

Defining a Truly Paperless Metrology Environment

A Prime Technologies, Inc. Guidance Document
February 2006

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Rev 1, Date: 15 Feb 2006

'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 itself to the entire paperless record management process including change management and out of compliance report processing.

The process of defining 'Truly Paperless Calibration' for a particular Organization will be tailored to the Organization's Business Objectives and Metrology Requirements which should be documented in an User Requirements Specification. The steps described below are meant to provide a path to a comprehensive paperless environment for Calibration and Metrology tasks. Not all the steps are necessary for every Organization. The numbering of the steps is loosely based on a typical Metrology process workflow and are not intended to be chronological.

This definition process assumes that the environment intended to support the 'Truly Paperless Calibration' solution is suitable for the industry and type of regulation to which it will be governed. The environment for the example described in the below is "21 CFR Part 11, Electronic Records and Electronic Signatures" compliant. It does not need to be. The User Access Security needed is dependent upon the industry environment regulations to maintain.

Remember ProCalV5 is the *only* solution that provides all the functionality you will need to build a 'Truly Paperless Calibration' environment to your objectives and specifications.

Step 1: Paperless Master Records

Record Types: Master Records contain the item description, identification, association and calibration procedure information for devices requiring calibration or maintenance. The Calibration Management Solution should manage Master Records for Equipment, Instruments, Loops, Systems and Test Standards

Data: The Calibration Management Solution should manage units, ranges, separate As Found / As Left readings, limits (distinguish between Control and Specification Tolerances).

Test Points: The Calibration Management Solution should manage unlimited Test Points, in unlimited Groupings, providing the ability to predefine each point in the Master Record or to refine any point during a Cal Event. It should perform calculations automatically

Associations: The Calibration Management Solution should manage Devices grouped by Organization, Location, Equipment, System, etc.

Relationships: The Calibration Management Solution should allow Parent / Child Systems, Loops, Systems, within Systems, Device / Test Standard relationships

Device Types: The Calibration Management Solution should manage multiple Device Types for Instruments, Test Standards, Lab Devices and Analyzers, (allowing data reporting based on complex and unique Parent / Child relationships)

Calibration Types: The Calibration Management Solution should manage Multiple Cal Types for each device: Scheduled Cal, Demand Cal, Preventative Maintenance Event, etc.

Step 2: Paperless Scheduling

Scheduling: The Calibration Management Solution should manage the Calibration Schedule by; Date, Week, Month, Quarterly, Semi-Annually, Annually, Bi-Annually and everything in-between or longer. It should provide the ability to role the next Cal Date forward (automatically schedule the next Cal Event based on selected rules).

Step 3: Paperless Test Standard Management

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 have 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.

Self-Documenting Calibrators: are a very special group of Test Standards. Each Vendor's offering has the ability to be used for the majority of the most common calibratable devices. The unique capabilities that allow these calibrators to complete each cal event in a paperless manner include:

- They accept downloaded task assignments.
- They automatically collect and store transient data for each cal event performed against the task assignment.
- They allow for electronic upload of the collected data to the Calibration Management System's Production Database.

Only ProCalV5 has the ability to communicate (download task assignments and upload collected data) from all the major Self-Documenting Calibrator Vendors.

Step 4: Perform Paperless Calibrations

Calculations: The Calibration Management Solution should have the ability to process captured Cal Event Data using simple logical rules or complex computations to yield reportable results:

- Logical Processing – Peak Picking, Switch & Relay Pass/Fail, etc.
- Computation Processing – Linearity, Hysteresis, Reproducibility, Area Under Curve, Uncertainty, etc.
- Analytical Device Calibrations and Computations – HPLC, GC, Dissolution-Chemistry, etc.
- HEPA Filter Calibration and Maintenance

Step 5: Maintain Paperless Record Compliancy

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 (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 a compliant manner suitable for the most stringent FDA Regulated Organizations. ProCalV5 Mobile Workstations meet “21 CFR Part 11, Electronic Records and Electronic Signatures” requirements just as rigorously as workstations connected directly to the Production Database. Your compliant environment extends to every calibratable device in your Metrology database.

Step 6: Paperless Anytime, Anywhere

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 based system. Use of ProCalV5 Mobile Workstations means Cal Event Data can be documented directly into Electronic Records without ever being written on paper. That 'original paper record' is eliminated! With it goes the need to maintain it as an 'original record', eliminating the need for storing it, eliminating the transcription errors common when entering data from original paper records to electronic, eliminating the interpretation errors when reading the original hand written paper records and eliminating the possibility of misplacing the original.

Gains of 50 to 100% in efficiency are real when utilizing Mobile Technology over conventional paper based systems. Technicians are provided with all the "paperwork" that they need, electronically, to complete each cal event including Master Records, Test Standard Records, Cal Procedures, Cal History and Cal Event Forms. All calculations are performed automatically including Out of Tolerance determination. Pass / Fail decisions are presented for Technician acknowledgement. Completed records are managed by the system, the Technician does not need to keep stacks of incomplete and complete paper records organized while working a hostile location. The time spent looking for one mis-filed document a day could account for an additional cal event accomplished.

The paperless calibration system also keeps track of each Technician's progress through the days assignment by time stamping each record save event. This provides an invaluable management tool for troubleshooting workflow bottlenecks. This alone can account for the entire 50 to 100% gain in efficiency. Paperless is Powerful!

Step 7: Paperless Field Calibrator Transfer

Paperless Self-Documenting Calibrator Interface

Self-Documenting Calibrators connect directly to devices being calibrated and automatically collect calibration data during the calibration event. The data is stored in a transient state waiting to be uploaded to Calibration Management Database. Use of Self-Documenting Calibrators allows for automatic data collection. Interfacing them to a CMS Production Database provides efficient error free data transfer from the single most versatile group of Test Standards available to Metrology organizations. The ProCalV5 Field Calibrator Utility provides a paperless, compliant interface to the vast world of transient calibration data automatically collected by Self-Documenting Calibrators.

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.

Step 8: Paperless for every Calibratable Device Type

Paperless Calibration of Lab Analyzers and other non-typical Devices

There are many devices requiring calibration 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.

ProCal Test Type Packages (TTP) allow you to break through the 'not supported' barrier. TTP provide the capability to establish unusual and/or complex relationships and computations.

- HEPA Filter Calibration and Maintenance on a simple basis involves multiple Down Air Flow measurements over a grid representing the area of the filter.

- A complete HEPA Filter Calibration and Maintenance program may involve:
 - Airborne Particle Count
 - Aerosol Challenge (Leak Test) and Repair Tracking
 - Enclosure Pressurization
 - Downflow 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.

Step 9: Paperless Out of Compliance

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 is essential for the inevitable Out of Compliance outcome for some calibrations, to complete a smooth running Calibration Management System. A paperless solution ensures that Out of Compliance events get documented and investigated in a timely manner. 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 – missing a calibration due date is as costly an event in a regulated environment as a Failed calibration.

Test Standards Management – use of a Test Standard that is out of cal or not appropriate for the task is eliminated.

Reverse Traceability Reporting – when a Test Standard is found out of cal, pin pointing each device it was used to calibrate is quick, automatic and painless. No more tedious paper record searches that leave you at risk of missing one or more use events.

Metrics Reporting – create any report needed to track your critical metrics or to uncover efficiency bottlenecks, the data is there just waiting to be mined.

Step 10: Paperless Metrology – Change Control

Paperless Change Control

ProCalV5 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 as 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.

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.

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 creates a systemic Out of Compliance work environment.

Step 11: Paperless Metrology – Review / Approval

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.

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 internal application and external 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.

Step 12: Paperless E-Mail Reminders and Notifications

Paperless Review / Approval Signatory Notifications

An efficient electronic approval process is essential to a paperless solution. The ProCalV5 E-mail Reminder Utility can cut the average approval cycle from weeks / months to days.

Paperless Reminders of Task Due Responsibilities

Efficient scheduling of all calibrations helps to reduce Out of Compliance events resulting from missed calibrations, but is only half the solution. The ProCalV5 E-mail Reminder Utility delivers the schedule of current task due lists to each responsible person in the system, driving missed events to a minimum.

Paperless Notifications of Calibration Event Results (Pass / Fail / Out of Compliance)

Once the cal event is complete, the ProCalV5 E-mail Reminder Utility supplies the mechanism to get the electronic “paperwork” completed quickly and accurately. Everyone who needs to know gets notified immediately.

Step 13: Paperless Training Records

Paperless Training Records

Course descriptions, qualified Trainers, course availability, required participation and individual training completion records are the basic components needed to establish Training Records for individuals involved in the Metrology and Calibration processes. Having these Training Records available to the CMS is a paperless bonus that can help insure the quality and integrity of each calibration performed. The Training Records can be maintained within the CMS as is the case with ProCalV5 or can be in a separate Training System interfaced to the CMS.

Paperless Qualification

Paperless Qualification begins with the ability to document the correlation between the training required to become qualified for each type of calibration procedure and the completed training of each individual.

As a Technician completes each training activity the Training System automatically determines and updates their qualification repertoire.

Finally, the Paperless Qualification process is completed with ability to select and assign only Technicians who have been qualified by the Training System to each calibration task.

Step 14: Paperless Procedures

Paperless Access to Procedures

Procedures are the backbone of any compliant Metrology / Calibration Management System. Paperless accessibility to the correct procedure, current version, at the point in the calibration process when they are needed is a huge advantage toward insuring the quality and integrity of each calibration performed. Like Training Records, Calibration Procedures and other pertinent information can be maintained within the CMS as is the case with ProCalV5 or they can be maintained in a separate Content Management System interfaced to the CMS.

The key is the ability to establish a correlation and a link within the Calibration Master Records to the correct documents and files for each specific Item. This correlation must be passed along to each Calibration instance, making it possible for the Technician to draw upon it, paperlessly, when needed during the calibration event.

Step 15: Paperless Data Interfaces

Paperless Interfaces to Other Applications

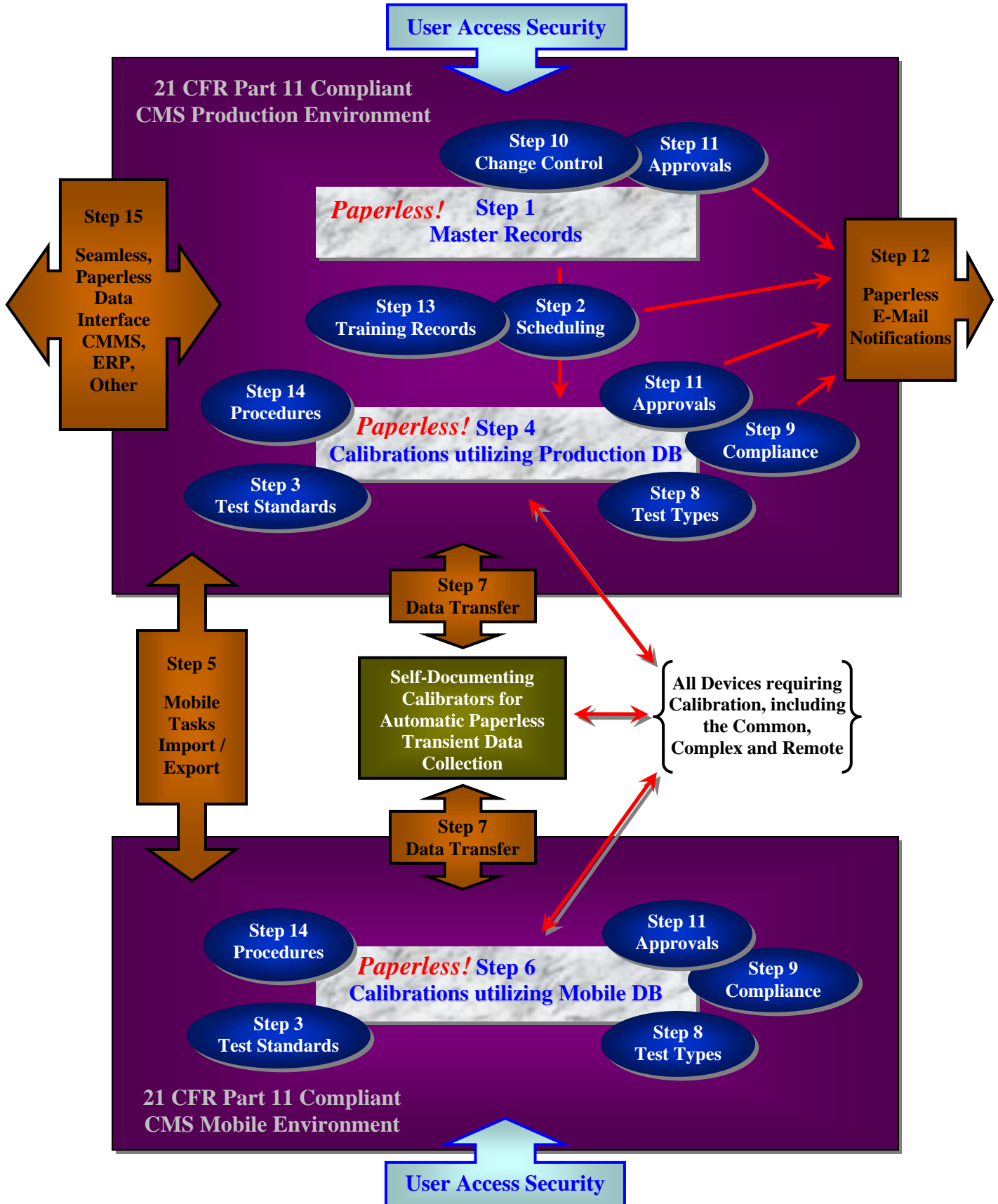
The 'Truly Paperless Calibration' solution living in the corporate world needs information from other systems within the Organization for Asset Management, User Authentication, and Integrated Real Time Resource Management, Technician Qualification, Content (Document) Management and Scheduling. No less important are the needs of other systems for access to the data maintained within the Calibration Management System for Integrated Maintenance programs, On-line Work Order Management, Resource Management, Integrated Metrics Reporting and Calibration Task Closeout. This can all happen seamlessly and paperlessly with ProCalV5 integration tools.

Last Step: Reap the Rewards of Paperless Efficiency / Productivity

- Dramatic Technician Efficiency / Productivity Improvements** – 50 to 100%
- Dramatic Reduction in Record Approval Cycle Time** – Months / Weeks to Days
- Managed Record Change Control** – Zero Records Unavailable for Calibrations
- Reduce Number of Events that result in Out of Compliance** – Missed Calibrations
- Every Calibratable Device can be Accomplished with All Paperless Advantages** –
Mobile Technology, Test Type Packages and Self-Documenting Calibrators
- Seamless Transfer of Metrology Data to Other Management Applications** – CMMS,
ERP, Asset Management, Others

'Truly Paperless Calibration' Workflow Diagram

15Feb 2006



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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.

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. 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/>.