

INTRODUCTION

FDA regulations are very clear in their expectations that calibrations occur on a regular and appropriate schedule, follow very specific and approved procedures, and be fully documented, with procedures in place for when problems arise. For example, procedures should be in place for when an instrument used in production is found to have been out of process tolerances or when a standard itself is found out of calibration.

Regulations do not go so far as to dictate what tools should be used to satisfy these requirements. They do not require, for example, that a computerized system be used. They do, however, require that whatever “system” is used be validated. While not dictating the use of computer technology, the FDA does realize the benefits of modern technology. They have introduced and continue to refine regulation to facilitate its use, including the 21 CFR Part 11 regulations on electronic signatures and the “Pharmaceutical cGMPs for the 21st Century”.

Computerized systems, however, are valuable tools. Once the number of instruments being managed and the number of metrologists managing them reach a certain threshold, most companies concede that paper-based and even Microsoft Excel-based applications simply are not practical both because of usability and validation concerns. A software system designed for managing those events is required.

This paper explores the calibration management system features and functionality common to best-in-class calibration management applications designed for life sciences. These features are demanded and used by some of the world’s most successful pharmaceutical, biotech and medical device companies and are intended to improve productivity and lower the costs and risks associated with compliance. Why are they so important to these companies? What are their benefits? How can you justify the time and energy required to implement and learn to use them?

WHEN IS A SCHEDULER LESS THAN A SCHEDULER?

Before moving on to more sophisticated features, a few words on scheduling functionality are worthwhile in a discussion of best practices. Most applications designed for scheduling work events cover the basic requirements, including flexibility in scheduling events, and assignment of person responsible for the work and the supervisor for the job. More advanced applications also offer the ability to manage work coming due, including reminders and warnings when work is past due, and provide a single access point for the procedures and basic information required for the work.

The answer to the question then “When is a scheduler less than a scheduler?” would be when it takes away from the efficiency of the user. With the volume of calibrations performed each year by the average calibration department in the life science industry, adding just 5 minutes per calibration performed adds up quickly to hours, days and up to weeks of lost time per year. For example, some organizations have experimented with using a CMMS (Computerized Maintenance Management System) to track calibrations. The difficulty they quickly encounter, however, is that the overhead of

dealing with the work requests and work orders of a CMMS can add significant steps to a calibration, just one of the many reasons why metrologists will argue aggressively against being included in a traditional CMMS implementation.

While sharing a CMMS implementation may not be the ideal solution, the ability to access and share calibration, maintenance, validation and other supporting documentation pertinent to the equipment through electronic means can greatly improve efficiency during regulatory inspections and improve collaboration throughout the lifecycle of an asset. To find a system that facilitates such sharing and collaboration without compromising anyone's productivity, companies have chosen to either integrated multiple single purpose systems for calibration, maintenance or validation or implemented a system designed to take into account each department's needs, such as Blue Mountain Regulatory Asset Manager.

THE PAPERLESS DREAM

Through the rules provided in 21 CFR Part 11, the FDA opened up the door for regulated companies to use a computer system to replace paper records as the official record of activity. The regulations explain under what conditions an electronic signature can be used as a replacement for a handwritten signature. Today, with most software designed for life sciences featuring 21 CFR Part 11 compliance features, a few companies are leading the way in pursuing the paperless dream. Clearly there are still some practical limitations – most people still prefer to read printed documents to electronic documents (in all likelihood you printed out this document to read) – but much of the applications that companies use paper for today are in fact better served electronically.

The benefits of going paperless are significant and straightforward, going beyond the mostly negligible financial and even environmental cost of paper itself. First, there are the non-trivial costs of keeping a history of paper records to the level required by regulations. As the number of instruments being calibrated increases and the years go by, these costs continue to mount. Also, with a vast repository of paper-based calibration and maintenance records, a misfiled data form can be all but impossible to locate. Other benefits of paperless operations include ensuring compliance to procedures, streamlining of work flow processes and the availability of electronic data for aggregate data analysis, all topics that will be explored in greater detail throughout the rest of this paper. Finally, electronic systems tend to “perform” better in a regulatory audit than paper-based systems, reducing regulatory risk and reducing audit length.

When it comes to paperless field data collection, most companies have found the PDA-form factor a bit too small for the amount of data collected for calibration events. There are however several more practical options for the computer used for recording calibration information, including a traditional networked computer, or a laptop or tablet PC connected to the network wirelessly. With some CCMS today, a laptop may not even need to be connected to the network during data collection. All the information required for the current jobs can be downloaded to the laptop. When the data collection is complete and the laptop is reconnected to the network the resulting data is then uploaded into the database.

COMPARING TYPICAL WORKFLOW SCENARIOS

Collectively, through maximum incorporation of available functionality, a paperless CCMS implementation can greatly streamline the workflow of maintaining and demonstrating regulatory asset management. Walking through the typical workflow scenarios will illustrate that point.

A typical paper-based regulated business flow would first entail verbal notification of end-users that an asset is coming due for calibration. This takes significant time and resources to first notify and then agree to asset downtime to complete these tasks. A paperless CCMS system can be configured to automatically notify target end-user groups of these routine tasks at specified intervals in advance of the due date. If the maintenance, validation and quality parties are users of the same closed system, these notifications are best handled within the system as procedures that involve external email notifications are very difficult to validate.

After coordinating schedules with other interested parties, the responsible party typically spends a significant amount of time preparing to perform the work, gathering the necessary documentation, including SOPs, manuals, drawings, controlled data collection forms, etc. These are often controlled documents obtained through formal requests and quality overview. Over time, the collective resources spent across multiple departments in the release and preparation of the necessary supporting documentation represent significant and unproductive overhead. In contrast, a paperless CCMS implementation can be configured and fully validated with electronic links to this documentation, greatly increasing efficiency of the business flow.

Even with the best intentions and regular training, ensuring conformity to standard operating procedures and business processes can be tricky, particularly as the size of the operations grows. Sequence of steps and details may be overlooked when reviewing steps on a printed document. However, using computer software designed for managing calibrations allows metrologists to focus on their craft and leaves retrieving procedures and processes to the database. Software designed for managing calibrations can even indicate which standards are appropriate for the work and ensure that the standard used has itself been properly calibrated.

While paper-based systems usually consist of pre-determined calibration test points and subsequent as-found / as-left measurement criteria on a data capture form, there is room for many common errors in the transcription of that data, the calculation of as-found / as-left deviations, in addition to other commonly missed intricacies, such as crossing out blank spaces, spelling errors, initialing and dating. Upon review of this documentation, it's not at all uncommon to find these errors scattered throughout a stack of calibration data turned in for review, which adds to the review of the calibration data itself. The paper-based remediation of these errors may then add days to the overall process of the business flow, where a CCMS, through electronic signatures and measurement data templates allows users to circumvent most of these errors. Furthermore, the software provides something that no paper-based system can offer: immediate feedback on measurements. Measurements that are out of tolerance are unavoidably clear. If it were a reading error, it can be quickly fixed. In more

serious cases, when the reading indicates an “As Found” problem with the instrument, remediation can start right away with notifications sent automatically to all concerned parties.

Next, we must consider the down-time typically associated with paper calibration records during the review and filing process. Once completed and reviewed, a calibration coordinator or document management group is typically responsible for manually filing the record, alongside subsequent documentation to demonstrate the filing occurred. In a CCMS, completed work is electronically advanced for review e-signatures to the appropriate personnel immediately upon completion of the field calibration, completely eliminating manual effort and saving considerable time and resources.

MAKING THE MOST OF LIMITED CALIBRATION RESOURCES

Through the above workflow scenarios, we have demonstrated how a CCMS can improve a metrologist’s everyday efficiency. However, the greatest benefit to operating paperlessly may not be data collection and storage, but instead information retrieval, how the information collected is used.

With a paper-based system, the paper records satisfy the regulatory requirements and can provide evidence that a certain calibration was performed. However, information retrieval is difficult and therefore paper-based systems take an extreme toll on an organization when problems arise. In a well-designed CCMS, performing a reverse traceability on a particular standard over a particular timeframe is a quick and easy process. In contrast, shuffling through the paper records and piecing together the remediation is a painful and time consuming undertaking in which little confidence can be had that all records were indeed discovered.

With increasing pressure to improve productivity and lower costs without impacting compliance, life science companies are going beyond measurement data collection and reverse traceability and looking at new ways to leverage the data stored in their CCMS. Looking at a history of calibrations in aggregate, opportunities for cost reductions can become evident. Metrologists themselves may have an instinct that a certain trend exists, but if the exact details and costs of that trend were clear, a case could more easily be made for investment to rectify the problem. Likewise, an analysis of the data may suggest opportunities to adjust the frequency of calibrations for greater efficiency. Such interval and trend analysis is often possible with reports that come included in the CCMS package.

SIMPLIFYING IMPLEMENTATION, VALIDATION AND MAINTENANCE OF A CCMS

Another growing trend amongst life science companies spread out over multiple sites is the centralization of enterprise applications. By far the greatest benefit of a centralized implementation of a CCMS is on the validation costs. In most cases, the majority of the validation costs for an enterprise application are on the server side. With just a single server implementation, the validation costs per site are lowered significantly. Centralizing a CCMS implementation also generally lowers other implementation and total license costs.

CCMS Best Practices: Making the Most of Limited Calibration Resources

Standardizing on a single application across an organization can facilitate greater communication and collaboration across sites, thus improving regulatory compliance and efficiency. Users at different sites can share their own best practices and ask each other procedural questions without worrying about proprietary information getting out of the organization. More flexible and economical training options are also often available when multiple sites are learning the same application versus each learning a different application.

HOW BLUE MOUNTAIN CAN HELP

If you already have Blue Mountain's Calibration Manager® or Blue Mountain Regulatory Asset Manager fully implemented, the next steps involve simply maximizing the benefits you gain from that implementation. Blue Mountain offers regular public and onsite training that go over the full length and breadth of the software. Alternatively, we offer two-hour web trainings that focus on particular functional areas of Calibration Manager: reverse traceability, measurement data collection, electronic signatures and key performance indicators. Depending on the initial validation, using additional functionality of the software may require validation of aspects of the software not previously validated. If resources are tight, our team of industry experts is also available to assist with the validation and / or the development of procedures that streamline workflow, improving both compliance and productivity.

If you think you could do more than what you can do with your current calibration management solution, we can work with you to develop the justification for upgrading to a best-in-class calibration management system.

