

Proven Paperless Performance With ProCalV5

A Prime Technologies, Inc. White Paper

ProCalV5
calibration management software

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1 Purpose

This paper will develop a definition of a Truly Paperless Calibration environment, discuss how it can be justified and show that ProCalV5, 'best of breed' CCMS coupled with a 'best of breed' CMMS is the only solution to demonstrate Proven Paperless Performance and will be the only solution for the foreseeable future.

2 Overview

Truly Paperless Calibration is more than the mere ability to capture calibration event results directly into an electronic record without intervening paper 'original' documentation. That's the easy part, the part that any calibration management database application built for the pharmaceutical industry had better do and do well.

Truly Paperless Calibration must deal with each and every type of calibrated device with equal ease from the straight forward bench calibration of a simple process transmitter to an in-situ calibration of the same device mounted in the ductwork high in an operating area, to a lab analyzer requiring complex computations on the captured data.

Truly Paperless Calibration goes beyond the Cal Event to the entire paperless record management process including change management and out of compliance report processing.

In order to justify the expense and effort of creating, validating and supporting the Truly Paperless Environment, the result must provide some sort of Business advantage such as assured compliance or improved calibration execution efficiency.

A calibration add-on module to a CMMS does not yet have the pedigree to become a Truly Paperless Calibration environment. Even the most ambitious Customer driven effort can't make a mongrel into a Westminster champion. It takes the 'best of breed' CCMS and careful, loving grooming to assemble the pieces of a Truly Paperless Calibration environment and produce a winner.

2.1 Differentiators of a Truly Paperless Calibration Environment

Paperless Change Control

At any point in time a metrology organization may have 25% or more of its master records involved in change. If records under change are not managed properly in a Change Control environment, Technicians would be forced to perform calibrations due, utilizing some master records with changes pending completion, review and approval. This would create a systemic out of compliance work environment.

Paperless Record Review/Approval

An efficient electronic approval process is essential to a paperless solution, cutting processing time from weeks to days and assuring paper records don't get lost on someone's desk for months, providing both efficiency and compliance improvements.

Paperless Mobile Capability

ProCalV5 utilizes Mobile Technology (see Mobile Technology Guidance document) to allow a Technician to be 50 to 100% more efficient than a typical paper system, while producing Cal Event Records free of transcription errors from original paper records to electronic, or interpretation errors reading the original paper records.

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Paperless Self-Documenting Calibrator Interface

Use of Self-Documenting Calibrators allows for efficient error free data collection from the single most versatile group of Test Standards available to Metrology organizations. ProCalV5 is the Only CCMS or CMMS to utilize the FCINTF Field Calibrator interface protocol developed by the Southwest Research Institute to communicate with Fluke, Druck, Beta, Transmation, Meriam and Beamex Self-Documenting Calibrators.

Paperless Calibration of Lab Analyzers and other non-typical Devices

There are many devices requiring calibration in some segments of Global Organizations that do not fit into the 'typical' direct linear / square root / $f(x)$ input to output relationships supported by even the most popular Calibration Management Solutions.

- HEPA Filter Calibration and Maintenance on a simple basis involves multiple Down Air Flow measurements over a grid representing the area of the filter. In this simple HEPA Filter calibration the procedures and calculations are still managed on paper. The complete HEPA Filter Calibration and Maintenance program involves:
 - Airborne Particle Count
 - Aerosol Challenge (Leak Test) and Repair Tracking
 - Enclosure Pressurization
 - Down flow Velocity
 - Inflow Velocity
 - Noise Level
 - Lighting Intensity
 - Airflow Velocity
 - Air Changes per Hour (w/Room Dimensions)
- Lab Analyzers require post data collection computation. HPLC's involve several layers of calibration on various components, often requiring Peak Picking, Linearity and Reproducibility among others. Other Analytical methods are just very complex mechanical / chemical procedures involving solution prep time, agitation, property readings and analysis calculations that all must be documented.
- Even simple devices are increasingly being subjected to data analysis after the calibration event data is captured such as Hysteresis and Uncertainty.
- Some devices are just too simple to fit the 'typical' input to output relationship. Switches require a simple on/off, relays a simple pass/fail. Both can be painfully difficult for some applications.

3 Definitions

3.1 Proven

1 archaic: to learn or find out by experience 2a: to test the truth, VALIDITY, or GENUINENESS of (the exception ~s the rule) b: to test the worth or quality of, specif: to compare against a standard 3a: to establish the existence, truth or validity of (they proved their appeal at the box office) b: to demonstrate as having a particular quality or worth ... 4: to show (oneself) to be worthy or capable ~ vi: to turn out esp. after trial or test (the new drug proved effective)

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3.2 Performance

1a: the execution of an action b: something accomplished: DEED, FEAT 2: the fulfillment of a claim, promise, or request: IMPLEMENTATION 4a: the ability to perform: EFFICIENCY b: the manner in which a mechanism performs 5 the manner of reacting to stimuli: BEHAVIOR 6: linguistic behavior – compare COMPETENCE

Webster's New Collegiate Dictionary, Copyright © 1977 by G. & C. Merriam Co.

3.3 Paperless

Not requiring paper because of the use of computers and other electronic media to record, convey, and store information: *a paperless office*

The American Heritage® Dictionary of the English Language, Fourth Edition, Copyright © 2000 by Houghton Mifflin Company.

4 A Truly Paperless Calibration Solution

4.1 Paperless Calibrations

Paperless Calibrations are the meat and potatoes of the Paperless Calibration Solution and even so it surprising to note how few Calibration Management products are really good at it. How few can do all devices and how few can document Calibrations Events taking place in any location. ProCalV5 utilizes Test Type Package Technology to deliver functionality allowing any device, no matter how complex or routine the procedure, to calibrated paperless. ProCalV5 utilizes Mobil Technology to allow the Technician to perform Calibration Events paperless anywhere a PC device can be carried.

4.1.1 Calibration Event Performance demands effective implementation of:

Scheduling: by Date, Week, Month, Quarterly, Semi-Annually, Annually, Bi-Annually and everything in-between or longer. Ability to role the next Cal Date forward (automatically schedule the next Cal Event based on selected rules)

Data: units, ranges, separate As Found / As Left readings, limits (distinguish between Control and Specification Tolerances).

Test Points: (unlimited points, groups) ability to predefine each point consistently or independently, ability to refine each during a Cal Event, automatically calculate and re-calculate Cal, System Cal, Loop Cal, allow Multiple Cal Types for each device, Demand Cal, Preventative Maintenance Event,

Test Standards: Instruments or devices used to compare the accuracy of a device under test to a recognized standard. A Test Standard should be NIST traceable or other appropriate certification. The Calibration Management Solution should manage Test Instrument Master Records and Certifications, manage Test Standard availability for use for specific devices under test and allow the Calibration Event Record to document Test Standards utilized.

Associations: Devices grouped by Organization, Location, Equipment, System, etc.

Relationships: Allow Parent / Child Systems, Loops, Systems, within Systems, Device / Test Standard

Device Types: Instruments, Test Standards, Lab Devices and Analyzers, (with data reporting based on complex and unique Parent / Child relationships)

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- ProCalV5 has already developed Test Type Packages to manage many unique devices such as Timers, Stopwatches, Switches, Relays, HPLC's, Dissolution, Photometric and Table Press Analysis.
- Prime Technologies has the technology already built into ProCalV5 to handle many more challenging simple to complex procedures in a Truly Paperless Calibration Environment and we are building new and exciting solutions now utilizing this technology for our Customers right NOW.

Calculations: ability to process captured Cal Event Data using simple logical rules or complex computations to yield reportable results not just captured data:

- Logical Processing – Peak Picking, Switch & Relay Pass/Fail, etc.
- Computation Processing – Linearity, Hysteresis, Reproducibility, Area Under Curve, Uncertainty, etc.
- HEPA Filter Multiple Airflow Monitoring / Calibration – ProCalV5 has delivered a HEPA Filter Test Type Package solution for this simple form of HEPA Filter management.
- HEPA Filter Calibration and Maintenance – Prime Technologies is actively involved in developing a complete Paperless HEPA Filter Calibration and Maintenance Program solution that will manage this intense aspect of drug manufacture environment protection.

4.2 Paperless Compliance

4.2.1 Paperless Change Control Record Review/Approval

ProCalV5 is now has second generation Paperless Change Control. This means that every master record involved with changes pending completion, review and/or approval is managed in a Change Control segment of the environment and kept segregated from the approved for production records. Technicians will always have the last approved version of each record available to them for each and every calibration event. Only when a Change Control record becomes approved, does it automatically replace the now obsolete current production version. The audit trail of the Change Control version that been kept independently from approved production version audit trail is merged into the production version audit trail maintaining a complete history of the record, its modifications, reviews and approvals.

Without Paperless Change Control, the Metrology organization in order to remain in Compliance, would either have to keep Change Control a paper system, external from the Calibration Management Solution or mark all records involved in change of any sort with a status of 'Unavailable for Calibration'. Either choice creates terrible inefficiencies and generates a whole other set of Compliance issues:

- Paper Change Control continues to require that paper documents be kept and circulated for review / approval, some are bound to become lost or stalled on someone's desk. Important changes to rectify Out of Compliance events may never get accomplished. Documentation for those lost or misplaced records would not be available for audits.
- Marking electronic records as 'Unavailable for Calibration' until the changes are finally approved inevitably results in calibrations coming due that cannot be performed on schedule. The device must be taken out of service until the record is approved, a calibration performed and in some cases an Out of Tolerance report completed.

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As you can see, a Computerized Calibration Management Solution without Truly Paperless Change Control is Not really paperless and leads to several types of Compliance issues, any one of which could eat away at the Compliance Integrity of the system. ProCalV5 is the only major CCMS or CMMS for that matter that we know of, with Paperless Change Control and that is unlikely to change anytime in the near future.

4.2.2 Paperless Out of Compliance

A Truly Paperless Calibration Environment would not be complete without a way to manage Out of Compliance events of missed or late Calibrations and Failed or Found Out of Tolerance devices. A paperless solution to this inevitable outcome for some calibrations is essential to a smooth running Calibration Management System. A paperless solution ensures Out of Compliance events get documented and investigated in a timely manner, so that the device can be returned to service or repaired or replaced quickly, limiting exposure to downtime and risk of non-conformance. ProCalV5 provides Electronic Out of Compliance record management and Approval routing to eliminate lost records, speed up processing and assure that each event is processed in a way that can be demonstrated during Audits.

Key functional capabilities involved with Out of Compliance management include:

- Calibration Schedule Management**

- Test Standards Management**

- Reverse Traceability Reporting**

- Metrics Reporting**

4.2.3 Paperless Record Review / Approval

The Review / Approval process for Metrology Master Records and Calibration Event Records in a large Organization can be a constant source of frustration, inefficiency and compliance headaches due to tardy signing response and the occasional missing or lost paper Record. A Truly Paperless Calibration Solution manages all Record Review / Approval processes electronically. ProCalV5 provides both in-application and e-mail reminders to next inline signatories. Each Record in the Review / Approval process is constantly monitored for progress against the predefined Approval Policy in effect for that group of Records, automatically and immediately putting completed approved Records into Production use. The ProCalV5 E-mail Reminder Utility can cut the average approval cycle from weeks / months to days. ProCalV5 Approval Policies also ensure that the right groups in the Organization are part of the process, heightening the level of awareness and compliance. Faster Review / Approval processing not only means shorter processing cycle times that enhance the overall compliance health of the system, but allow shorter response efforts for each individual signatory, building buy-in for the process and the system.

There is left the small matter that the opposite also has its impact on the Organization. Longer paper record cycle times and less efficient paper record signing practices result in probable situations where Technicians are asked to perform calibrations for devices whose Master Record is currently unapproved. This could be a serious Out of Compliance event for the Organization. It could be compounded if an Auditor drills down and finds many unapproved Master Records, some that have been in that state for a long time and some that the paperwork to approve them has been lost or cannot easily be retrieved.

4.3 Paperless Mobile Technology

“A Mobile Database is an image of the Prod DB. When it is populated with appropriate Production configuration, data and security parameters, it can function independently

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(disconnected) from the Prod DB for a finite period in a compliant manner based upon the Prod DB compliancy.” This definition is taken from “**Mobile Technology - A Generic Users Guide**” and implies that the Mobile Environment must meet the same Compliance criteria as the Production Environment.

Prime Technologies has taken great effort to perfect its use of Mobile Technology and ensure that its Mobile Workstations perform in compliant manner suitable for the most stringent FDA Regulated Organizations.

4.4 Paperless Use of Self Documenting Calibrators

Compliant use of this technology is highly dependent upon the manufacturer of the Self Documenting Calibrator and the care they have taken in complying with relevant aspects of “21 CFR Part 11, Electronic Records and Electronic Signatures” and the interpretation taken by the Quality and Compliance groups of the responsible for the compliance of the Paperless Calibration Environment.

ProCalV5 provides a compliant interface to all of the leading manufacturer’s offerings of Self-Documenting Calibrators when used in a Transient Data mode as defined by Section 4.5 – Transient Data from the “**Good Practice and Compliance for Electronic Records and Signatures**.”

5 Performance

5.1 Paperless Efficiency

Only Truly Paperless Calibration Solution can handle every calibrated device no matter where it is located, no matter how complicated the procedure and only a Truly Paperless Calibration Solution can handle the complex and routine calibrations in a way designed to make the Technician’s job flow naturally. Only a Truly Paperless Calibration Solution can deliver efficiency gains of 50% improvement over Conventional Paper Calibration Management Systems.

Example:

A large Global Pharmaceutical Company can easily have 100,000 to 500,000 calibration events per year. Well use 100,000 for this example. A typical Conventional Paper Calibration Management System Technician’s efficiency is about 5 or 6 devices per day. Well use 6. That’s over 16,500 workdays per year or over 73 Technicians working full time 225 days a year. With a 50% improvement from a Truly Paperless Calibration Solution, each Technician can perform 9 calibration events per day or a reduction to just under 50 Technicians. Of course the actual reduction will be based on many other factors, such as distribution and type of devices, distribution of Technicians and typical ‘other’ tasks that the Technicians perform.

The example above does not take into account the savings in efficiency that will be gained from Truly Paperless Change and Compliance Management, or the possible device frequency adjustments that can be derived from improved Calibration Metrics, a side benefit of a Truly Paperless Calibration Environment.

5.2 Prime Technology’s ability to deliver Advanced Calibration Enhancements

Although Prime Technologies’ ability to deliver advanced enhancements to our products isn’t an important issue in deciding to make ProCalV5 your Truly Paperless Solution since we already have a Proven Solution, but in general and especially with CMMS Vendor’s who have a large infrastructure, their performance in producing the complex enhancements necessary to complete a Truly Paperless Calibration Solution should be investigated carefully. Performance in this arena is

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essential to the sustained development effort necessary to bridge the gap between routine calibrations and a Truly Paperless Calibration Environment that can deliver improved Technician efficiency vs. one that can actually set you back.

Just for Record, in 2004, Prime Technologies delivered ProCalV5.3 that included Truly Paperless Change Control and Truly Paperless Approval Policies in addition to other enhancements. ProCalV5.3 was delivered along with a ProCalV5 / DataStream 7I Interface On Schedule and On Budget. In 2005, Prime Technologies delivered ProCalV5.4 that included Truly Paperless Compliance Reporting and over fifteen Test Type Packages that provide the functionality for Truly Paperless Lab Calibrations including HPLC's. ProCalV5.4 was delivered On Schedule and On Budget. Not only are these functionality enhancements critical to the success of a Truly Paperless Calibration Solution and that they are unmatched in the CCMS or CMMS industries, but Prime Technologies' Enhancement Delivery Performance is also unmatched in these industries.

Prime Technologies has several types of Product Releases:

- a. Major Releases driven internally to respond to market demands for a step change in Product design
- b. Major Releases driven by Customers to add Enhancements, both simple and complex, to help meet specific Project User Requirements
- c. Minor Releases to add small Enhancements and fix bugs

All ProCal Product Releases are designed to be backward compatible to all previous versions of ProCal, even Releases driven by Customer Requirements are designed to compliment previous Releases and how previous Customers use ProCal. Producing and delivering Major Releases that both satisfy a specific Customer and is compatible with all pervious Customers is a fine line that Prime Technologies does very well and is rare in the industry. This is a valuable asset when selecting a Software Vendor to Partner with, in undertaking a long-term president setting, culture defining endeavor such as Truly Paperless Calibration.

5.3 ProCal CCMS / DataStream CMMS Integrated Performance

Prime Technologies has proved that a CCMS / CMMS Integration is not only doable but quite simple and reliable. This allows the Metrology organization to have a 'Best of Breed' CCMS with all the benefits of working with a Solution and Vendor dedicated to Metrology with a focus on Compliance. While the larger Research / Manufacturing organization can have its 'Best of Breed' CMMS, delivering a powerful Equipment / Time / Resource / Task & Inventory Scheduling tool set focused on Asset Management.

6 Proven

6.1 ProCalV5 – The Only Proven Truly Paperless Solution

ProCalV5 enjoys the distinction of being the Only CCMS or CMMS to be implemented in a Truly Paperless Environment for any major Pharmaceutical Organization, rigorously and fully validated. Delivering a proven 50% Technician productivity improvement on a sustained basis and 100% improvement when ITS Technicians are utilized. As Tom von Gunden, Editor in Chief of Pharmaceutical Online reported in that journal's 8/12/2005 **Prepare To Go Paperless** article:

The "paperless calibration-management initiative at Schering-Plough reveals more than just an FDA-supported willingness to rethink records-keeping approaches. It also shows the company proactively seeking efficiency gains, as well as increased assurances of process control. As I learned in a recent conversation with Schering, the company is

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already achieving reductions in the space, time and labor commonly associated with maintaining calibration records."

This implementation delivered:

- Paperless Environment at 3 Sites Globally
- Rigorously Validated CCMS
- On Schedule and On Budget
- Exceeded Productivity expectations
- Met High Profile, High Stakes Compliance expectations On Schedule
- Complex ProCal Enhancements of Change Control and Approval Policies as well as many secondary Enhancements, On Schedule and On Budget
- ProCalV5 CCMS / DataStream CMMS Interface On Schedule and below Budget

All this delivered in less than one year from Project Authorization to successful CCMS Production Deployment and its been in production operation everyday since, saving money.

CMMS software vendors have been talking and promising a Paperless Calibration Module for years. Some have been involved with implementations lasting years. They are not talking about True Paperless. They haven't implemented True Paperless. They haven't delivered Calibration Technician Productivity improvements and they aren't close.

We at Prime Technologies and those at Schering Plough know what it takes to go Truly Paperless. It took hard work by both parties and a Vendor / Product that knows calibration, has been evolved over many years and many successful stages, has been repeatedly tested and refined to produce a bug free environment.

If you want a Calibration Management Solution with the bare minimum calibration functionality, perhaps a CMMS offering can be encouraged to play this role, perhaps not, but a CMMS is not in a position to deliver a Truly Paperless Solution for 3 to 5 years and only if everyone involved stays focused and resources and financial support is maintained and increased. ProCalV5 and our Customers are there NOW with Proven Performance and 3 to 5 years will still be 3 to 5 years ahead of the CMMS Calibration Solution.

One of our Top 10 Pharmaceutical Customers actually investigated using a 'Best of Breed' CMMS for Calibration Management. Their due diligence solution selection process decided upon ProCalV5, the 'Best of Breed' CCMS coupled with DataStream, a 'Best of Breed' CMMS. That was over two years ago and they haven't regretted that decision since.

Two major Companies, one Biotech and one Pharmaceutical who stopped implementation of a CCMS to explore and develop a S.A.P. Calibration Solution have dropped that approach and are back to a CCMS with Interface to S.A.P. Solution. One of those Companies is in their selection process and the other is has already selected and purchased ProCalV5 with S.A.P. Interface capability.

Another Top 10 Pharmaceutical Company has just completed implementation of a major CMMS (DataStream) with Calibration functionality and discovered a 10% DROP in Technician Efficiency over their previous CCMS (not ProCalV5).

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8 About Prime Technologies, Inc.

Prime Technologies is committed to the development of quality compliant software. ProCalV5 systems are installed in many of the top pharmaceutical and ISO certified organizations. Our software development and testing procedures have been fully audited and approved by numerous fortune 100 companies.

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. A full complement of additional staffing is available to assist you with all aspects of your project implementation needs.

9 About The Author

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.