

Tailoring a CMS Validation Implementation To Your Organization's Compliance Agenda Using Intensity Profiles

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CMS Validation Implementation Intensity Profiles

ABSTRACT

Prospective Calibration Management System (CMS) User Organizations can better conceptualize what to expect from a CMS implementation / validation project by using *Intensity Profiles*. An Intensity Profile, when describing a CMS implementation / validation project, is a set of business characteristics and compliance needs that affect the cost, duration and complexity of the project. Three Intensity Profiles (High, Medium and Low) will be developed in this paper focusing on the following parameters:

- Validation
- Scope
- Requirements
- Resources
- GAMP 4 Software Categorization
- Environments
- Data Migration
- Documentation
- Vendor Assessment

By identifying itself within one of the three Intensity Profiles, an organization can gauge the effort that will be required to successfully deploy its particular CMS. The ultimate goal being a validation effort tailored to the organization's specific business and compliance needs.

INTRODUCTION

There is plenty of discussion on the growing expectations of the FDA with regard to the management of instrument calibrations. While many regulated organizations have adopted software designed specifically for this task, others have lagged behind advancing technology. This is in part due to the belief that the implementation and validation of such systems has become too complex and is therefore a risk not worth taking. It is important to remember, however, that not all software implementation projects are created equal. Each depends heavily on the business objectives, organizational complexity and resources of the organization undertaking the validation effort.

The Food and Drug Administration (FDA) rule relating to the use of Electronic Records and Electronic Signatures (21 CFR Part 11) requires the validation of computer systems used to maintain electronic records and apply electronic signatures when utilized to meet the requirements of GxP Predicate Rules. There are guidelines for compliance, but the FDA does not mandate the use of specific systems or validation processes. Also, although electronic records and electronic signatures are now acceptable / desirable under the right circumstances they are not a requirement of a validated GxP system. Part 11, like many FDA regulations, leaves room for interpretation. Regulatory interpretation combined with the Intensity Profile parameters discussed in this paper provide an understanding as to why the *effort* required to implement and validate a CMS will vary greatly from one organization to the next.

CMS Validation Implementation Intensity Profiles

INTENSITY PROFILES

There are many parameters that can be evaluated in creating Intensity Profiles. For the purpose of this paper, analysis is limited to the nine parameters that most affect the effort required to implement and validate a CMS for a particular organization.

Validation: The Validation Plan is the vehicle that brings all of the high level validation planning together. Every CMS validation project should have a Validation Plan to establish expectations, for this reason it is not included in the individual Intensity Profiles below. The Validation Plan documents the compliance needs of the organization and realistically describes the validation requirements necessary to satisfy those needs. A well-prepared Validation Plan lists the tasks and documents that need to be delivered, defines the expected content and format of documents, and assigns responsibility for task and document preparation and approval. Trimming the Validation Plan of unnecessary requirements and excess expectations will reduce the overall project intensity effort. This is more specific than simply cutting project scope. It implies a serious effort to curb individual enthusiasm to do more than is necessary to establish a validated system, particularly non-value adding exercises.

Scope: Defines how the CMS project effort addresses the *business* objectives of an organization.

The size and complexity of the CMS deployment plays a large role in establishing the cost, duration and intensity of the overall validation effort. Important factors to consider include the number of sites involved and the diversity of their organizational relationship, work practices, network and database architectures, the magnitude of enhancements to commercially available CMS packages (if any), and the need for customized reporting and special/complex configuration. An implementation for an international enterprise level CMS, for example, may require multiple Time Zone capability, a 'Staged' validation effort to bring each site online sequentially, leveraging of a pilot site's effort, and perhaps a parallel effort to rationalize diverse site workflows and SOP's into a global structure. A single site CMS, on the other hand, does not require any of these efforts.

Requirements: Define how the project effort is going to address the CMS user *expectations*.

The key to a successful validation project and CMS deployment is in the User Requirements Specification (URS) document. The URS should accurately describe the complete solution needed to meet project goals and satisfy user expectations. Each requirement included in the URS must be addressed/verified in every phase of planning, design, implementation and testing. Because excess requirements result in greater overall project effort, the care taken to develop a clear URS that truly represents the justifiable needs of the users and the objectives of the business will set the stage for an efficient, well run project.

Resources: Include the amount of funding and the number of personnel an organization can devote to a software implementation project.

A small organization will generally not have the resources to execute an intense validation effort. Personnel will be available on a limited basis, dividing time between project responsibilities and core functions within the organization. A small organization will have to establish a compromise between project size and outsourced resources.

CMS Validation Implementation Intensity Profiles

GAMP 4 Software Categorization: Describes how software and hardware components of a system may be analyzed and categorized. These software and hardware categories may then be used along with risk assessment and supplier assessment in the determination of a suitable validation strategy.

Most CMS implementations will fall into Category 4 for Configurable Software and/or Category 5 for Custom Software. A low intensity CMS implementation will probably be completely Cat 4, whereas a high intensity implementation will probably be Cat 4 with Cat 5 elements. Cat 5 software elements consume resources and complicate decision-making, resulting in a more intense validation effort.

Environments: Refers to the GxP or non-GxP, Network / Infrastructure /Hardware / Software / Procedure structure built to provide a specific set of conditions for the work processes intended to satisfy the Validation Plan.

Many projects provide the three customary implementation project environments of Development (Dev), Test (Test) and Production (Prod). If there is little or no development work to be performed, as may be the case in low intensity projects, then a separate Dev environment is not required. Test or Prod can be used in a development role until needed for other purposes. As project complexity increases, so do environment complexity needs. Multiple database instances in one or more of the basic environments are valuable when a complex project demands numerous parallel tracks to compress project duration.

Data Migration: Defines how information in the form of data is moved from a legacy data source or system into the new CMS.

Many issues should be considered before beginning Data Migration:

- How to maintain the validated status of data from an already-validated legacy system.
- How to migrate data from a non-validated legacy system into a validated CMS.
- How much data to verify after migration.

A Data Migration Plan may be developed to document data migration decisions that are tailored to the intensity level of a particular project and the condition of the legacy data.

Documentation: Whether paper or electronic, documents are the backbone of any validated CMS. The more complex the Validation Plan requirements are for documentation, the more intense the validation effort becomes. Where a small CMS deployment may satisfy its compliance needs with the standard documents provided by its software product vendor, a large operation will require numerous additional planning and execution documents. Each document has specific format and content requirements and extensive control and approval processes.

Vendor Assessment: A Vendor Audit is a valuable effort in reducing the cost and duration of any validation project. It provides the basis for establishing the acceptability of leveraging the software vendor's testing in the user's validation.

If this is of interest, the Vendor Audit should accomplish the verification of the vendor's testing, documentation and execution processes. Leveraging vendor testing can range from utilizing a portion of the vendor's test scripts in the user's OQ, to fully accepting the executed vendor testing for all non-critical requirements without repeating those tests in the user's environment.

CMS Validation Implementation Intensity Profiles

DETERMINING PROJECT INTENSITY

Using the parameters set forth above an organization can determine the validation intensity that is appropriate to satisfy its particular business and regulatory requirements. Below is a comparison of typical high, medium and low intensity efforts developed based on experience with many user implementation projects.

High Intensity CMS Validation: A high intensity project, often referred to as an Enterprise Level Project, results in a full-featured CMS requiring the deluxe validation package. Organizations requiring a high intensity implementation effort will probably not suffer from a lack of resources, but should be prepared for a long project justification and authorization process as well as tedious decision-making and document approval processes.

Key High Intensity Characteristics (see Table 1 on page 6 for a High Intensity Profile):

- Customization likely – adding to the validation burden.
- QA very outspoken and demanding.
- The needs of many individuals and organizations need to be addressed.
- Paperless is both an organizational need for compliance and efficiency as well a metrology need for improved records management.

Medium Intensity CMS Validation: It is important to note that the medium intensity project group has a broad spectrum of characteristics ranging from low to high intensity. While most validation projects fall somewhere in the medium intensity range, overall effort varies greatly from project to project.

Key Medium Intensity Characteristics (see Table 2 on page 7 for a Medium Intensity Profile):

- The Scope is less than the high intensity effort but the Requirements could be substantially the same.
- Commercially available CMS package customization unlikely – reducing the validation burden.
- QA participation is active but subdued allowing work to flow easily through decision, review and approval cycles.
- Paperless is both an organizational need for compliance and a metrology need for records management and efficiency, but the focus of efficiency shifts from a cost cutting desire to a limited resource reality.

Low Intensity CMS Validation: A low intensity CMS validation satisfies the requirements of a small-scale operation that does not have the resources or the need to implement a complex system. Projects in this category tend to move along easily as long as resources remain available. Although there are few formalities in a low intensity project, the organization must decide whether or not to go paperless. In a small organization paperless is more a way to force standardization and discipline than it is an effort to realize cost and efficiency savings. The organization must decide whether this is enough to justify the increased project effort. (*see Table 3 on page 8 for a Low Intensity Profile*).

CMS Validation Implementation Intensity Profiles

Table 1 – High Intensity CMS Validation Effort Profile

Parameter	High Intensity Profile - Likely Characteristics
Scope	Multiple Sites / Multi-National / Multiple Time Zones Mid to Large Size Oracle Platform Thin Client or Web based network infrastructure Interfaces to other Data Stores (CMMS, EMS, etc.) Enhancements to commercially available CMS package Substantial Custom Reports Paperless Calibrations and/or Metrology Processes Formal Project / Validation Management
Requirements	Audit Trail E-Records & E-Signatures Configurable Record Approval routings Electronic Change Control Mobile Work Interface to self documenting Field Calibrators Paperless Calibrations E-mail Reminders, Mass Update, Barcode Utilities Analytical or Complex Calibrations with Computations
GAMP 4 Category	Cat 4 (configurable) with Cat 5 (custom) elements
Resources	User Resource Teams – many individuals full-time Five or more Vendor Resources – many full-time Vendor Project Management
Environments	Dev, Test and Prod Multiple Databases
Data Migration	Several Legacy System Sources Validation of Conversion Program - possible Data Verification after Migration Complex Data Mapping and Augmentation
Documents	QA very involved and has Special Document Requirements Required use of Approved Document Templates Extensive Review and Approval Processes Multiple Site / Department Decision Making Formal Document Control Procedures
Vendor Assessment	Vendor Audit – face-to-face User Organization has Software Vendor Auditing Group

CMS Validation Implementation Intensity Profiles

Table 2 – Medium Intensity CMS Validation Effort Profile

Parameter	Medium Intensity Profile - Likely Characteristics
Scope	One, possibly several closely related Sites Small to Mid size SQL or Oracle Platform Thin Client or Web based network infrastructure - possible Interfaces to other Data Stores (CMMS, EMS, etc.) Enhancements to commercially available CMS package Substantial Custom Reports Paperless Calibrations and/or Metrology Processes Formal Project / Validation Management
Requirements	Audit Trail E-Records & E-Signatures Configurable Record Approval routings - possible Electronic Change Control - possible Paperless Calibrations - possible Mobile Work Interface to self documenting Field Calibrators Analytical Calibrations - possible Complex Calibrations and Computations - possible E-mail Reminders, Mass Update, Barcode Utilities
GAMP 4 Category	Cat 4 (configurable) with possible Cat 5 (custom) elements
Resources	Five or more User Resource – some full-time Five or more Vendor Resources – part-time and full-time Vendor Project Management
Environments	Dev, Test and Prod
Data Migration	One or More Legacy System Sources Data Verification after Migration
Documents	QA involved, but has no specific agenda Approved Template Format Requirements Moderate Review and Approval Procedures Single Department Decision Making
Vendor Assessment	Vendor Audit – face-to-face

CMS Validation Implementation Intensity Profiles

Table 3 – Low Intensity CMS Validation Effort Profile

Parameter	Low Intensity Profile - Likely Characteristics
Scope	One Site Access Database Platform or small SQL / Oracle Platform No Interfaces No Software Enhancements Minimal Project / Validation Management
Requirements	Audit Trail E-Records & E-Signatures Configurable Record Approval routings - possible Electronic Change Control - possible Paperless Calibrations - possible Mobile Work Interface to self documenting Field Calibrators E-mail Reminders, Mass Update, Barcode Utilities Complex Calibrations and Computations - possible
GAMP 4 Category	Cat 4 (configurable)
Resources	Less than five User Resources – all part-time Two or three Vendor Resources – all part-time
Environments	Dev – Possible Test – Possible Prod – Needed
Data Migration	Informal Single Legacy System Source
Documents	Minimal Format Requirements No Required Templates Minimal Review and Approval
Vendor Assessment	Vendor Audit – informal or via Questionnaire

CMS Validation Implementation Intensity Profiles

DISCUSSION

A high intensity effort to implement and validate a CMS is costly and time consuming. The motivation to undertake such a project comes in part from a changing regulatory environment and also from a desire to improve productivity and cut costs with a more efficient system. The project team seeks to justify a heavy implementation burden with the payback of improved compliance and/or efficiency.

A smaller organization should not be intimidated by the talk of increased regulatory demands and costly implementation projects. It is clear from the Intensity Profiles that not all implementations are created equal even though each satisfies a particular organization's compliance needs. The discussion behind a CMS implementation of medium to low intensity should shift away from regulatory fears and cost cutting desires to the opportunity for enhanced productivity and maximized use of limited resources.

A carefully tailored Validation Plan that adequately addresses business and regulatory needs allows any organization, large or small, to take advantage of the improved productivity that Calibration Management Systems have to offer. The belief that *all* implementation and validation projects have to be overly complex and costly is misguided.

CMS Validation Implementation Intensity Profiles

ABOUT PRIME TECHNOLOGIES, INC.

Prime Technologies is committed to the development of quality compliant software. ProCalV5 represents the latest in our ongoing quest to provide the ultimate in sophisticated calibration management solutions. All ProCalV5 products are validated by our quality staff before release and successfully validated by our customers under intense internal Quality and Regulatory scrutiny. ProCalV5 systems are installed in many top pharmaceutical and ISO certified organizations. Our software development and testing procedures have been fully audited and approved by numerous fortune 100 companies. A full complement of additional staffing is available to assist with all aspects of project implementation needs.

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Frank Gellner is the Quality Assurance Manager at Instrumentation Technical Services and Prime Technologies, Inc. With over thirty years of leadership experience in Instrumentation technology, Control System design and Project execution with DuPont, Frank has a vast and diverse perspective on instrumentation and calibration management. His current role with Prime Technologies, producers of ProCalV5 Calibration Management System (CMS), is deeply involved with many of the world's top 10 Pharmaceutical Companies in the planning, compliance and successful project management of their Enterprise Level CMS Implementation Projects. Frank has played a leadership role in many international projects involving global and enterprise level Control System and CMS Solutions. Frank is also the author of other papers on validation implementations and a full set of calibration procedures now available on the Instrumentation Technical Services web-site <http://www.calservice.net/>.