Effective Communication with FDA Before and During an Inspection

June 23, 2021

Medical Device and Radiological Health Operations/Division 1 (East)

Agenda

- Before inspection
  - Changes in communication due to COVID-19
  - FDARA
- During inspection
  - tips for communicating during an inspection
- Questions?

Polling Question

When did you last have an FDA inspection at your site?

- Less than 2 years ago
- More than 2 years but less than 5
- More than 5 years
- Never

You will receive a pre-announcement call for any FDA inspection for the duration of the pandemic

- During the pre-announcement call, the CSO will go through a standard checklist specific to Covid-19
- Toward the end of the questionnaire, you will be given a proposed start date and asked whether your facility will be operating on that date

Covid-19 related communication changes

- As part of the questionnaire, you will be asked:
  - if there are any restrictions at your facility, including
    - Visitors
    - Operations (types of operations, capacity)
    - Any imposed by local government
  - what your business and operating hours are
  - if there are dates/times when ability to social distancing could be optimized
  - what Covid-19 related procedures or restrictions your firm has in place for employees and visitors
    - you will be asked to provide a copy by e-mail prior to an inspection
  - if there are any questionnaires required to be completed by visitors
  - if your facility is taking temperatures of visitors
    - If so, how is it done and with what device, and
    - what limits are being used

Covid-19 related communication changes

- As part of the questionnaire, you will be asked:
  - if your firm has a process to monitor health of employees and what that process includes
  - what guidance is given to employees with symptoms
  - what protocol your firm has with respect to social distancing of employees and if appropriate facial coverings are provided to employees who cannot socially distance
  - If your firm requires use of face coverings and if the investigator can wear their own or needs one provided by your firm
  - how you are cleaning your facility to reduce risk of transmission, including disinfectants used

Covid-19 related communication changes

- You will also be asked if
  - the investigator can take documents off-site for review or if you can provide documents electronically
  - there is an outdoor area, weather permitting, where meetings can occur
  - whether your firm has had positive cases of SARS-CoV-2 (COVID-19) or presumed positive cases at your firm over the past 14 days
- We will request contact information for the person at you site who is responsible for Covid-19 health and safety
- We also request that you let us know ASAP of any positive cases at your site prior to our arrival
  - And to notify us if someone tests positive with 14 days after our inspection

Covid-19 related communication changes

- During the pandemic, the investigator will attempt to limit inspectional time in your facility
  - Electronic records are preferred so they can be reviewed remotely if possible
    - Firms can consider contacting SecureEmail@fda.hhs.gov to obtain a license to send encrypted messages to FDA via electronic mail
  - Back and forth sharing of documents and records should be kept to a minimum
  - Any FDA-483 could be issued remotely via teleconference

Covid-19 related communication changes

FDA Resiliency Roadmap

In May, FDA released the Resiliency Roadmap for FDA Inspectional Oversight

- The roadmap provides
  - highlights of the effects of the pandemic on inspections for all FDA commodities
  - how we plan to address postponed inspectional work

Polling Question

Does your site participate in MDSAP?

- Yes
- No
- Not yet

FDARA driven communication changes

FDARA requires FDA to update its processes and standards for inspections other than for-cause

- Final Guidance for Industry "***Review and Update of Device Establishment Inspection Processes and Standards***," was issued on June 29, 2020 to:
  - achieve uniformity (with appropriate exceptions),
  - provide advance notice of inspection,
  - provide the establishment with a reasonable estimate of the timeframe (and an opportunity for advance communications), and
  - regular communications during the inspection regarding its status, "which may be recorded by either party with advance notice and mutual consent."

- Reasonable efforts to make contact with the firm to preannounce the inspection
  - By phone
  - Will seek acknowledgment of notification but will not delay inspection start if not acknowledged
  - Should be no less than 5 calendar days prior to start of inspection
  - Expected duration and working hours of inspection will be communicated
    - Inspection duration is generally 3-6 continuous business days
  - To the extent possible, will provide notice of certain procedures and records that will be requested

FDARA Driven Communication Changes

FDARA driven communication changes

During the inspection:

- Reasonable efforts will be made to discuss all observations as they are observed, or on a daily basis
  - Includes "Discussion Items" that will not be on the FDA Form 483
- Either party may record communications if there is advance notice and mutual consent

Tips for Communication During an Inspection

Explain company vernacular and “terms of art” ahead of time

In responding to a request, make sure your response actually answers the question

Be up front about delays involved with retrieving documents and records

When possible, sample devices, diagrams or “exploded” Bills of Materials can help us understand

Tips for Communication During an Inspection

To the extent possible, provide complete records

Don’t be afraid to ask for clarification if you don’t understand a request

Don’t dismiss questions about submissions related to device changes. “Design creep” happens!

We understand that daily business does not stop during an inspection

--We have a common goal of completing your inspection in a timely manner

Helpful Links

- Review and Update of Device Establishment Inspection Processes and Standards: Guidance for Industry
  - https://www.fda.gov/media/139466/download

- Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff
  - https://www.fda.gov/media/99812/download

- Resiliency Roadmap for FDA Inspectional Oversight https://www.fda.gov/media/148197/download


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