hyperCision

Validated SaaS LMS

SuccessFactors Viability

Executive Summary

SuccessFactors has a long history of working with validated organizations and has brought this expertise to their validated SaaS LMS package. SuccessFactors validated SaaS LMS solution supports the functionality required by FDA regulated organizations and meets the technical requirements of a validated LMS. Because no LMS can be delivered pre-validated, it is important to understand the procedural processes required to validate the SuccessFactors LMS. The hyperCision team has the expertise to support your organization during their validated SuccessFactors LMS project.

INTRODUCTION

Life Sciences and Healthcare companies must comply with U.S. Food and Drug Administration (FDA) quality system standards to ensure that all products are produced in a controlled and safe manner. Training records are a key component of showing that employees and contractors are able to deliver quality products in alignment with an organization's quality standards.

A Learning Management System (LMS) supports management of employee and contractor training requirements, ensures training compliance of these employees and contractors, and maintains traceability for all training content. An LMS can

- Provide immediate proof that an organization is tracking exactly what an employee or contractor must know to perform his or her job correctly.
- Ensure that updates and additions to required training are immediately made known to impacted learners via their requirements profiles and notifications.
- Confirm that the employee or contractor took the required version of training within the specified timeframe, and provide complete traceability through well-managed and documented training records.
- Enable an organization to be certain that it's training records are "inspection-ready."

Organizations may be able to support the management of training records via a paper or hybrid (paper and electronic) solution. However, the challenge of ensuring that all records are available and in order for an inspection using either of these options is time-consuming and error-prone. An LMS can provide the ability to track the required information electronically. The LMS must also comply with the requirements of 21 CFR Part 11 of the Code of Federal Regulations. Key to this regulation is the need to ensure that any computerized system used for regulatory purposes has been validated to "ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records." [1] In other words, if electronic technology is used to manage (create, modify, maintain, archive, retrieve or transmit) records required to be tracked per FDA regulations, these electronic records and any related electronic signatures must be reliable and equivalent to paper records and handwritten signatures.

At a high level from an LMS perspective, organizations need to ensure that the LMS is secure, supports audit functions or electronic records, provides the ability for electronic signatures, and delivers non-modifiable audit reports. FDA-regulated organizations must consider a solution that complies with the technical requirements of 21CFR Part 11.

Organizations themselves must also have documented procedures in place to ensure that the LMS is secure and the data is maintained and managed appropriately. Formal documentation of such procedures via Standard Operating Procedures (SOPs), Work Instructions, and other Controlled Documents are key to ensuring the LMS meets the requirements of 21 CFR Part 11. Note that while your LMS may support the technical requirements of 21 CFR Part 11, it is only through implementation of structured procedures that you ensure the LMS becomes 21 CFR Part 11 compliant. Continual review and revision of these procedures is crucial to ensuring your LMS remains compliant.

GxP (Good Manufacturing Practices or GMP; Good Laboratory Practices or GLP; and Good Clinical Practices or GLP) requirements also impact the types of training records that must be kept by regulated organizations. Key to these requirements is the need to be able to illustrate that any person involved in the manufacturing, processing, packing or holding of any drug product or medical device, or any person responsible for the supervision of such processes, has the education, training and experience to do so.

In addition, anyone responsible for processes, systems or solutions related to the manufacture, processing, packing or holding of these items must also be educated, trained and experienced to do so. Formal processes or SOPs should be in place to ensure that this information is tracked appropriately. Your LMS implementation team is also impacted by this requirement and should be trained and experienced to both implement your selected LMS and understand the requirements of a validated implementation process.

Because the LMS is so tied to the quality procedures related to these types of organizations' research and manufacturing processes, most organizations determine, via a system-level risk assessment, that they must follow a formal validation process during their implementation, generally managed by their Quality team, to ensure the LMS is checked and proven prior to moving into production. The FDA considers software validation to be "confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled."[1]

The validation process is typically incorporated into a formal System Development Lifecycle (SDLC), as most organizations categorize an LMS as a commercial configurable product. As part of this validation process, Quality must ensure that the solution implementation is installed, tested and documented in alignment with their SDLC. While validation plans may vary among companies, the general stages follow FDA guidelines and process phases. A good rule of thumb is that validation can add between 25-35% to an implementation's timeline.

For many years hyperCision has worked with organizations implementing on-premise and cloud LMS's, including both the SuccessFactors LMS and SAP's Learning Solution. We have found that the implementation of the SuccessFactors LMS has a positive impact on the validation timeline and streamlines the implementation. While the process and ownership of some validation steps is different from that of an on-premise LMS implementation, accepting and embracing these differences as value-add to their implementation is essential for organizations interested in validating their SuccessFactors LMS.

Typically, a validated organization goes through three phases of implementation: the Installation Qualification (IQ); the Operational Qualification (OQ); and the Performance Qualification (PQ).

- Installation qualification (IQ) – Demonstrates that the process or equipment meets all specifications, is installed correctly, and all required components and documentation needed for continued operation are installed and in place.
- Operational qualification (OQ) – Demonstrates that all facets of the process or equipment are operating correctly.
- Performance qualification (PQ) – Demonstrates that the process or equipment performs as intended in a consistent manner over time. [2]

SuccessFactors provides documentation of initial set up of the application and database, demonstrating that all required steps were followed for proper installation of each environment and delivers a formal IQ for validated SaaS customers. This accelerates the due diligence which organizations must perform for the IQ when implementing their validated LMS. SuccessFactors also supplies an OQ Toolkit which provides sample test cases and OQ templates. Organizations still must support their OQ and PQ processes as outlined in their SDLC and documented in their Validation Plan.

VALIDATION PHASES RESPONSIBILITIES

IQ = successfactors™
An SAP Company

OQ =
PQ =
customer

In addition to providing the IQ and OQ Toolkit, organizations with the SuccessFactors Validated SaaS LMS solution will find that there are additional differentiators from the non-validated LMS solution to support their internal validation needs. Validated Customers receive one release of the SuccessFactors LMS per year to provide them with adequate time to complete their testing processes. If validated customers were to receive four releases per year, as with non-validated customers, most would not have time to test their LMS appropriately.

Generally new releases will be delivered for the Staging and Sandbox environments in September with the move to the validated Production environment the following March. This provides all customers with a six-month timeline to support testing and other validation needs.

With this type of timeline, it is imperative that customers remain aware of the SuccessFactors validated LMS release schedule. Most organizations will want to avoid going live and then repeat the validation process for the next release.

With an integrated SuccessFactors validated LMS, Bizx integrated customers will still receive Bizx updates on a quarterly schedule. Integration with Bizx allows customers to take advantage of SuccessFactors Talent Management suite including, SSO, branding/theming, shared user and competency data via connectors, SuccessFactors Mobile, and career development planning (CDP) and JAM integration.

For a validated SuccessFactors LMS implementation, the system landscape typically includes the Sandbox, Staging and Production instances, as noted above. The Sandbox and Staging instances are made available ("provisioned") by SuccessFactors right before the project is initiated. The Production instance for a Validated LMS implementation is provisioned only after validation testing has been completed and documented by the client. SuccessFactors delivers an IQ after the provisioning of each client for review.

All functional configuration is performed in the Staging instance and is moved across the landscape using the snapshot process. A snapshot from the staging system can be applied to any other instance to ensure that the configuration is consistent across all instances. Snapshots used to move configuration from the staging instance are taken before any test data is added to the system. Non-validated testing may be performed in the sandbox. This ensures that irrelevant test data is not introduced into the Production instance from Staging and that the Staging environment remains tightly controlled.

Validated

STAGING

Non-Validated

SANDBOX

Validated
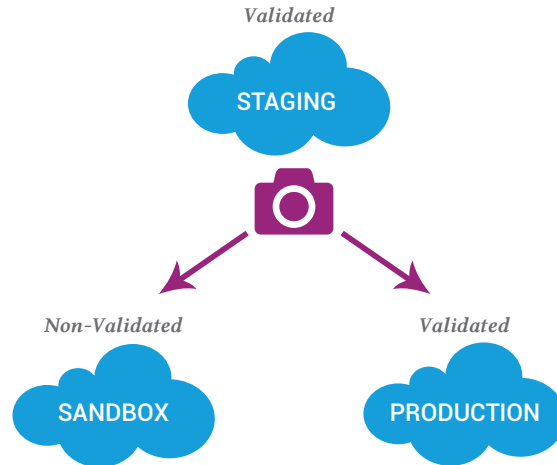
PRODUCTION

SuccessFactors recommends that a non-validated staging environment be set up in addition to the environments noted above, to be on the same version as the production environment. This provides an additional testing ground for the customer when the SuccessFactors validated Staging environment is not on the same release as the Production environment.

PROJECT PHASES

A validated LMS Implementation project plan typically separates phases for Project Planning; Requirements and Design Confirmation; System Configuration; Testing and Training; and Rollout. This aligns with the SuccessFactors LMS implementation methodology and supports validation efforts. We have found that most Life Sciences organizations have an established SDLC in place, and we work closely with the team responsible for the SDLC to ensure that all aspects of the SuccessFactors methodology are aligned with it to ensure an optimal and validated implementation of the SuccessFactors LMS.

SuccessFactors BizXpert Methodology includes the following phases:

PREPARE → REALIZE → VERIFY → LAUNCH

Prepare Phase

The Prepare phase involves the typical project planning activities, such as project kickoff and initiation of project plan. The business team will attend Project Team Orientation (PTO) training in preparation for requirements discussions. The Validation Plan is also created and defines the roles and responsibilities of the project team, outlines the implementation life cycle, and identifies all supporting documentation that must be delivered. The Staging customer instance is provisioned and SuccessFactors will deliver the IQ documents for customer review. While SuccessFactors methodology includes Requirements Gathering in the initial phase, for many organizations, the requirements workshops and creation of the User Requirements Specification is a separate phase.

During Requirements Gathering Workshops, business process requirements are identified and captured using standard SuccessFactors configuration workbooks. At this time, validated customers create their formal User Requirements Specification. hyperCision's team works closely with the project team to ensure the capabilities of the LMS are well-understood by the client before design requirements are finalized. If possible, we want to avoid reworking these documents because multiple approvals are often associated with changes. We also want to ensure that user requirements align with elements in the configuration workbooks to support the creation of a Trace Matrix during the next phase.

A final key aspect of the User Requirements Specification is that it can help identify new procedures that must be documented and existing procedures that must be revised. Because the creation and revision of SOPs and related Work Instructions can be time consuming, it is important to identify the amount of work required as early as possible in the implementation timeline, so the approvals of these controlled documents do not impact the project timeline.

Realize Phase

As we progress into the **Realize phase**, system configuration is performed, as well as any technical activities, such as data migration, report creation, integrations, and extensions. All configuration takes place in the staging system and is based on the configuration workbooks finalized during the requirement gathering workshops. During this phase, we also work with the validation team to ensure that all configuration and technical activities are aligned with User Requirements and documented appropriately, typically in additional specification documents. We also work with the team to create the aforementioned Trace Matrix to ensure that each documented requirement can be traced to an element in the configuration and later, to the appropriate test scripts.

After configuration is complete on the staging system, a snapshot is taken of the staging environment and applied to the sandbox. The sandbox allows for initial configuration review to be performed in a non-validated environment and also allows the business to become familiar with the LMS without impacting their staging environment, where validated testing will take place in the next phase.

Verify Phase

The Verify phase is typically customer-driven, per the standard SuccessFactors methodology. hyperCision's team recognizes that successful testing activities are key to ensuring the success of a validated LMS implementation and works with the validation team to ensure that all testing activities align with their Test Plan. hyperCision often works with the business to support the creation of test scripts and drive the approvals process. In addition, we may either deliver or support System Testing and Integration Testing activities, based on the customer's needs. Testing activities occur after multiple iterations of configuration to ensure that the LMS configuration meets the User Requirements Specification. An example of the iterations of system testing that take place is as follows:

- Iteration 1 for baseline configuration
- Iteration 2 for data import validation
- Iteration 3 for roles, notifications, and approvals testing

If more complex activities—such as integration and interfaces—are included in the implementation, additional iterations may take place. As configuration for each iteration is completed in the Staging environment, we recommend that a snapshot is created and moved to the Sandbox environment. This allows the creation of detailed User Acceptance Test scripts without impacting the staging environment, supports change control processes, and ensures that staging is kept in a validated state for the eventual move to production.

SuccessFactors delivers detailed job aids to support creation of test scripts during this phase, but because process details vary among organizations, validation test scripts are not delivered. Once System Testing is complete, User Acceptance Testing is initiated. The business team typically works with their QA/Validation group to ensure that all the User Requirements are tested. The hyperCision team may support management of the Trace Matrix and will provide support to the business team during testing as required.

Launch Phase

Upon successful completion of User Acceptance Testing, the client confirms to SuccessFactors that validation testing and any other validation requirements are complete. SuccessFactors initiates provisioning of the Production system upon this notification, and the project moves into the Launch phase. When provisioning is complete, SuccessFactors provides the customer with a Production OQ for review and approval.

SuccessFactors then applies the validated snapshot from the staging system to Production, ensuring that the production LMS is setup with the latest, validated system configuration. The Launch phase is used by the Client Project team to train LMS Administrators and for cutover activities to the Production LMS instance. During this phase, hyperCision supports integration activities, such as finalizing the required setup for SSO and setting up SuccessFactors FTP access for data transfer from the client's HCM system, whether it be on-premise SAP, Employee Central or another system of record.

During Project Closeout, the Validation Summary report will document the implementation, identify any discrepancies or deviations from the initial Validation Plan, summarize test results, and provide all information necessary to ensure that the LMS project has satisfied all requirements and is suitable to be released into production.

CONCLUSION

As organizations move to a SaaS LMS, validation of these solutions will become less controversial. The SuccessFactors LMS meets all of the technical requirements of a validated LMS and is delivered with an eye to supporting even the most stringent SDLC during an implementation. The SuccessFactors LMS delivers an elegant solution to meeting both the requirements of CFR 21 Part 11 and GxP requirements as they relate to tracking and managing training assignments. Working with hyperCision's team of consultants ensures that your organization will have trusted advisors on your LMS implementation team with the education, training and experience to make your validated SuccessFactors LMS implementation a real success.

Let's Start a Conversation!

Call us at **312.893.5557**. We'd love to learn about your specific SAP and SuccessFactors support challenges! We'll craft the best approach to provide the help you need!

ABOUT HYPERCISION

hyperCision Inc. is a SuccessFactors and SAP Partner with expertise in HCM services and solutions. We are specialists in Learning, Performance and Goals, Recruitment, Compensation and overall HR technology. Our long-term focus on learning management system implementations for regulated industries is one of the many key differentiators that set us apart. Please contact us if you have questions on any of your SuccessFactors implementation projects.

For more information, please visit www.hypercision.com or call us at 312.893.5557.

ABOUT THE CO-AUTHORS

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Sharon has worked with validated and non-validated LMS implementations in configuration, business process, project management &validation manager roles for almost 20 years. Prior to joining hyperCision, she was a Platinum Consultant for SAP with a focus on Learning. Sharon has provided leadership on numerous validated LMS implementations and speaks regularly on best practices for LMS implementations.

ALAN YANG: PRACTICE MANAGER, LEARNING

Alan has over 14 years' experience implementing large scale Learning Management Solutions for federally regulated customers. Alan has significant experience in SuccessFactors Learning, SAP Learning Solution, and migration of SAP Learning Solution to SuccessFactors Learning.

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REFERENCES

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