

# VALIDATION

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SIMPLIFY AND REDUCE YOUR LIMS VALIDATION EFFORT

## VALIDATION: REGULATORY REQUIREMENT OR STRATEGIC RISK REDUCTION TOOL?

At LABVANTAGE, we realize that the process of satisfying validation requirements can be challenging to your staff, as well as demanding on your bottom line. However, it is important to realize that validation isn't just a regulatory requirement; it is simply a good business decision. Using the analogy of buying a home, one would never buy a house without considering the family's growth plan, analyzing the quality of the school system, comparing one home configuration to another, conducting a professional home inspection and title search prior to the family's transition to the new environment, etc.

Basically, it is no different when it comes to one of your most precious resources: laboratory information and the solution that houses that information. It is important that you qualify, verify and validate the solution to ensure it performs to its specifications. This process can be greatly simplified with LABVANTAGE, featuring Evergreen, our property driven configuration tool.

LABVANTAGE simplifies and reduces your validation effort by providing:

- Internal Validation of LABVANTAGE through LABVANTAGE's Quality System;
- Documented Implementation Leveraging LABVANTAGE's Proprietary Compass Implementation Methodology; and
- Configuration/Change Management through Evergreen.

Internal Validation of LABVANTAGE is governed by key practices as defined in our Standard Operating Procedures in our Quality System. By following these well-defined procedures, LABVANTAGE generates complete release documentation, including a Certificate of Release along with installation qualification and operational qualification scripts.

The LABVANTAGE Compass Implementation Methodology supports your validation efforts by paralleling a modified "V-model" as defined in the Good Automated Manufacturing Practices (GAMP) methodology. We follow a life cycle validation model incorporating best practices to ensure that once validated and operational, your LABVANTAGE solution remains in a validated state.

Using Evergreen to configure pages is fast and easy, and no coding or code validation is required.

## A CLOSER LOOK AT THE INTERNAL VALIDATION OF LABVANTAGE

Through these quality processes, LABVANTAGE creates a Solution Requirements Document (SRD) for the released version of LABVANTAGE. This SRD incorporates select:

- Enhancements requested by customers;
- Innovative technologies and architectural improvements available in the marketplace; and
- New functionality and bug fixes garnered from our product management and marketing organizations.

Once a draft of the SRD is completed, LABVANTAGE drafts a Software Quality Assurance Plan (SQAP) following IEEE standard 730. After discussions with our Development organization and review of the SRD, the Quality department produced and executes a test plan following IEEE standard 829. During the testing cycle, any bugs that were fixed are again tested using reproducible test cases created on our online bug testing repository. At the conclusion of testing, we generate a report to summarize the testing done and the successful metrics for exit criteria. Once approved, our technical service team is alerted as to the "Release to Production" status. They finalize the packaging to a Master CD to include:

- The LABVANTAGE software
- Installation instructions
- A release bulletin
- List of enhancements
- List of bugs fixes

The final element is a Certificate of Release – objective evidence that we have complied our internal validation procedures for verifying the software as having passed through our Quality System.

An intuitive configuration tool, Evergreen enables you to rapidly make changes in user administration, business process automation, and end-user interfaces, without complicating the validation process. Because Evergreen allows you to manipulate a LABVANTAGE web page without the need to write a single line of code, it simplifies and reduces the validation effort. Test cases only need to be written around the integrated functionality of the web page and not the coding of the web page (unit testing), or design specifications.

## RELY ON A BEST-IN-CLASS INTERNAL VALIDATION PROCESS

In alignment with current best practices, LABVANTAGE has defined and follows a documented process for Installation, Verification and Validation (IV&V) (see side bar). IV is focused on our ability to define specifications and plans that support coding and qualification practices. The end result is a Certificate of Release issued by our Quality department to supplement user validation.

## A CLOSER LOOK AT THE COMPASS IMPLEMENTATION METHODOLOGY

At LABVANTAGE, we not only take care in building world-class software, but we also follow a rigorous methodology to deliver our solution.

- **PLAN:** Create a project plan with identified roles and responsibilities
- **ANALYZE:** Review user requirements and business processes by experienced professionals with knowledge of industry best practices
- **CONSTRUCT:** Configure LABVANTAGE based on your functional requirements
- **TRANSITION:** Run parallel tests to document acceptance of the solution
- **DEPLOY:** Go live with new LABVANTAGE solution, shut down your old system, and turnover LABVANTAGE to your organization with LABVANTAGE support
- **OPTIMIZE:** Streamline and fine tune LABVANTAGE based on user feedback

Our Compass Methodology shadows the GAMP V-model (shown here for comparison). Consistent with the first leg of the V-Model, we complete the Requirements/Planning phase documentation for the solution. From the validation perspective, we know what we want, what to build, what requirements have changed during the project, and what to test.

A Statement of Work (SOW), which incorporates by reference your User Requirements Specification (URS), outlines the high level solution requirements, including project management, process workflow, instrument and system integration, and reporting. Working together, LABVANTAGE's experienced team helps analyze your user requirements and processes to develop a thorough and approved Functional Requirement Specification (FRS) for the solution. Based on this FRS, an Acceptance Testing Plan (ATP) is established. Moreover, a detailed change control process is followed to ensure software quality throughout the project.

Following the second leg of the V-model, we enable you to complete the Qualification/Reports phase of the project. LABVANTAGE offers installation scripts for the out-of-the-box LABVANTAGE release, and the feature list produced for the ATP enables you to develop test cases for your specific LABVANTAGE solution. Together, these scripts enable you to satisfy your Installation Qualification (IQ) requirement. Ultimately, you can construct a traceability matrix to map the SOW/URS items to the FRS items to the test case items.

LABVANTAGE has partnered with subject matter experts to assist you with Operational and Performance Qualification, and help you build your standard operating procedures for solution use, backup, recovery, change control, and change management. Based on these procedures, appropriate actions can be taken to ensure that the solution remains in a validated state.

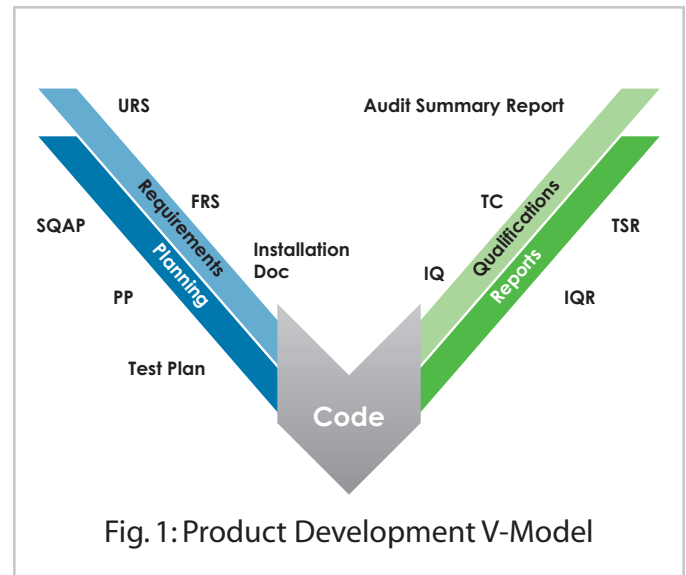


Fig. 1: Product Development V-Model

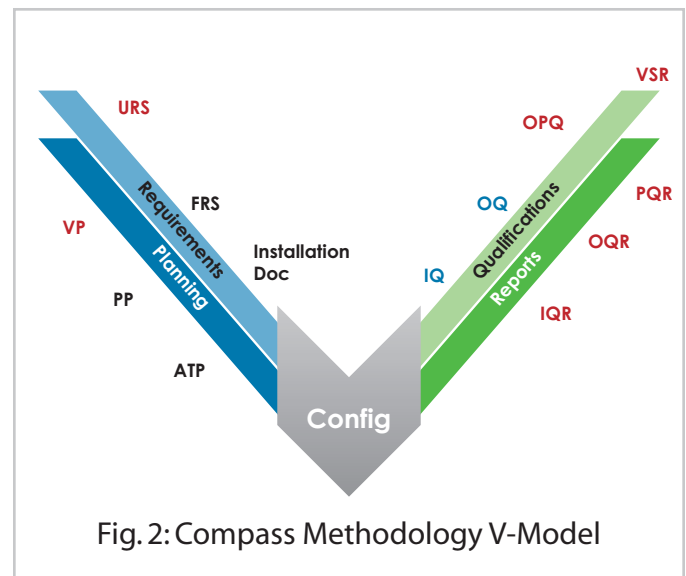


Fig. 2: Compass Methodology V-Model

Best practices are determined by set standardized methods for testing, validation and software development processes that are generally accepted by leading institutions, such as IEEE, ISO, ASQ, GAMP, ASTM, EMEA, ICH, US FDA, and US EPA. These methods are derived from:

- IEEE 610, 730, 829, 1008, 1074
- ISO 12207, ISO 17025, ISO 15504
- 21 CFR 11, 58, 210, 211, 314, 820

### BENEFIT FROM A RIGOROUS IMPLEMENTATION METHODOLOGY

LABVANTAGE's professional services team work together with you to ensure LABVANTAGE is tailored to meet your business needs and integrates seamlessly with your IT and lab environment. LABVANTAGE recognizes that development and validation of computerized systems must be done in line with the

system life cycle principles. Accordingly, our Compass Implementation Methodology is comprised of six progressive phases (see side bar). From developing an initial plan to optimizing your newly installed solution, each successive phase ends in predefined deliverables and documentation that support your validation effort.

Furthermore, LABVANTAGE offers Installation Qualification (IQ) and Operational Qualification (OQ) scripts that allow you to document the qualification of the installation and operation of LABVANTAGE per its specifications. The validation process can be further simplified by performing a risk analysis between the pre-validated LABVANTAGE release and your configured solution. This reduces the number of test cases needed to provide objective evidence that the solution is configured to its specifications for its intended use.

### LEVERAGE A PROPERTY-DRIVEN CONFIGURATION TOOL

Although LABVANTAGE is designed with robust functionality out of the box, LABVANTAGE recognizes that your ideal solution may require some tailored configuration. These changes can be made for your initial configuration or to keep your LABVANTAGE solution up-to-date with your changing business requirements.

Evergreen is a property-driven, web page design and configuration tool that enables you to rapidly construct and configure functionality in LABVANTAGE (see side bar). Evergreen does not require programmer or development skills. Instead, utilizing an intuitive interface and easy to use functionality, system administrators can leverage the vast functionality and flexibility within LABVANTAGE. Moreover, since each page within LABVANTAGE is inheritance-based (i.e., a LABVANTAGE configuration is in a hierarchical structure

such that pages lower in the hierarchy inherit properties from pages higher in the hierarchy), it is easy to maintain or update a configuration throughout the life of the LABVANTAGE solution.

As a component of LABVANTAGE, Evergreen is validated as part of our Quality System described above. Therefore, you are able to use a validated tool to change configuration or add new functionality without the need to write a single line of code. This simplifies and reduces your ongoing validation effort because if you alter your business processes and need to reflect the change in your LIMS, you do not need to re-validate the entire LABVANTAGE solution, or even large aspects of the solution. Instead, you can execute simple test cases around the integrated functionality of the web page.

In less configurable LIMS, such changes would need to be done through custom coding. From a validation perspective, this requires you to (i) create coding standards and naming conventions, (ii) produce a design specification, (iii) test all pathways used in the page design (i.e., the unit testing), and (iv) test the integrated solution. With Evergreen, the coding and validation has been done for you allowing you to get to the final step, testing the integrated LABVANTAGE solution.

### GET THE RESULTS!

In implementing a LIMS solution, it is essential to understand the validation approach needed to provide evidentiary support that the system functions as intended. Through our three-pronged approach, LABVANTAGE provides you the results you need in your LABVANTAGE validation process:

- Improved compliance with regulatory requirements;
- Decreased validation effort; and
- Reduced cost to achieve compliant systems.

Footnote: Definitions are based upon the Glossary Of Computerized System And Software Development Terminology, [http://www.fda.gov/ora/inspect\\_ref/igs/gloss.html](http://www.fda.gov/ora/inspect_ref/igs/gloss.html) and IEEE 610 Standard Glossary of Software Engineering Terminology.

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