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Are You Gambling on Your Next Inspection?

Ten questions you must answer to ensure FDA inspection readiness.

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Believe it or not, there are device companies that have convinced themselves that inspection preparation is not necessary. Maybe they've had a positive inspection history, are familiar with an FDA investigator, are overwhelmed with day-to-day business, or simply have become complacent. Whatever the rationale, deciding not to prepare for an inspection can be risky and costly. Problems can be avoided with some simple organization and by taking a risk-based approach to your inspection readiness.

There are 10 key questions to assess your inspection readiness:

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1.) Are you aware of current trends as they specifically relate to your products?

With an increase in the use of a global supply chain and international manufacturers sending products to the United States, a critical part of FDA's charter is ensuring the integrity of the supply chain, and inspections are key to that process. With 50% of devices originating from outside the United States, FDA is operating on a global basis like never before.[1] The number of foreign inspections has increased from approximately 1400 in 2010, to 2000 in 2011.[2] Being able to answer yes to this question means that you are fully informed and aware of FDA strategies, their areas of focus, and current enforcement trends in inspections as they relate to your device products.

2.) Have you reviewed your processes from FDA's perspective?

Device companies should examine current inspection and enforcement trends through FDA's web site, by assessing what is going on with other businesses in their own industry, and participation in regulatory groups. An excellent and timesaving approach is regularly reviewing warning letters and other enforcement information found on FDA's web site.

This means not only reviewing the information on current enforcement trends or changing CGMPs pertaining to device companies, but also understanding how this may specifically apply to your product(s). To be successful requires a critical, independent, and unbiased view. This can be achieved through your internal audits, as long as you are confident in the ability to be objective. Otherwise, you can use third parties to accomplish this. Confidently answering yes to the review process question means that you are fully aware of all of the areas of FDA focus during inspections and that you know where the bar has been raised, how this may apply to you, and where you may have similar findings.

So what should you do if you find that you have a compliance issue that matches a current trend? You will need to determine if your company has adequately addressed it.

It is essential to fully understand where the specific issue is covered in your quality

system and review the documentation to ensure it is adequate. There are several questions you must answer:

- Is there a CAPA?
- An investigation?
- Has the issue been documented in a quality record?
- Is there an identified root cause?
- Is there an action plan?
- If so, is it being completed according to schedule?

Some common mistakes that device companies make include the following:

- Being unaware of an issue because they are not keeping up with cGMP and enforcement trends.
- Significant internal audit findings that go unaddressed.
- Empty CAPA – a document is opened in the CAPA system but not populated.
- Believing an FDA investigator won't find the issue.

3.) Have you addressed all potential compliance risks?

Identification and remediation of all internal and external compliance risk requires due diligence. You should examine any current or past product issues, both internal, related to device testing or manufacturing, and external, such as product performance in the field.

- Review your internal quality data to see what trends are evident and how you have addressed them.
- Review your CAPA and complaint data just as they would be provided to an FDA investigator, sort it, and see how it matches up to what your routine trending has shown.
- Examine your manufacturing processes, monitoring data and any related CAPAs. You need to demonstrate that processes are validated where required.
- Understand the areas in your system where you make decisions related to risk and critically assess how robust those decisions are (adverse event/MDR reporting, recall decisions, whether or not an investigation is performed, and risk management files).

This approach also needs a critical, unbiased eye. The best practice here is to identify these items utilizing some level of independent review, whether from a corporate group or external consultants.

If you are diligent, you will come away with specific areas and topics for inspection preparation based on where you have identified risk and areas that require action. This information then becomes the focus for topics in your preparation efforts and for practice with your subject matter experts (SMEs).

Companies may be tempted to say that issues are not readily visible to others outside the company. Another misconception is that this methodical and risk-based approach to preparation is not necessary because of successful past inspections or a good rapport with a particular FDA investigator. The problem with this thinking is that FDA personnel changes and you are just as likely to see new investigators. Ultimately, whether you have identified all compliance risks means that you have comprehensively assessed and addressed all internal and external vulnerabilities associated with your products and your quality systems.

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4.) Are your employees able to answer questions and provide clear definitions?

You need to understand and prepare for all the possible risks associated with your SMEs and other employees who may participate in an inspection. There are two key questions to answer:

- Do you have new personnel in key positions or other staff who may be part of an FDA inspection? Are they fully prepared?
- How will SMEs and other participants perform when they are in a stressful situation and feel challenged?

Simulated inspections are an accepted best practice to prepare SMEs. You must ensure that all of the personnel involved in the FDA inspection process are competent to represent your device business.

5.) Do you have an established process to fulfill the FDA investigator's requests?

Prior to an inspection, testing your back room process is critical. First, you need to ensure that your back room process is clearly defined and understood by the support team. Next, managing and minimizing risk and examining the outputs and types of errors that arise is key to understanding how your request fulfillment process holds up during times of stress.

The best way to test your back room process is to conduct dry runs with the support team during simulated inspection sessions with SMEs. Answering yes to this question means that you have an organized process that accurately delivers documentation requested by the FDA investigator in a timely manner.

6.) Do you have a trained inspection support team, and is your management team prepared?

In risk-based inspection preparation, an effective model for decision making relies on the training and alignment of all SMEs and management. In times of stress, should issues arise, multiple chiefs may emerge—all of whom have the best intentions, but whose actions and comments may actually result in even more chaotic situations during the inspection.

Effective inspection training for SMEs and management minimizes or prevents confusion during critical times when organization and clear decision making is the most critical. When a device company has highly trained and well-defined inspection team roles, and a specific process for the management of inspections, the odds for successful outcomes increase.

7.) Can you provide electronic data?

During inspections, it is FDA's expectation that information can be readily retrieved electronically. For example, common requests during inspections include CAPAs, nonconformance, and complaint

and change history documentation. A device company needs defined processes and procedures that outline how that information is obtained and how you will verify the accuracy of the documentation. Are your reports validated—and if not, how are they verified? Another best practice is to pull the data in advance to test your process and have a trained SME who can explain the electronic records in detail.

8.) Do you have strategies for handling potential compliance vulnerabilities during an inspection?

Once you have identified areas of risk and other important topics for an inspection, it is time to prepare. You will need to prepare SMEs and management to ensure that all compliance vulnerabilities have been addressed. Experiential learning is one very important key to successful inspection outcomes.

One of the most effective methods to prepare SMEs and ensure your strategies are adequate is to conduct simulated inspections—practice sessions designed to prepare participants to respond to both specific and general topics. These sessions pose both common and more challenging questions to allow the SMEs and participants to answer as they would during an actual FDA inspection.

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One approach, also considered a best practice, is to design these simulated inspections using independent personnel to conduct the sessions (e.g., staff from the company's corporate group, another site, or external consultants). One of the many benefits of this approach is that SMEs learn in a safe environment through experience, understand what the results are when a less-than-optimal response is given, and can improve on the accuracy of any incomplete or incorrect responses.

These simulated inspections review all topics and associated documentation with a very high level of detail. This minimizes or prevents any surprises in verbal responses or document content that may contradict your strategies and conclusions.

When the simulated inspection is complete, participants receive feedback on their responses regarding the potential risks of incomplete or incorrect responses, as well as any other actions that may be necessary to reduce compliance vulnerabilities. Performance feedback is also provided for the support process, including the accuracy and timeliness of records requested. After a practice session, adjustments to your strategy may be required as part of further preparation.

Multiple sessions are conducted until responses on all topics are prepared. This means the SME, other participants, documentation, and any follow up actions associated with the topic are accurately and fully addressed. This experiential learning approach builds a very high level of confidence among the SMEs and other inspection participants.

9.) Has a third-party assessed your vulnerabilities and provided practical, cost-effective strategies?

This means that you have thoroughly answered the prior questions. Whether you use independent personnel from your company or retain external consultants to assist in your preparation, obtaining an unbiased review process is an essential best practice for inspection readiness.

10.) Would you pass an inspection today?

Being ready to pass an FDA inspection means that you have done the following:

- Identified all of your vulnerabilities and can demonstrate through your responses and documentation that you have addressed them.
- Organized and defined inspection support processes.
- Trained and prepared personnel as a result of experiential learning—your SMEs are confident and ready to interact with any FDA investigator.

When you have taken the risk-based approach to inspection readiness and have positive answers to all 10 key questions, you have a confident, prepared team and have done your best to prevent surprises and prepare your device business for any FDA inspection.

References

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