



## Preparing for Success – How to have a positive FDA Inspection

Success does not come about by coincidence. Success is an outcome of preparation. When it comes to successful U.S. Food and Drug Administration (FDA) inspection outcomes, preparation is at the foundation. Finding out that the Site is not in a position to meet the Agency's requirements during the process of the Inspection is not a desirable position for any site. Unsuccessful FDA inspections can impose a lengthy time impact on a company's strategic plan.

Those of us who have had the experience of FDA inspections are well aware that they can be challenging. However, the chances of having the inspection process run as smoothly as possible can be greatly improved by implementing the proper preparational tools. In the following article we will discuss a few simple but useful tools and offer guidance that you, and your team, can use to help you set up for success in your next FDA inspection.

### Ship Shape

First impressions are everything. You have worked hard as a team to get your Site to where it is, now take pride and show it off at its best. It is important that the areas the Inspectors are going to see are clean, tidy and in a state of control. This does not just include the inspection areas, all areas that the Inspectors are going to see need to be treated in the same manner. If your areas are well presented, clean, tidy, and organised this will build the Inspector's confidence in the Site. Sites that are visually well maintained and well-presented speak to the Site attitude as a whole. Consider the implementation of a 5S program in your area. 5S helps to establish an orderly work environment in addition to improving efficiency. Some helpful tips on how to implement a 5S program can be found here.

### Do what you Say you Do

This is a common pitfall during inspections. Many observations have been assigned to sites for lack of procedural accuracy. Always be clear and concise in your SOPs. Ensure that the overall requirements of your procedures are described in enough detail

to document the procedural activities. However, it is essential to have the appropriate balance in your level of detail. Do not be tempted to add too much granularity and get into minute detail as you will inevitably be caught out. Extensive detail in procedures opens you up to non-compliance when the Inspector reviews the process.

Be sure to keep on top of periodic review of your procedures. To keep procedures accurate, efficient and effective in terms of their intended use, it is important during this process to involve the people who use those procedures on a regular basis. They can provide valuable hands on experience and insight resulting in robust procedures.

### Know the Process

It is important to understand the FDA's inspection process and it is an expectation from the Inspectors that sites have an understanding of their inspection process. The FDA Website contains some useful guides which can be referred to such as What should I expect during an inspection?. The Site also contains a set of Inspection Guides which are useful in preparation for inspections as they contain reference material that the Inspectors will use during the inspection. These guides will provide information as to what the Inspectors will be looking for, specific to that inspection area.

### Have a Play Book

A good tip is to put together a folder of documents in advance of the Inspection that you anticipate the Inspector may request. This way the documents will be quickly to hand should they need to be provided during the Inspection. For documents that may simply be too large to do this with, compile a categorised list including location, so you can easily find the document. Make sure that you, or the identified SME, are familiar with the documents and prepared for any potential queries that can be anticipated from the Inspectors.

### Practice makes Perfect

An effective Self Inspection program is vital in preparing the Site for inspection success. Self-Inspections may seem an inconvenience at times, however they are a great opportunity to ensure your area is compliant in advance of inspections and remediate areas of concern. Discuss the Self Inspection in advance with the Self Inspection Team and request a review of any areas of concern within your department. Whilst this may be challenging, it is far more preferable to identify potential deficiencies and resolve them than to have them identified by an Inspector as an observation. An effective Self-Inspection process will help ensure a compliant state within your department and place it in a strong position of inspection readiness.

In recent times where COVID-19 has resulted in travel restrictions and therefore the requirement for virtual audits, inspection skills may not be as honed as they once were, and some personnel may have no direct inspection experience at





all. Self-Inspections are a great training opportunity where you can practice and develop your inspection approach, Use this time to role play, polish your inspection skill set and train in-experienced personnel.

The internal audit schedule needs to be at an appropriate frequency and needs to be effective. Senior management should empower the Self Inspection Team to be able to make effective changes. Rather than simply make recommendations, Internal Inspectors should have the required level of authority to hold functional areas accountable and ensure that they push actions through to completion in order to ensure compliance.

The internal audit program should also be assessed to ensure that the Self Inspections are not only performed on independent functional areas, but also laterally across departments, using a system based approach so that all the interconnected elements between processes are audited.

### **Become Comfortable with the Uncomfortable**

Each team should review their list of investigations/ discrepancies for their area identifying those they anticipate the Inspector may request to review, or the ones believed to be an area of concern. The person who is likely to discuss the issue with the Inspector should be well versed in all aspects of the investigation. Have all required supporting documentation readily available. Consider putting together a presentation to 'tell the story'. This can provide clear context to the event should the Inspector take a deep dive into it. This strategy can be applied to not just investigations, but any area of concern. Try to identify other areas that review of an investigation, or similar document, may lead to. An FDA inspection can feel like threads being pulled, leading to larger and larger holes! To prevent this,

make sure that every question arising from the review of any issue, leads to a dead end, with documented information and if required, a documented position or strategy to prevent risk to the product.

### **Prepare your Team**

Area Subject Matter Experts (SMEs) should be identified in advance of the Audit. Ensure that they are confident in their abilities to engage with the Inspectors and are well prepared to discuss any areas of concern that may be identified.

Personnel should be appropriately equipped with the tools to interact with the Inspector. Inspection skills and behaviours should be part of an internal training programme and should be retrained upon appropriately. As part of this training try to include role play workshops where personnel present on their particular area of specialty, as they would in a real inspection situation. This can really help to build confidence and therefore result in stronger and more confident responses to the Inspectors queries.

Ensure that personnel are fully trained on the procedures required to complete their tasks and that training records are up to date, reviewed and readily available during the Inspection.

Promoting the correct mindset in this area is also very important. Remember why the FDA are inspecting your Site. They are there to ensure that the products being supplied are safe for the patient; you, your family and your friends. This is a necessary and positive process.

### **On the Front Line**

When speaking with the Inspectors there are a few golden rules that need to be observed:



- Be prompt with a documentation request. Should the Inspector request a document, provide it as quickly as possible. If it is not available do not evade the Inspector's request, admit this up front.
- Admit to, rather than hide known deficiencies, the plan for remediation should be prepared during inspection readiness and readily available. It is better to show you have identified issues and have a plan in place to remediate them, rather than hoping an Inspector doesn't find an issue and give the impression the Site was unaware.
- Provide only the information directly related to answering the Inspector's question, don't offer any additional information.
- If you do not know the answer to a question, say so. Tell the Inspector that you will find the answer and come back to them as soon as possible.
- Do not use language like, 'Sometimes', 'Occasionally', 'To be Honest'.
- You may find that there are pauses in conversation with the Inspector, do not be tempted to add more information in order to break an uncomfortable silence. Wait for the Inspector to re-initiate the discussion.
- Maintain a very high level of professionalism. Questions should be directed at the auditor in a polite and professional manner.
- Be courteous to the Inspector and do not get into an argument.

Inspectors can vary widely in terms of their inspection style or approach in order to obtain the required information and sometimes those approaches can be testing. If you are finding the interaction with the Inspector challenging, remember the tips above and try to keep in mind that they are just a person, like you, and you are simply interacting with them.

### Be Pro-Active

During the course of, and at the end of, the inspection the Inspectors may have a list of observations for the Site. Review these with the Inspector as they arise during the Inspection and attempt to remediate them immediately if this can be achieved. It will show the Inspector that the Site is committed to achieving and maintaining a compliant state. This helps to promote and build a positive relationship with the Agency. Fostering a good relationship with Inspection Agencies is important as it shows the Agency that the site is supportive of the process. This will stand to the site in future inspections.

### Always Ready

Sites should strive to be in an audit ready state at all times. This approach not only promotes a constant state of control and continuous compliance but saves much energy and resources in the long run. It also saves your team a lot of pressure and stress by removing the possibility of 'audit scramble'.

### Support your Team

In a hectic inspection it is often easy to forget that not everyone is experienced in the inspection process, some team members may be new to the industry and unfamiliar with inspections. As discussed above, COVID-19 has resulted in the need for many inspections to be conducted virtually meaning that not everyone has had direct interaction with Inspectors. Be mindful of this and offer support/advice where necessary. Also, be



mindful of your colleagues in other departments. If support is needed and can be provided, do so. Remember, a successful inspection is a site wide goal, not just for the area that you are working in.

### Do your Homework

It is advisable, in advance of any upcoming inspections, that you perform some reconnaissance. Complete a review of publications and articles and see what the current trends are in terms of what areas or topics the Agency is frequently looking into during their inspections. Information on FDA observations given to sites, or 483s, can be found on the Agency's website and can be reviewed according to the industry area and fiscal year. These findings should be communicated across the team so that all are aware of the current trends.

If you happen to have a network of sites within your company, it is in your mutual interest to maintain lines of communication and share your inspection experiences to aid in and support each other's preparation. Often, when an Inspector discovers a discrepancy at one site they will look for the same at another site.



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