIBs "will either handle the issue for you via a discussion or direct you to the lowest-level individual, which would be that investigator's immediate supervisor, who would likely be physically located in a different state than the director of investigations is," Chase said.

8. "What do I do if I have a recall event?" FDA has set up three general email mailboxes to receive recall correspondence; firms should use the one that corresponds with where their facility is located:

- Division 1: *oradevices1recalls@fda.hhs.gov*
- Division 2: *oradevices2recalls@fda.hhs.gov*
- Division 3: *oradevices3recalls@fda.hhs.gov*

In the email, consultant Chase advises firms to write: "I need to speak to a recall coordinator regarding a potential issue at our firm. Please have a recall coordinator call me or email me in response."

Recall coordinators should also be contacted:

Division 1:

- Melinda Ruiz, 718-662-5470; *Melinda.Ruiz@fda.hhs.gov*
- Andrew Lang, 513-679-2700 x2117; *Andrew.Lang@fda.hhs.gov*
- Cynthia Aycock, 313-393-8162; *Cynthia.Aycock@fda.hhs.gov*

Division 2:

- Neisa Alonso, 407-475-4712; *Neisa.Alonso@fda.hhs.gov*

- Meredith Andress, 407-475-4722; *Meredith.Andress@fda.hhs.gov*
- Marie Fink, 504-846-6109; *Marie.Fink@fda.hhs.gov*

Division 3:

- Theresa Kirkham, 949-608-4437; *Theresa.Kirkham@fda.hhs.gov*

10. "What if I have a general question about FDA inspections?" The agency has set up an email inbox to accept inspectional inquiries: *ORAHQDeviceInspectionPOC@fda.hhs.gov*

"The good thing about this new inbox is that your question will go directly to CDRH [FDA's Center for Devices and Radiological Health] headquarters. It doesn't go to the field, so there's no impetus for them to drop in on you for an inspection because you're asking questions," Chase said.

"Firms are always afraid to ask questions, because if the question indicates that maybe there's an issue, they're worried that they're going to be inspected. But that's just not how it works," she said. "The agency is trying to be more transparent and more user-friendly, and part of being more user-friendly is to establish this general question inbox where you can send a question, and somebody will get back to you with a reference or a resource. Or sometimes they'll say, 'Give me a call and we can discuss it.'"

From the editors of The Gray Sheet