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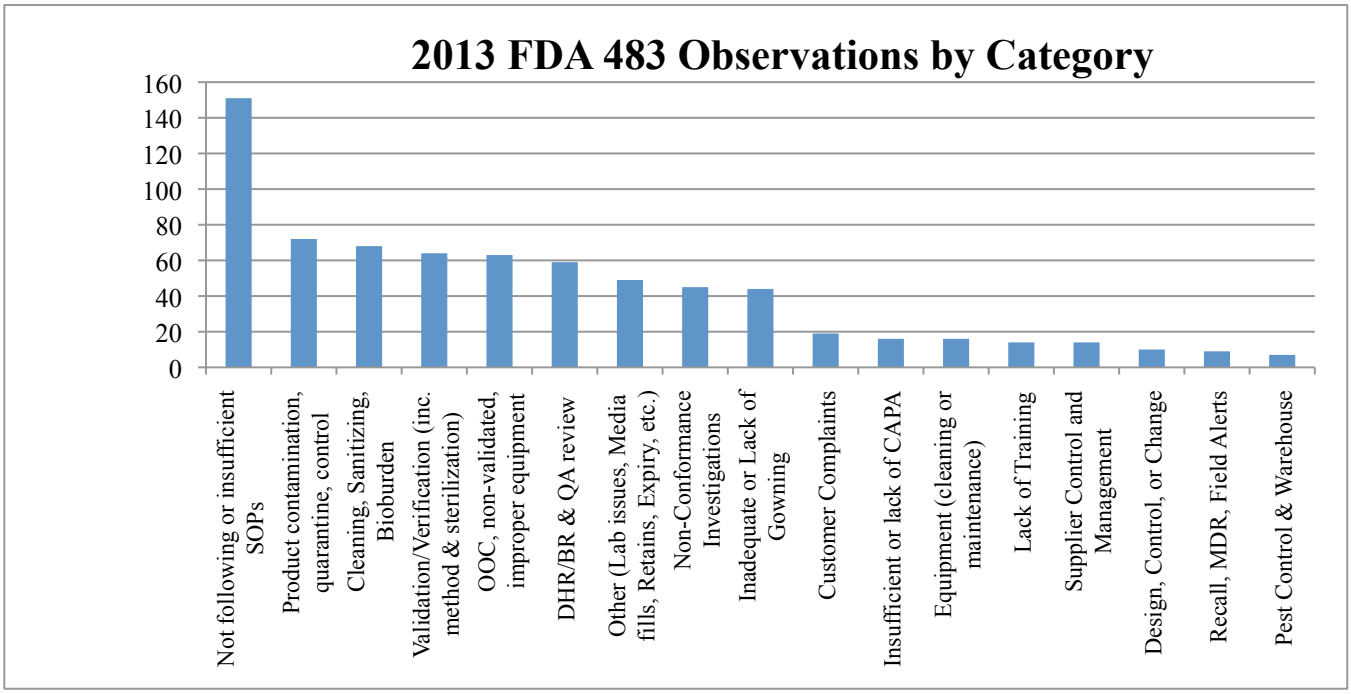
Failure to follow written procedures or an overall lack of robust procedures sufficient to satisfy the requirements of the cGMPs remains the highest overall category for FDA 483 observations.

Human Error

Human error and data integrity issues are common causes for FDA 483 citation within the Pharmaceutical, Medical Device, and Biotechnology industry. Online articles, journals, blog posts, news articles, and various other forums frequently report details on organizations with compliance issues stemming from data integrity and simple human error. Failure to follow established company procedures was one of the top three reasons for 483 observations in 2013.



But what can organizations do to prevent these types of problems or even to correct them? To err is human, after all. You can't eliminate all errors but you can greatly reduce the opportunity for error and the risks associated with errors.

How does one address human error within an organization?

1. Documentation - Often the biggest source for error lies within the company's own controlled documentation. In performing an assessment for documentation quality be sure to ask the following questions:

- Do procedures match practice?
- Are procedures written in a way that everyone can understand them easily? Adults learn through visual, oral, and written methods. Complex process documents should include photos, simple words, and step-wise instruction that is easy to read and recall.
- Does everyone have easy access to official documents?
- Are documents routinely revised by subject-matter-experts to ensure they remain current?
- Are production batch documents easy for operators to complete?
- Are batch documents simple and step-wise?
- Is it easy for a user to clearly identify errors or missing information from batch documents?

2. Training is another opportunity for error reduction. Firms frequently perform routine good documentation training but seldom ensure the training is effective or employees fully understand the business significance of documentation errors. When reviewing the training program, consider these questions:

- Do all employees clearly understand what data integrity and documentation quality requirements are and why they are important to the firm's sustained success?
- Are employees invested in actions that promote good documentation practices? For example, do operators take time to ensure documented information is the best it can be and double check to ensure errors are not overlooked?
- Is refresher training provided to ensure employees maintain focus on good documentation practices and data integrity?
- Do employees, who are also company stakeholders, fully understand the risks and costs associated with documentation errors and simple mistakes? For example, does the refresher training review any recent news articles on 483 observations issued by the FDA to other organizations regarding simple error or data integrity issues?
- Are employees well trained on procedures, correcting errors, and how to investigate the cause for errors and correct them?

3. Management. Management entails activities such as planning, organizing and controlling. Part of the control function means ensuring that the operations remain in compliance with company expectations. Managers have to be fully invested in ensuring the opportunity for error is eliminated, risks are mitigated, and team members are vigilant in the efforts to control the error rate.

- Do employees have performance goals associated with good documentation, actions taken to reduce human error or near-miss events, and ensuring data integrity?
- Are employees and teams focused on continuous improvement activities designed to reduce error rates?
- Are performance metrics tracking the error rates as well as causes?
- Does the performance management program reward positive performance in addition to holding negative performance accountable?

- Are managers using effective methods to investigate the cause for errors as well as long-term actions to correct and prevent them?
- Does the correction system include methods for checking effectiveness of actions taken?
- Are Quality and Compliance a vital part of your organizational culture?

In many cases, the underlying causes for human error and data integrity are difficult for employees and managers to fully identify. It's easy to overlook bad habits or risky practices when you see them day-in and day-out in the same workplace. Often companies find success through external audits or gap assessments conducted by professional consultants who are industry experts. They are able to view company practices with a different perspective and find ways to identify and resolve problems that may otherwise be overlooked. Professional consultants can provide technical training on reducing human error and help engineer sustainable solutions. Proactive firms invest in a variety of techniques to ensure that the opportunity for error is reduced and associated risks are mitigated in order to avoid costly compliance issues, FDA citations, lost revenue, or compromised product.

Have Questions?
Need Help?

Contact Us:

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