Implications of the FDA's Quality System Inspection Technique on Calibration Management

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Abstract

The FDA's Quality System Inspection Technique (QSIT) - which includes calibration management as part of its "Facilities and Equipment" category - is changing how the FDA inspects regulated sites and is driving the recent harmonization, integration, and application consolidation between systems for managing distinct aspects of a quality system.

In this presentation, we will focus on this issue as it relates to calibration management and the larger "Facilities and Equipment" category. The different disciplines within this category - most notably calibration, maintenance, and validation - interact with and affect each other in the context of an equipment's total life cycle to maintain the validated state. With these interactions and understanding the impact decisions in one department can have on another department, there are possible synergies between the departments to increase productivity through reduced downtime and better use of human resources. Likewise there are advantages to be had for sharing information across systems that manage these activities. Before heading down the path of system integration or consolidation, it is important to understand how the system requirements differ for each department, what requirements they each have in common, and how each prefers to interact with the data. For example, whereas the calibration department prefers to look at its data from an equipment-centric standpoint, the maintenance department is much more driven by work orders.

When looking to harmonize the different systems, essentially three approaches can be taken. First, a company can continue to use legacy systems that are already validated and handle sharing of information manually through double entry where necessary. However, depending on the size of your operation, it will become increasingly more difficult to justify this approach to the FDA. The second option is to develop custom integration to share information automatically between best-in-class applications. This option clearly involves the least compromise on functionality for each department, but there are certain practical considerations to keep in mind. The third option is to implement a single consolidated solution. When taking this option, which involves the greatest potential for synergy, it is important to establish guidelines for determining what minimum functionality must be available for each department. In most organizations, one department will have more clout and influence than another, which tends to be the leading force in such harmonization projects if a more objective approach is not taken. Software not designed with each department in mind can also have a profound impact on productivity. A thorough evaluation of this impact before purchasing a software package could pay big dividends.