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Maximizing the Business Value of your LabWare System

LabWare's Enterprise Laboratory Platform (ELP) is a comprehensive laboratory informatics system that combines the typically separate domains of a Laboratory Informatics Management System (LIMS) and an Electronic Laboratory Notebook (ELN) into a single, integrated system sharing a common database. As such, the LabWare solution provides the benefits of both a LIMS and an ELN in a single platform that is both stable and supportable, allowing customers to avoid the IT complexity, expense and validation requirements of a customized interface layer.

"The Labware platform is extremely flexible and can be configured to meet practically any business need."

Based entirely on open standards, the LabWare platform is extremely flexible and can be configured to meet practically any business need. While this flexibility offers many benefits, it also presents unique challenges when implementing, enhancing or upgrading the system. There are, in fact many important considerations to take into account when developing or maintaining your LabWare system in order to capitalize on the its full potential to transform your laboratory operations. In this white paper, we'll discuss key best practice recommendations to follow during your LabWare project that will help to ensure your deployment maximizes business value and delivers a superior return on investment (ROI) for your organization.

LabWare Implementation Best Practice Guidelines

When implemented properly, the LabWare solution can provide significant benefits to your business – streamlined laboratory management and automation, improved information availability and collaboration, enhanced product quality and regulatory compliance, and much more. In order to ensure success for your LabWare implementation project, there are key best practice recommendations to consider during the development and implementation of the system. ***These include:***

Keep System Customization to a Minimum

The LabWare platform is extremely flexible and can be customized to automate virtually any laboratory operation. However, just because you can do something does not mean it makes sense to do so. When designing your LabWare system, it is best practice keep system customization to a minimum and utilize as much of the standard configuration as possible. There are a number of reasons for this:

- **Customizations increase the complexity of future upgrades or enhancements.**
- **Customizations make it more difficult for your IT support to solve issues when they arise, and there is usually much more vendor support available for issues related to the core system.**
- **Any data entry and/or data migration plan must consider customized fields.**

The bottom line: ***Don't automate just for the sake of automation – ensure there is a business case for it. Get the right LabWare template for your industry and strive to use standard module functionality as much as possible to minimize system customization.***

Implement LabWare in Stages

An effective way to determine if you really need to customize is to iterate your implementation, with the first iteration being the minimum viable solution to go into production with. Once this first iteration is operational, users can give feedback about the pain points that they are experiencing, and then decisions can be made as to whether it makes sense from a financial and time perspective to customize the system to facilitate further automation.

Only Experienced and Skilled Developers Should Program Customizations

It is critical that individuals programming customizations in LabWare be experienced developers who understand how to create compliant, scalable and maintainable systems. You

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can do almost anything with LIMS Basic and, while this level of flexibility certainly provides benefits, untrained individuals can end up creating more problems than they solve. Just a few of many potential problems that could be created by untrained developers:

- **Compliance issues due to uploading incorrect data**
- **Slow system performance due to poor coding**
- **Poor maintainability due to duplicated logic**

"Current best practice is to fully detail the desired user roles and the permissions associated with each role before you build the system."

Download Only the Modules You Need to Satisfy Your Requirements

Modules in LabWare are enhancements that are incorporated into the main application using its core language (Small Talk). Best practice with a LabWare system is to start with the basic system and only download the modules that have the functionality you need to satisfy your requirements. The reality with complex software like LabWare is that everything you add on to your system has the potential to cause issues with what you already have. Installing modules using a targeted approach will reduce system complexity and lower the chance of introducing unforeseen errors. Additionally, every module you add to your system will likely make your validation efforts more complex and costly. Since there are a lot of LabWare modules, this means that someone on your project team will need to be a LabWare expert to help you identify the best modules to download for your implementation.

Create a System Map of All the Templates and Modules in Use

It is common for complex LabWare implementations to have a large number of modules installed. Given that any new module you download can create problems with the modules currently in use, it is important to have a map of all the modules installed in your server and clients, as well as the industry template being used. This will allow the support team to have all the information they need to recreate the customer's installation in a sandbox where they will try to reproduce the error.

Design the System Security Framework at the Beginning of the Project

Designing and implementing user permission layers is often a bigger job than anticipated. Waiting until the end of the project to implement a security framework is a recipe for going over budget. Current best practice is to fully detail the desired user roles and the permissions associated with each role before you build the system.

Create a Master Plan for Instrument Integrations

LabWare provides several different ways to integrate instruments into the system:

- **Web services**
- **Direct connection via RS-232 ports.**
- **XML data mapped to specific fields in Labware, or to an XSD provided by external applications. LabWare now supports the AniML XML standard for analytical chemistry data, allowing LabWare to more easily bring in data from various sources.**
- **The system can be configured to monitor and process database tables created by an external instrument.**
- **Modules that support various complex laboratory instrument systems like Empower CDS.**

With all these integration options, it is quite possible to get bogged down in trying to integrate too much too soon. Some instrument integrations can be challenging and cause project delays. Current best practice is to conduct a site survey of all the instruments in your facility and develop a master plan that identifies which instruments are worth integrating. Critical path instruments that provide a high ROI and add a lot of value to the business should be integrated in the first phase of the project.

Designate a System Architect for Your LabWare System

All LabWare implementation projects should have a designated System Architect (separate from the System Owner) that is also a stakeholder. This person will create and manage design documents to ensure that the overall configuration adheres to a set of standards. ***The design documents should:***

- **Clearly outline the rules for naming conventions and shared functionality.**
- **Detail the technical design of the functionality**
- **Utilize a consistent design template to improve readability and conveyance of information**
- **Enable new resources get up to speed much quicker.**
- **Explain what was done and why it was done.**

The System Architect is especially important with distributed teams or teams where turnover is high, as they can play a key role in ensuring the system adheres to standards that will maintain the consistency and scalability of the system.

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Master Data Configuration in LabWare

The design and configuration of the master data (static data objects that are agreed upon and shared across the enterprise - analysis, products, locations, etc.) is the most important aspect of any LabWare system, as much of LabWare's functionality is data and template driven. For both the initial implementation and ongoing activities, master data configuration has a dramatic impact on the scalability and maintainability of your system.

A few of the many considerations for effective master data design in LabWare are presented below. Following best practice recommendations such as these when configuring your master data will help to keep the core of your implementation solid and help to ensure that the system delivers a superior ROI for your organization over its full lifetime.

Formulate a Master Data Management Strategy

As with the security framework, master data management for LabWare implementations almost always turns out to be a much bigger task than one might have anticipated, especially for those projects that involve replacing a legacy system. Neglecting to formulate a Master Data Management Strategy at the beginning of the project can lead to much frustration and system re-work in subsequent phases, not to mention time and cost overruns. It is important to take the time to understand all the various data elements and how they interact and plan for static data requirements before you begin the implementation. Questions to ask include: How are we going to get data out of the legacy system and into LabWare? How are we going to harmonize data across multiple sites?

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Make Sure You Configure E-Signature's Rules and Events Properly

LabWare provides a lot of flexibility when it comes to configuration options for e-signature rules. It is important that the project team has the expertise to utilize this flexibility to your advantage, as overall system compliance is strongly tied to e-signatures and audit trails. A misconfigured rule could lead to a missing e-signature prompt or an unnecessary prompt, leaving your laboratory subject to data integrity violations. In addition, effectively combining multiple rows of rules into a single rule can reduce validation time. The bottom line is that, while configuration of rules and events can be tricky, knowledgeable expertise can increase both laboratory compliance and efficiency.

Utilize the Analysis Variation to Improve both Scalability and Reporting. Labware's Analysis Variation is a powerful feature that can significantly improve your system's scalability if configured properly. This feature simplifies and allows for better external interfacing. For example, if an external system has one analysis entry but Labware contains 4 similarly named analyses, the complexity of mapping relevant values between the two systems can become prohibitive. Additionally, using Analysis Variations as opposed to additional analyses with similar names will allow for better trending and reporting. Report queries are more efficient at searching for specific analysis and parsing variations than using wildcards for alternate analysis naming conventions.

Keep Naming Conventions Generic

Objects and code in a LabWare implementation are often named to mirror an external system (e.g., EMPOWER, Trackwise, etc.). While this practice can provide some benefits (e.g., linking references in documentation), it can also lead to problems down the road. If the external system is changed, all of the LabWare objects that link to that system will need to be updated.

In addition, it is best practice to keep analysis naming conventions generic as well (***Good:*** ASSAY, ***Avoid:*** ROOM7_ASSAY). Use the Product Specifications and Variations to drive the behavior. This will reduce the overall amount of static data that needs to be configured and help ensure uniformity.

Name Routines According to Area and Function

Routines should be named according to area and function. ***For example,***

- **ET = Event Trigger, AS = Automation Script, FN = Functional Routine, etc.**
- **MNU_LM_SHORT_DESCRIPTION (MNU = Menu, LM = Lot Manager)**
- **FN_SHORT_DESCRIPTION (Utility Function, Shared Logic)**

This can be especially helpful in systems where the configured objects number in the hundreds or thousands, as it can help reduce duplication of logic and speed up problem assessment time. Additionally, new developers or administrators will be able to find configuration much more easily.

Establish Coding Standards

Coding standards facilitate quicker development time, easier troubleshooting and improved readability. ***For example, headers and comments should be consistent throughout the code:***

- **Headers should state the purpose, inputs, outputs, and revision history of the routine.**
- **Comments should state what the code is doing and when necessary why it is doing it.**
- **Variable naming conventions should be meaningful and consistent.**

Developers should also strive to consolidate core and shared logic to their own routines. This will reduce duplication of functionality and testing effort.

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Maintaining and Upgrading LabWare LIMS

Once your LabWare system has been implemented, it is important to develop a plan to keep your system up to date AND a plan for periodic review and maintenance. Both are necessary to ensure your system remains cost-effective and compliant over its full lifecycle. Not having a plan, or having a plan that isn't thorough, will inevitably result in a costly, non-compliant system. A good LabWare upgrade and maintenance strategy takes into account the organization's specific needs and circumstances, the cost saving benefits of being proactive, and the resources provided by the LabWare Company.

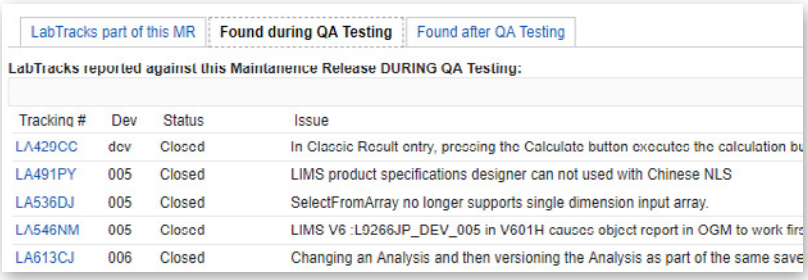
Keeping Your System Up-to-Date

With many LIMS systems, it can be difficult to tell which point version is the latest and if that version will add any unnecessary features. LabWare utilizes a letter system to clearly distinguish between different letter upgrades to a particular version that wrap many individual fixes into one package.

"Having an up-to-date and maintained LabWare system lowers costs and reduces system downtime."

LabWare identifies issues in their platform by doing internal QA testing and by documenting the issues reported by customers after their own QA testing. Each letter upgrade will contain a set of issues that have been identified and fixed. Detailed documentation is available on the issues identified and fixed in each separate letter version, and this information can be utilized to focus validation testing on higher risk areas.

Example of Letter Release System and Documentation



Periodic Review and Maintenance

Having an up-to-date and maintained LabWare system lowers costs and reduces system downtime. By maintaining LabWare, support calls and the time it takes to fix them goes down significantly. You don't want your system to go down at an unexpected time, or discover a bug that puts your data integrity at risk, just as you wouldn't want your engine to seize or a tire to go flat on a busy highway. The costs go up exponentially if your organization is being reactive instead of proactive.

Conducting quarterly or bi-annual reviews of your LabWare system is highly recommended. Items to consider during periodic review include letter labtracks, letter releases, and module updates. Labtracks contain bug fixes for specific issues and are released constantly. Letter releases combine many labtracks into a single package but do not typically include bug fixes for modules. Some modules are still on version 1, while others have gone through several versions (Stability, Empower Interface, etc.), so it is an important item to keep an eye on.

Reviewing new code/functionality in the system to ensure that the design is consistent with SOP's should also be a part of your periodic system review. Code reviews are a good way to identify duplicated or sub-par logic, dead code or logic structures that reduce efficiency, missed error traps and situations where the logic might break in the future. The System Architect should participate in these code reviews and will have final say in any design disagreements. This is important as code reviews do not always catch design issues.

Periodic reviews elevate organizational knowledge of the LabWare LIMS and ensure that any relevant documentation (URS/FRS/DS) is current and complete. A better understanding of the system will help address any concerns an auditer may have when reviewing the LIMS system and ensure the most effective testing senarios when it comes time to validate. Having subject matter experts and LIMS admins as part of the process will minimize the effort and time to fix any new issues that arise.

Conclusion

A properly implemented, integrated, validated and maintained LabWare system can provide significant business value to your organization. There are, however, many factors to consider in order to realize this potential. In this white paper, we have presented several key best practice recommendations that will help you get the most from your LabWare system and maximize ROI over the full system lifecycle. For any LabWare project, a combination of skilled and experienced resources (both internal and external) and best practice methodologies are vital to ensure success.

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