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GMP Calibration Software Implementations: Containing Costs and Managing Risk

Abstract

As expectations from and complexity of calibration management software implementations increase, many leading regulated Life Science manufacturers have chosen to outsource some or all of these implementations. The issues propelling this decision include:

- Increased expectations to reduce risk and contain costs
- Desire to achieve the full productivity benefits offered by calibration management software
- More thorough system life cycle regulation by the FDA
- More stringent validation requirements
- Greater pressure on time and personnel limitations
- More sophisticated systems requiring more varied expertise

This white paper explores the growing complexities of calibration software implementation and the potential for outsourcing all or part of the implementation as a means to address these challenges in a timely and cost effective method.

Introduction

The management of instrument calibrations is a requirement for all FDA-regulated manufacturing organizations. There are several well-established software systems designed specifically for this task that have been adopted by many regulated organizations[1].

The regulatory (specifically FDA) expectations for computer systems validation continue to evolve, becoming more robust and demanding. However, now the FDA's new risk-based approach[2] to GMPs provides new opportunities to develop more efficient systems, as long as careful attention is given to identify and control the risk associated with those gains.

For many organizations, the concerns about the implementation and validation of a calibration management system have prevented them from taking advantage of the latest technology despite the quick payback in terms of improved productivity and cost reduction of these systems. Increasingly, companies are outsourcing these headaches as a means to reduce the cost and risk associated with calibration software implementation and validation.

Implementation Life Cycle

The expectations from FDA for a complete life cycle model for systems have certainly increased the complexity of rolling out any GMP-compliant system.[3] The life cycle, as defined by current GMP, treats the implementation in detail, from developing the business process through to the retirement of the system. The major components in a system implementation include (although the order might vary slightly):

Baseline assessment: A close and honest look at where your calibration procedures are today to highlight potential areas for improved productivity and cost reduction.

Assigning project leadership and preliminary budget: Determining the person or people responsible for keeping the project on track is an important early step. This selection can become more challenging if you are planning on introducing a calibration management system for multiple sites. A preliminary budget can also be set at this time, based on estimated savings and an acceptable payback period.

User Requirement Specification (URS) development: The URS describes the required functionality from the system. This document establishes what the product should be able to do, however it is important at this stage to remain open to different approaches on *how* the systems does it. You should also differentiate in this document between mandatory and regulatory requirements versus desirable features.

Vendor evaluation and selection: The URS plays an important role in comparing and evaluating potential vendors. Other important considerations include flexibility, ease of use, and reliability. Because of the difficulty of validating new systems, it is also important to choose a vendor you can work with for the long term. How well do they respond to changing customer requirements and new technology advancements? What do their current customers think of them?

Gap analysis between URS and Functional Specification (FS): Once you've decided on your top vendor candidate, you should take a close look at the gap between what you need (URS) and what the current software can provide (the Functional Specification). Often the software vendor will be able to offer alternative methods to satisfy your core needs, in some cases adding functionality in future releases.

User group blueprinting: If you are implementing a calibration management system across multiple sites or diverse groups, it will be necessary to synchronize and standardize procedures across those sites. The amount of standardization required will depend on the type of data sharing you want between sites and the software's ability to accommodate different procedures at different sites. The user group blueprint is the output of these standardization discussions.

Project planning: With the software chosen and the procedures determined, it is a good time to establish the framework for the project, including pilot site, data migration plan, event timeline, goals and evaluation plans.

System Configuration: Before implementation, you will want to configure your system to more closely match your current and ideal procedures. The amount of configuration possible will depend on the amount of flexibility in your selected system. The decisions made here will directly affect how much you get out of the new system.

Prototyping: In most cases, you'll want to have a prototype or pilot installation before beginning the complete system implementation. Learning from a limited installation can greatly reduce the disruption caused during the complete implementation. During this phase you discover bottlenecks that can be avoided or reduced and uncover valuable insights about the system's features.

Hardware and network qualification: Your computer hardware and network should be qualified to be sure that they can support the system you're implementing. Without the appropriate equipment, the system might completely fail to run, encounter awkward errors, or be so slow that it hampers productivity. Be certain to understand where investments in computing hardware will have the greatest impact, on the user end or on the network or server side.

Installation: The installation of the software on local and server computers, including in the test and production environments.

Data migration: If you have legacy data and your selected system can accommodate it, the introduction of this data early will allow for an early benefit from the data analysis features of your calibration management system. Before initiating the data migration, data cleaning – making sure the data is all in the right fields and is accurate – may be necessary.

Training: Bringing users and managers up to speed quickly on the software can be both a considerable expense and profoundly improve the system's payback period. In some cases it may make more sense to have one or two people trained who can then train the rest of your people and in other cases it makes more sense to have an on-site training for all the users at once.

Validation: The validation can be a significant portion of the time and expense required for a system implementation. Today the application validation has to include not only the software and the hardware, but the network it runs over as well, further complicating the validation process. Your selected software vendor's level of experience with validation can have a significant impact on how smoothly the validation process goes as they can often offer help and tools to improve the experience.

Software installation qualification (IQ): Make sure that the installation is completed according to written and pre-approved specifications.

Software operational qualification (OQ): Document the system's actual operational functioning versus specification. Does the software behave as documented and expected?

Software performance qualification (PQ): Document that the system performs as required. Does the system perform as required within the overall processes and while in its specified operating environment?

Maintenance and upgrades: Technology continuously evolves, from routine bug fixes to major functionality enhancements, to fundamentally new technology platform migration. While existing customers usually get these upgrades at reduced costs, any associated costs of revalidating the system will need to be factored in. Again, the software vendor's experience with validation can reduce the business impact of the re-validation.

Reducing Costs and Risks by Outsourcing Implementation Steps

The motivation behind outsourcing is to transfer activity not associated with the organization's core strengths from internal resources to external resources. Ideally it is transferred to someone with unique strengths in that area. By outsourcing, the organization not only benefits from the unique strengths of the other organization, but they also free up their resources to focus on what they do best.

Outsourcing can be justifiable for many of the steps in the implementation life cycle outlined above. For starters, few companies would claim calibration management system implementation as one of their core strengths. Additionally, the difference in costs incurred and productivity gains achieved between an implementation done by inexperienced implementers versus one done by someone with the experience and know-how to be able to avoid the pitfalls and capture the opportunities during the implementation is significant.

One of the key decisions an organization makes is which aspects are best suited for internal resources and which are best done by an external organization. Some organizations would benefit from help with just a handful of the implementations steps, while others can easily justify the outsourcing of the complete implementation, essentially acquiring a turnkey system.

The cost savings and risk reductions for outsourcing the system implementation derive from several different sources:

- Minimized interruption to ongoing operations with fewer personnel resources required to execute Implementation
- Shortened implementation duration with more concentrated resources, allowing for more simultaneous activity which brings quicker return on investment

- Access to personnel resources with broader, more specialized skill sets
- Coordination of multiple sites to maximize positive business impact
- Best practice knowledge transfer from validations at other similar companies offer unique insights for smoother and quicker implementation and lessons on implementation or validation risk areas
- Create familiarity with system secures greater access to the full benefits of the system, improving work flow and access to data for better management decisions

How to Choose a System Implementation Partner

After the decision on which calibration management system to implement, your choice of implementation partner is perhaps the greatest factor that determines the scope of the positive impact the system can have on your business and the level of distraction the implementation process itself has on your ongoing operations.

Several factors should be considered when evaluating a system implementation partner, including:

Experience: Your partner should have experience implementing calibration management systems at companies with needs similar to your own. This experience will not only result in a more efficient implementation process, but will also offer you access to a reservoir of best practices in calibration management.

Familiarity with software: In order to ensure that you are getting the most of your new calibration management system, your implementation partner should be one with deep familiarity with the features and capabilities of the software.

Personnel with broad skill sets: As mentioned above, one of the advantages to outsourcing is gaining access to personnel with unique skills. Your implementation partner should be able to offer access to personnel that are not only experts in the software, but also in computer networks, and calibration management and general workflow.

Experience with complex implementations: Particularly if yours is a multi-site (including multinational) implementation, you should be certain that your partner has experience managing the more sophisticated dynamics these implementations involve, including coordinating with multiple site managers and efficiently allocating personnel across different sites.

Offering a range of scalable services: Each company's implementation needs will differ. Your implementation partner should work with you to determine exactly what you need – from help with one or two key steps in the implementation to a complete turnkey implementation – and scale its services to the size of your implementation.

Assessment and evaluation services available: One of the greatest values an outside resource can provide is as an honest outside assessment of your calibration management procedures and methods. The ideal partner would be able to offer valuable assessment at the beginning of the process, with unique insights that will further enhance the implementation's impact. Likewise, you and your partner should establish clear goals and expectations from the implementation and clear measures to determine if those goals have been met, including evaluation services that would highlight possible adjustments that can be made early in the software's direct use.

In some cases your software vendor will offer system implementation services, often packaged with your software purchase. Clearly they would have an intimate familiarity with the software, but before contracting with your software vendor to handle the implementation, you should verify that the company truly understands their customers' needs and daily demands. It is not uncommon for software developers to become infatuated with the technology and lose track of their customers' challenges. Make sure, for example, that the company's implementation staff includes experts in calibration management, not just experts in information technology.

About Blue Mountain Quality Resources

Blue Mountain Quality Resources has 15 years of experience implementing calibration management systems for FDA-regulated life science manufacturing companies. Their suite of implementation services, available individually or as part of complete solutions, was specifically designed to leverage their experience toward reducing costs and risks in implementing and validating these systems.

The company's own calibration management system, Calibration Manager, with many features designed specifically to meet the rigorous demands of FDA-regulated companies, has been installed in over 1600 companies, from small single-site implementations to large multi-site multinational organizations.

For more information about how Blue Mountain Quality Resources can help you contain your software implementation costs and reduce risk visit www.coolblue.com, email us at BlueMountain@coolblue.com or call 800-982-2388.

References

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