

Validation of a Calibration Management Software System

INTRODUCTION

The need for control over manufacturing processes has never been higher than in today's regulated manufacturing environment. As this requirement has increased, so has the need for better management of the measurement equipment used to measure and control these processes. Fundamental to managing this measurement equipment is assuring it is properly calibrated and maintained.

Most companies today are being faced with an increasing number of instruments requiring calibration, while simultaneously reducing the resources available to maintain them. One popular method for minimizing the resources needed for maintaining instrumentation is the implementation of a calibration management software (CMS) system. Under cGMP's and 21 CFR Part 11 Electronic Signature/Electronic Records requirements, this software application must be validated, as it is a part of the quality assurance of the manufactured product.

CMS systems have increased tremendously in functionality. The typical calibration software system not only tracks equipment inventory, calibration schedules and histories, but increasingly ties into calibration procedures, contains calibration interval analysis capabilities and other advanced features.

With the increased capability of this software, manufacturers have come to rely on this software. Validation provides assurance that the system is reliable and demonstrates that the system operates in a state of control.

With current staff reductions and increased work loads, it becomes a matter of prioritizing validation projects and identifying the level of detail needed for the particular system to be validated. A current topic among validation specialists revolves around the identification of the level to which a system must be validated. A useful technique for doing this is the Risk Assessment Analysis (RAA). This method identifies the relative risk and the corresponding level of validation required. In addition, the FDA is realizing this is a viable methodology and is reflected in their new initiatives, "Pharmaceutical cGMP's for the 21st Century, A Risk Based Approach."

It is therefore prudent to select a validation process that produces the highest level of compliance with the minimum of resources. This paper identifies 3 key aspects to implementing & validating a CMS system. The basic aspects identified in this paper are based on Blue Mountain Quality Resources' experience in implementing over 1,000 FDA calibration management software systems.



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The first two aspects, the *User Requirements Specifications* and *Software Vendor Qualification* provide the ground work for the third aspect, the *Validation*.

USER REQUIREMENTS SPECIFICATIONS

When validating a CMS software system, a fundamental aspect is to verify the functionality of the software against the user's application requirements. Since the purchaser of a CMS software system does not have control over the specifications the developer uses to design the software, the user must identify his own requirements and match these to the available systems.

The most common method for doing this is through the generation of User Requirements Specifications (URS). This document describes the application from a functional view point. The emphasis should be on the required functions and not on the method of implementing those functions. A requirement specification should be written for each function the user will require the software to perform. According to Good Automated Manufacturing Practice Guide 4 (GAMP), the following guidelines are given for establishing URS.

- Each requirement statement is to be uniquely referenced, and not longer than 250 words.
- Requirements statements should not be duplicated or contradicted.
- The URS should express requirements and not design solutions.
- Each requirement should be testable.
- The URS must be understood by both the customer and supplier; ambiguity and jargon should be avoided.
- Whenever possible, the URS should distinguish between mandatory/regulatory requirements and desirable features.
- There may need to be a formal review of the URS between the customer and supplier to check understanding and that requirements have been met (or not) in the functional specification.

For a calibration management system, some general areas for requirements include:

- Ability to add, maintain and retrieve master equipment records
- Ability to add, maintain and retrieve calibration history records
- Ability to track schedules of future calibration due dates
- Ability to print calibration forms
- Ability to compile reports for calibration interval analysis
- Multiple level password protection capability



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- Audit trail capability to track changes to the database
- Internal back-up and restore capability

It is the purchaser's responsibility to assure that the software system selected meets the requirements in the URS. A comparison of the software specifications to the URS should be made and documented. Since not all software systems meet every user's requirements, the user must also document any discrepancies between the software and the requirements, including any work or procedures which eliminate the discrepancies.

The preparation and verification of the URS is vital for showing that the system is suitable for use in its intended application.

SOFTWARE VENDOR QUALIFICATION

Since CMS software systems are intended for use in a regulated environment, it is the vendor's responsibility to use an appropriate development quality assurance methodology. It is the purchaser's responsibility to verify that the vendor has the appropriate methodology in place and that it is capable of developing high quality software.

There are many software development models commonly accepted as being capable of producing high quality software. Among these are the Life Cycle model defined by the PMA's Computer Systems Validation Committee and GAMP 4. It is the purchaser's responsibility to understand which model the vendor uses and whether it is sufficient to develop the quality of software for a given application.

Verification of a vendors development process can be accomplished in a number of ways, including vendor surveys, audits and review of vendor supplied documentation. The method with the highest level of assurance is the vendor audit. The vendor audit is also the most costly and for a calibration management software system it is rarely justified. The need for an audit can be eliminated by a combination a written survey the purchaser sends to the vendor, as well reviewing documentation which the vendor supplies. Some vendors make copies of their software quality assurance procedures and records available to their users, it is recommended that you ask for these.

One other important method for determining a vendor's software development capability is by examining the company's reputation in the industry. Check with other users and also maybe even



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users who have audited the vendor already to see what their experience has been. Most software users are willing to share their experiences using the software and working with the vendor.

VALIDATION

Once the software system and vendor have been qualified for use in the user's application, the software can be implemented. The implementation of the software involves many aspects including installation, training, procedure writing, and validation. The validation requires specific attention and a description of this activity follows.

The key to validating a CMS system is the preparation and implementation of a validation project plan. The validation project plan provides a prospective plan that when executed, produces documented evidence that the system operates in a state of control. With a properly prepared validation project plan, the work is planned in advance, carried out in logical order and easily documented.

There are several formats commonly accepted for organizing a software system validation project plan. The following format has been found to be acceptable by both manufacturers and regulatory agencies. It was designed to provide an appropriate level of detail, while not encumbering the manufacturer with unnecessary work. Each of the main sections of a sample plan is discussed below.

Scope

This section identifies the goals and objectives of the validation. It typically contains information on where the system is implemented and the products or processes it affects.

Validation Team Approvals

It is important to list key individuals involved in the validation effort. Their responsibilities during the validation should be listed for reference. Typically, one individual is designated the Validation Manager. This section should contain a form which should be signed by all individuals with project and system oversight responsibility. The corporate organization structure and the scope of the project, in conjunction with internal policies, will determine the highest level approval required.

Validation Certificate

The Validation Certificate is a concise summary of the basis for determining that the system has been successfully validated. It should be designed to identify the benchmarks, initials and dates.



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System Validation Plan

This section contains the overall plan and basic validation requirements. It should include a system characterization and reference to any supporting documentation, such as user requirements, vendor qualifications and software user manuals. It can be in outline form with numbered steps identifying the aspects of the plan.

System Validation Protocol

The protocol provides an outline of expected test outcomes which would indicate that the software's performance is satisfactory. It can also include information on how the test results should be documented. This section is an overview of the tests to be performed in the Operational Performance Qualification.

Installation Qualification

For a CMS system the Installation Qualification can be broken down into 4 subsections.

Standard Operating Procedures (SOP)- These procedures describe the rules under which the software will be operated. The key areas for a calibration management system are security, operator training, system/data backup and recovery and any use of customizable software functions.

Hardware Configuration - This is a list of hardware used to run the software. It should include system processor, operating system and version and any network connections.

Software Configuration - This is a list of information about the software being used, such as version, release ID and file dates. The date installed and who it was installed by should also be noted.

Documentation Library - This section should indicate all relevant documentation pertaining to the software installation. This can include user manuals, SOP's and validation documentation.

Operational/Performance Qualification

This portion of the validation plan describes how the critical aspects and functions are to be tested. It contains test scenarios, which try to consider all unusual situations to which the system might be subjected. The tests should define the methods and the acceptance criteria. This is usually the area which requires the most thought and care in preparation.

Validation Currency Maintenance

There are various situations that will require re-validation and these should be addressed before they occur. These situations include moving the software to a new system and installation of new



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versions. Procedures should be identified which describe the process for implementing these changes and what revalidation should occur.

In most cases, the majority of time spent implementing the plan will be in the Operational Qualification stage. This stage is critical, it is where the actual tests which challenge the software occur.

When documenting the tests, screen captures of the software in action can eliminate some of the documentation demands. Each test should be dated and signed or initialed. It is suggested that notes, check marks and dates be hand written, showing active participation by the validation team. The plan and resulting documentation should be kept in a 3-ring binder, with each page numbered and dated.

SUMMARY

Upon completion of the validation plan, vendor qualification and user requirements, all of the resulting documentation should be organized in a central location. Plans should be prepared to identify what is to be shown to an auditor and the order in which it presented. If this is identified up front it will save time in the audit and help demonstrate that your software system is under control.

By proving the software meets the application requirements, the vendor meets industry accepted development criteria and the software meets the validation plan criteria, the manufacturer can be confident that the software system is suitable and that it will hold up under regulatory scrutiny.

ABOUT BLUE MOUNTAIN QUALITY RESOURCES, INC.

Blue Mountain Quality Resources is the Validated Leader in Calibration Management Software. With over 10 years of experience in FDA regulated markets, Blue Mountain offers a complete solution to calibration management needs, from set-up and installation to training and validation. Through our calibration productivity tools, Blue Mountain assists users in maintaining and monitoring the full cycle of calibration management. This allows companies to improve their operating efficiency, maintain requirements for FDA compliance, and maximize their return on investment.



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