FDA "LIVE REVIEW": MANAGING THE NEW APPROACH TO INSPECTING QUALITY SYSTEM DOCUMENTATION

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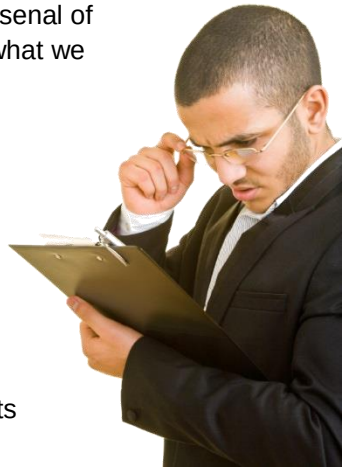
May 2016

Introduction

There are many training sessions conducted each year by GMP Training Managers and company quality and compliance staff on "How to Manage an FDA Inspection". Regularly, FDA inspection management is a "headliner" on the agendas of industry trade association meetings. And of course, there are numerous industry experts who consult and advise companies on how to manage FDA inspections as one of their key offerings. We're one of them!

Times are changing though. The FDA is adding a new, modern, significant approach to its arsenal of approaches for conducting site inspections. This change is not a subtle change. It is more what we would consider a "disruptive change".



For context though, let's review the *traditional* approach to FDA inspections.

FDA Inspections 101: The Traditional Approach

In general, the start of an FDA inspection process includes:

- The Investigator serving the FDA Form 482 stating the purpose of the inspection;
- An opening presentation/overview on the site organizational structure, layout, products produced/developed, key changes since the last inspection, etc.; and
- A tour of the facilities or site, where appropriate.

The Investigator would then commence gathering key information on the site, in addition to any changes at the site since the last inspection. Prior enforcement commitments would be reviewed, and commitment closures checked. Once the overview and history were gathered, the Investigator would initiate his/her request for procedures for the quality systems within the scope of the inspection as well as the summary output data for each quality system. This output data was usually presented as a hard copy "log book" or "summary table" from the IT system to the investigator. Additional review elements generally include:

- A thorough review of hard copy SOPs for the quality systems executed at the site; and
- A detailed review of output data ***from*** the quality systems executed at the site.

What's important here is that traditionally, this detailed review was a **paper-based** review, and, the output data has historically been presented in **hard copy** format.

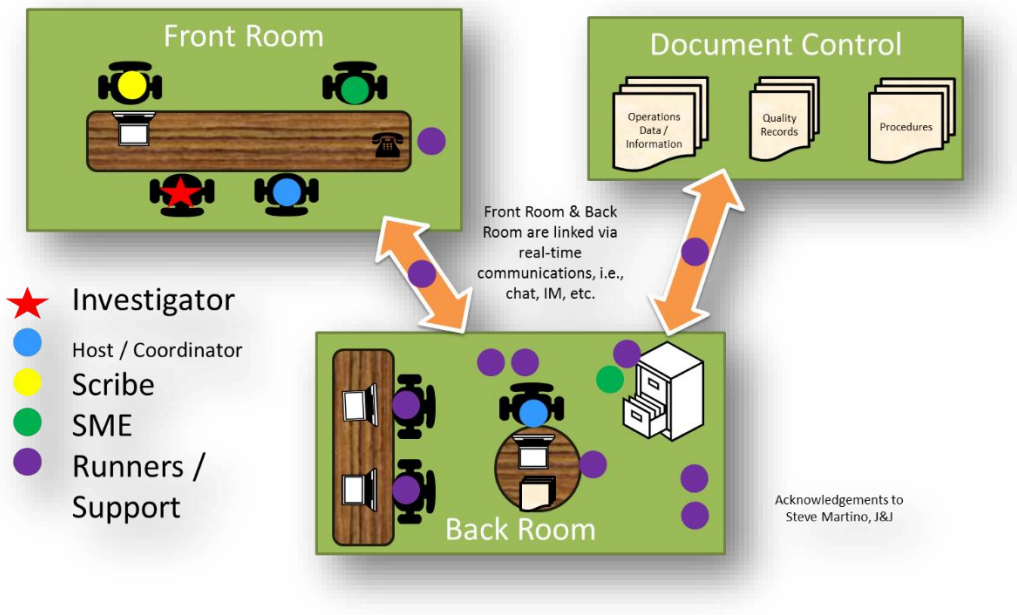
Throughout the FDA inspection, the Investigator would ask questions and company representatives would provide (sometimes) clear, concise answers and written documentation, as appropriate, in response to the Investigator's requests and questions.

Timely retrieval and presentation of documentation and data by the company to the Investigator has been, and continues to be, a critical to quality attribute of the inspection process. FDA has, on occasion, pursued enforcement action against companies for failure to provide documentation in a timely manner.

Managing Inspections: The Back Room

To ensure timely and accurate presentation of documentation and data, many companies have developed an extensive "back room" process to retrieve and review documents requested by FDA prior to presentation in the front room. This process often includes a "pre-review" and "dress rehearsal" with the individuals presenting the documentation. A recent addition to back-room / front-room communications includes the use of computer-based tools (IM / chat / screen presentations) to enhance communications and document availability responsiveness.

The traditional "back room" inspection management process is depicted below:



The "Live Review": A New, Modern Record Review Technique

Recently, I had the opportunity to participate first-hand in a different type of FDA inspection. Having directly managed (and saved) many, many critical FDA inspections, I know what to expect, and how to work the system. However, when the detailed document reviews began, the traditional process depicted above was circumvented when the FDA Investigator requested a "live review" of the documents contained within in the IT system deployed by the company to manage its one of its core quality systems and documentation. In this case, the Investigator was reviewing the complaint process. As part of the "live review", the Investigator:

- requested an electronic copy (on a memory stick) of the summary tables for the past x years of product quality complaints for "y" products; and
- requested the ability to "browse" through the company's complaint management system to review documentation at the Investigator's whim.

"A live review? Browsing? Of my computers? Can they even do that? How does that work?"

Be sure, FDA inspections that now incorporate a "live review" approach have the potential to challenge years of FDA inspection management technique within companies.

"Live Review" Impacts

How does the new "Live Review" inspection approach impact the traditional FDA inspection process?

1. **FDA's Data Analysis:** FDA can sort the data provided to determine if there are any trends in the data. FDA can then easily "connect the dots" with other quality management systems executed within the company.

   In the example discussed, FDA was easily able to verify the adequacy of the CAPA quality system through the product quality complaint quality system audit. Specifically, for trends identified which impact the drug product or device quality in a substantive manner, the company should have an active CAPA with specific actions to correct and prevent the identified root causes for the product quality issues identified in their product quality complaint trending program.

2. **Lack of SME Preparation:** There is no opportunity to "pre-review" the data in the back room prior to review by FDA. The data is viewed in "real time" in the front room of the inspection with the FDA Investigator. Because of that, the opportunity to have each subject matter expert present, and rehearse each document in the back room prior to review in the front room, ***is significantly reduced or eliminated.*** The core team leading the inspection in the front room will need to manage the initial review of the documentation and data. "Filling in the blanks" with documents will become much, much harder when dealing with this new technique.

3. **Increased Document Challenges:** In situations where the documentation and data do not "stand on their own" without significant explanation by the company's subject matter experts, FDA will have more opportunity to indict the timeliness and adequacy of the documentation and data.

Adapting to "Live Review"

Although the new inspection approach presents new challenges to "managing" the inspection process and the information FDA ultimately sees, there are a number of specific actions that can be taken to ensure a successful FDA inspection outcome. We recommend that companies think carefully about incorporating the following into their inspection management playbook:

- Understand FDA's expectations for timely delivery of requested documentation and data. Conduct "mock" FDA inspections to assess the site's capability to provide requested documents and data in a timely manner. This should **specifically include** the time for retrieval of large volumes of data requested **in electronic form** as well as well-rehearsed protocols for accessing QMS data and explaining the IT tools and processes when a "live"

review of individual records is requested.

- Develop "standards" for company documentation and data; implement periodic internal assessments of the timeliness and adequacy of each document and data type in the internal audit program.

- Establish protocols for live review data requests, data downloads, mirror-copies of data, requests for FDA deletion of data in possession, etc. Review these protocols with your legal counsel.

- Establish subject matter experts or "coaches" in each functional area where quality and compliance documentation is generated to train and coach functional area team members on timeliness and adequacy of quality and compliance documentation. NOTE: This is very useful in functional areas where the frequency of creation of quality and compliance documentation is low.

- **Ensure writing skills are a core competency** in the functional areas where quality and compliance documentation is generated. (See our highly-acclaimed Writing for Compliance® Workshop Training Program at writingforcompliance.com.) Integrate this competency in the training curriculum for all employees responsible for quality and compliance documentation. Assess training effectiveness and development of this critical competency through review and evaluation of real examples produced by each individual trained by company experts.

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- Create a culture of "right first time" for quality and compliance documentation. There are no second changes when the FDA Investigator is reviewing your computer system, looking at your documents "live". Support the creation and evolution of this cultural element by setting goals with measurable outcomes for the timeliness and adequacy of quality and compliance documentation in functional areas where compliance documentation is generated.

Conclusion

The FDA's new "live" technique for inspecting quality system documents and quality records will substantially change the traditional inspection management process, eliminating many steps. To ensure a successful outcome, we recommend companies adopt and follow the approaches presented here to ensure a strong sense of control in this highly-dynamic interaction between the Agency and your critical quality system records.

For further information on FDA's new approach to inspections, please contact Teresa Gorecki at teresa.gorecki@compliancearchitects.com, or at 310-465-7285.

Interested in learning more? Contact us to set up a meeting: 888.734.9778

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