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Best Practices and
Lessons Learned

COMPUTER SOFTWARE VALIDATION

BASED ON LABVANTAGE PHARMA PACKAGE

Computer Software Validation based on LabVantage Pharma Package

Best Practices and Lessons Learned

By Johanna Schröter, Consultant, LabVantage Excellence, FrontWell Solutions

Introduction

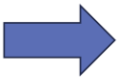
The goal of this whitepaper is to share knowledge and experience regarding Computer Software Validation with the LabVantage Pharma Package. The document will cover the necessary tasks for a LIMS Validation project. Even if you are not using LabVantage, you will likely find this white paper useful since there are common pain points in LIMS Validation.

Your journey begins

After a long and time-consuming process of deciding which LIMS vendor to select, you have decided to go with LabVantage, and now your journey of implementing LabVantage begins. One of the reasons for choosing LabVantage is that it offers a pre-validated application and a robust document package to work with. Within this document package, there are documents that cover **out-of-the-box (OOB) functionality**, such as:

Generic Validation Documents:

- valid for OOB Functionality
- Generic URS
- Generic FRS
- Can be used as template
- Adaption needed to your:
  - URS,
  - FRS
  - Rights and Roles
  - Use Cases



- Generic Validation Plan including Test Strategy and Deviation Management
- IQ Protocol and executed Script
- OQ Protocol and (executed) Test cases for OOB Jobtypes
- PQ Protocol and (executed) Test cases covering common used workflows
- Validation Report
- Test Summary Report
- System Release Memo
- Traceability Matrix

You are quite impressed by this package and are excited to take part in the FRS workshops that the vendor is offering you to configure and customize your application.

As general advice for any implementation: As soon as you get access to an application, get familiar with it. Additionally, before you attend the workshops, create flowcharts documenting your current Quality Control workflows. In parallel or shortly before/after the workshops, you should create the Initial Risk Assessment, Supplier Assessment, and Data Integrity Assessment. During the FRS workshops, you will share and discuss your workflows with your Business Analyst. In these workshops, you should ask for a response to your individual URS items and if you haven't yet, consider asking for an URS/FRS-Mapping.

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During that time, you will become aware of how much there is to see, learn, and know within the LabVantage application. If you aren't able to receive administration training from the vendor before the workshops, you may be uncertain whether you can manage the entire upcoming validation process, especially creating the Test Cases, by yourself.

You see multiple challenges:

- Your staff needs to have deep knowledge of the application to create and review the required documents.
- You must free up multiple people to perform time-consuming and repetitive tasks like Test Case execution and Master Data Creation.
- You must train those people, taking time away from their day-to-day business.
- There is a risk of rework when things are not done correctly the first time.

You will need to consider the following tasks and documents:

Regulatory Tasks	Validation Documents	Training Material (SOP Creation)	Master data
Create Change Control	Define Rights and Roles Concept	OOB Functionality	Define Naming Convention
	Validation Plan	Configurations/ Customizations	Define Concept
	Clarification of Responsibilities		Upload and Transfer
	Define Test Strategy		
	Functional Risk Assessment based on your workflows and configs		
	Operation Qualification Script and Testcases		
	Performance Qualification Script and Testcases		
	Interface Integration and Regression Testing		
	User Acceptance Testing		
	Traceability Matrix		
	Validation Report		

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During that process, you should:

- Review intensively and, if possible, re-use the test cases provided by the vendor.
- Specify how to proceed in case of failure within a Test Case Run.
- Define how to set up your Master Data, especially with regards to Naming Convention.
- Upload your Master Data using Mass Import (DFD/MDCT) and transfer it via CMT.

Many employees at FrontWell Solutions have been in your position, on the client side, facing this immense workload. At FrontWell Solutions, we have experienced Business Analysts and a Validation Excellence Team who can support you on this journey. We can provide assistance and guidance throughout the entire process.

Before the workshops

We can set up your workflow in an application and test it for you. Often, there is a workaround where, ideally, minimal configurations are needed. This minimizes extensive testing, as existing functionality within the application is utilized. This exercise will result in less time consumed during OQ and PQ and will ultimately lead to an earlier Go-Live date.

During the workshops

We can help and support you define your Rights and Roles Concept as well as creating the URS/FRS Mapping on behalf of the vendor. We have already worked with multiple pharmaceutical companies and are aware of the complexity of various organizational structures and workload distributions.

As an example: The OOB job types and roles are quite useful but tend to not reflect the individual needs within your company. For instance, you may have a Laboratory Support Group responsible for receiving samples, preparing labels, aliquoting samples, and maintaining stability samples and shipping/packaging. This group must handle samples from all laboratories. To further complicate matters, people in this group do not work in shifts, only from Monday to Friday. This means that on weekends, analysts from the testing labs must handle sample reception, label preparation, and aliquoting themselves. The question now is how to display this in the LIMS without overcomplicating it and, with regards to validation, how to create a test case that covers the potential risks that may arise.

Within the validation process

We can help you create the Master Data Concept and Setup, create all validation documents (including Validation Plan, Test Strategy, Functional Risk Assessment, and Test Cases), perform Interface Integration and Regression Testing, and create the Traceability Matrix and Validation Reports.

A common pain point in defining the Master Data Concept and Setup is deciding between the multiple options available in LabVantage. You need to define a strategy as well as a naming convention that is ideally easy to follow and similar to your current QC-related documentation. During PQ, it is beneficial to select a meaningful set of Master Data to demonstrate that your processes can be successfully executed in your LabVantage LIMS. The recommendation here is

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to select the most complex process you have within your Functional Risk Assessment to reveal the highest risks related to process, product quality, and patient safety.

To identify the different risks that may arise within your process, as well as those related to the added configurations or customizations, you will need to create a Functional Risk Assessment, as mentioned earlier. To create this, you need to not only understand your processes and workflows but also have a deep understanding of the functionality of the application and the potential effects that may arise within LabVantage. It's important not only to undergo training but also to use this application frequently, not only to mimic your processes but also to explore edge cases and negative test cases to uncover any loopholes that could unintentionally undermine your defined processes. You will need to determine whether the use of discovered loophole can be easily detected; if so, then perhaps restrictions within a standard operating procedure (SOP) may be sufficient. In the worst-case scenario, if detectability is medium or low, then you may need to revert to your Functional Requirements and add that certain functions, stops, or lines are hidden for specific roles.

Planning is crucial, especially when it comes to SAP Interface Integration and Regression Testing. Updates to SAP setup and configurations are typically difficult to schedule, so it is important to synchronize LIMS Validation activities, particularly the Go-Live, with the department responsible for SAP. To put it into perspective, an entire validation process and upcoming Go-Live could be postponed by up to six months solely due to asynchronous SAP updates.

A vital aspect for a smooth Go-Live after Validation is the training of your end users. It is crucial to have documentation ready in the form of SOPs that cover the relevant workflows within your LIMS, from receiving samples and entering data to storing samples and releasing batches. Although LabVantage documentation is quite powerful, end users become more familiar with the application when you include application handling within your own written procedures. Whether it is in the form of a Wiki page covering all the necessary information, PowerPoint presentations, e-learning modules, or video guidelines, it is important to find the method that effectively gets your team up to speed and knowledgeable.

Closure

In conclusion, consider Computer Software Validation with the LabVantage Pharma Package as a journey. Along the way, you might encounter unexpected challenges, even if you have planned well. At FrontWell Solutions, we are here to navigate this path with you, standardizing the process of getting your LIMS system operational and therefore saving you time and effort. Ultimately, you will reach Go-Live with a system that meets your requirements within a reasonable timeframe, thanks to the pre-validated documentation provided by the vendor and the expertise you have gained (perhaps with our assistance?).

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Our Company

FrontWell Solutions is an expert in the digital transformation of the pharmaceutical manufacturing process. Our team of experts is engaged in providing digital solutions to 10 of the 20 leading pharmaceutical, biotechnology, chemical, and medical device companies and suppliers spanning Europe, the United States, and Asia.
Our expertise lies in delivering specialized consulting services, primarily centred around Manufacturing Execution Systems (MES), Laboratory Information Management Systems (LIMS), seamlessly integrating these Level 3 systems with Enterprise Resource Planning (ERP) platforms and driving Manufacturing Intelligence initiatives such as Overall Equipment Effectiveness (OEE) reporting.
Moreover, we have partnered with prominent digital solutions platforms in the market, showcasing our proficiency in leveraging cutting-edge technology.
We can support you with our well trained LabVantage experts (Business Analysts and Solution Engineers) as well as our Validation Excellence Team with long term experience in the field.

Next Steps

Thinking about taking your next steps towards the digitalization journey? Our experts are ready to support you! Contact us at ReachUs@frontwell-solutions.com or via +49 (6101) 595 89 85.

Reference

- ISPE GAMP Good Practice Guide: A Risk-Based Approach to GxP compliant Laboratory Computerized Systems
- LabVantage Pharma Package Documentation

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