

# Leveraging Vendor Testing within User Validations

*A Prime Technologies, Inc. Guidance Document*  
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## 1 Purpose

This Guidance document is intended to give the potential User of Configurable Software Products supplied by Prime Technologies, Inc. (PTI), a recommended course for reducing their internal validation testing burden by leveraging PTI Product Validation testing.

## 2 Definitions

**2.1 Intended Use:** Testing that is specifically developed to test a User requirement in a way that represents as nearly as possible the conditions that will be expected during actual operation in the User's own Production Environment

**2.2 Configurable Software Packages:** (from GAMP 4, Appendix M4) GAMP 4 Category 4: Configurable software packages provide standard interfaces and functions that enable configuration of user specific business or manufacturing processes. Software packages and the platform should be well known and mature. A Supplier Audit is usually required to confirm that the software package has been developed using appropriate quality systems and that application development and support organizations are robust and competent.

**2.3 Product Validation:** Generic testing, as opposed to Intended Use testing, performed in the Vendor's Environment to verify the operation and performance of intended Product Functionality.

## 3 Overview

User Companies (Users) can reduce their testing burden for implementing and validating a Configurable Software Package by leveraging testing developed and executed by the Software Vendor (Vendor). This can take several forms:

- **Use Vendor's Unexecuted Test documentation directly for certain User Validation Test documentation:** The User can obtain Vendor unexecuted test scripts and incorporate selected sections directly into the User's own test protocol. This is a suggested approach for either GxP non-Critical requirements or that do not need 'intended use' testing. This approach is straightforward and does not impose any special Vendor assessment burden on the User. It can be a very effective means for reducing the User's test script development effort.
- **Use Vendor's Unexecuted Test documentation as a basis for any User Validation Test documentation:** The User can obtain Vendor unexecuted test scripts and use them as a basis for creating their own test protocols and scripts. This approach can be used for any type of requirement, GxP Critical or non-Critical since the User would add whatever additional information is needed during the editing process. This approach is also straightforward and does not impose any special Vendor assessment burden on the User. It also affords the least opportunity for reducing the User's testing effort.
- **Replace certain User Validation Testing with Reference to Vendor's Executed Testing:** The User can, with proper due diligence of the Vendor's processes, accept the Vendor's executed testing as suitable to replace selected portions for the User's validation testing burden. This is a suggested

approach for either GxP non-Critical requirements or requirements that do not need 'intended use' testing. This approach has the greatest potential to reduce the User's testing effort (cost and resources) and places the highest burden on the User to assess the processes of the Vendor. This approach will be discussed in the remainder of this Guidance document.

## 4 Replacing certain User Validation Testing with Reference to Vendor's Executed Testing

Prime Technologies, Inc., makes the following recommendations for the User who desires to reference PTI Product Validation documents and records within their Validation as documentation of successful satisfaction of certain testing requirements without the User having to execute those tests:

- User must perform an appropriate Vendor Assessment, typically in the form of a Supplier Audit of PTI QA and Product Validation processes, documentation, records and test execution to ensure that PTI meets the requirements of the User QA and Validation Organizations.

[Supplier Audits are an expected part of the Sales process to FDA regulated industries.](#)

- The Supplier Audit should include a Gap Analysis review of PTI Product Validation documents and records for completeness against User requirements.

[PTI can develop a Traceability Matrix from User Requirements to PTI Validation testing.](#)

- The User should augment PTI Product Validation testing with specific and intended use testing for any requirements not adequately addressed.

[PTI can provide resources to write additional testing.](#)

- The User should obtain PTI Product Validation Final Report along with their own internal Supplier Audit Report as evidence of the test execution.

[PTI provides the Final Report with the Product Validation Package.](#)

## 5 Supporting GAMP 4 References

Sion Wyn, Director, Conformity Ltd., Editor of GAMP 4, "Good Automated Manufacturing Practice Guide for Validation of Automated Systems", published by ISPE and member of the GAMP Steering Committee, commenting based on agreed guidance that is in GAMP 4:

["Based on guidance given in GAMP 4, user companies can use supplier test evidence, if they have confirmed through assessment, such as a supplier audit, that the evidence is sufficiently well documented and controlled. Note the following quotations from GAMP 4:](#)

[Section 6: 'Use of supplier documents, if suitable, will simplify the overall validation process. For example, the supplier's own software and hardware installation, inspection procedures, and documentation may meet the requirements of the normal IQ activities, if reviewed and approved by the user. Correspondingly, the supplier's development and testing methods, quality procedures, and documents may supplement or replace some of the normal OQ activities.'](#)

**Section 8.1.5:** 'It should be noted that the supplier is normally involved in all levels of testing, and that records of supplier testing may form part of validation documentation, if properly controlled'

**Section 9.13:** 'The SAT may be combined with equipment and plant commissioning, and this will provide a basis for IQ and OQ. This incorporation of SAT into qualification testing is acceptable where the level of detail and documentation of the tests meet the requirement of user company policies and procedures, and are acceptable to user company QA. For further guidance on this topic, see the ISPE Baseline® Guide on Commissioning and Qualification' "

## 6 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.

## 7 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/>.