Regulations and Compliance Requirements in Managing Software as a Service Environment

Moving to a cloud-based enterprise application provides unique advantages not available in traditional on-premise enterprise resource planning (ERP) systems, such as flexible cost structures, scalability, and comparative ease of system consolidation. Successful companies must now learn how to maximize value from a cloud-based implementation and address a different risk profile. Companies across industries are moving to Software as a Service (SaaS) solutions, such as Microsoft Dynamics 365 for Finance and Operations, to learn how they can extract the maximum value from a cloud-based implementation. Business operations can be streamlined and standardized, which enables companies to make rapid and more insightful decisions.

While these new technologies can provide measurable benefits and help promote development and growth, the opportunity to maintain an always updated environment adds a challenge to maintaining compliance within regulations, such as Sarbanes-Oxley (SoX) and the FDA good practice quality guidelines (GxP) that require validation of all changes going into a covered environment. For example:

- Sarbanes-Oxley requires organizations to assess changes to IT systems key to financial controls to measure the impact of the change on the reporting and control environment.
- GxP regulations, which define good practice guidelines within the pharmaceutical and food industries, require organizations to assess and measure impact of all changes introduced to validated IT environment in order to determine the extent and impact of the change on the entire software system.

Frequent updates require attention to prevent the risk that your controls framework is impacted. Most regulations (e.g., SoX, GxP) allow for a risk-based approach to be taken when dealing with system changes. This means the company is responsible for confirming the requirements of their regulations. The question to be asked is, "How can my organization effectively utilize the features and functionality of a SaaS Dynamics 365 for Finance and Operations environment, all while minimizing risk, to implement an efficient, focused process to validate all updates going into my environment?"
Key Customer Considerations for Dynamics 365 for Finance and Operations Update Cycle

Microsoft has introduced a new approach to updating their Dynamics 365 for Finance and Operations SaaS solution that incorporates all updates into a service update cycle called One Version. One Version introduces a solution to the Microsoft Dynamics 365 for Finance and Operations SaaS update model to give customers the opportunity to update their environment with the latest hotfixes, improvements, and new functionality.

To meet compliance requirements for different regulations (e.g., SoX, GxP), customers going through a regular update cycle for their Dynamics 365 for Finance and Operations environment should apply a set of considerations to their update cycle. While each customer’s environment is unique, the following are core considerations that Dynamics 365 for Finance and Operations customers are responsible for:

1. **Change Policies and Procedures**
   The business needs to understand how often updates will be issued and develop policies and procedures for addressing these changes. Policies and procedures should encompass the other areas of a customer’s responsibilities.

2. **Impact Assessment**
   A company is responsible for understanding the impact of any change, determining the nature and extent of what the change does, and any testing that is required. Through review of Microsoft issued release plans and tools, such as Microsoft’s Impact Analysis tool*, customers should understand the aspects of their environment impacted by the change and assess any greater impact on their system as a whole, including regulated functionality or data. This exercise will help the customer define what testing is required, and how it may affect data and processes under regulatory requirements.

3. **Risk Assessment**
   After determining the areas of impact, the company needs to assess the risk on their environment based on the areas impacted. Using the Impact Analysis, customers should evaluate the areas of their environment impacted by the update and assess these areas relative to the risk to the organization (e.g., compliance, operational, financial). This could include an evaluation of a population of the company’s risk and control environment and related IT dependencies to the Impact Assessment in order to identify high-risk areas impacted by the change.

4. **Customization/Extensions**
   Identifying integrations or other customizations deployed is critical to understand where, when, and how the customizations may be impacted. Unique test scripts for these customizations may be required prior to implementing a change in production SaaS environment based on impact from an update. Customers should develop a list of the following to assess impact to its production environment that may not be covered by Microsoft’s other tools and processes:
   - List of integrations
   - Population of customizations
• List of independent software vendors (ISVs) used
• Population of key configurations and IT dependencies within company’s risk and control environment

Microsoft has worked with a population of ISVs to confirm compatibility of updates with ISV solutions with Dynamics 365 for Finance and Operations. When assessing the impact of Dynamics 365 for Finance and Operations updates on customer’s ISV solutions, customer should speak to their ISV to understand their collaboration with Microsoft as part of One Version and obtain any necessary documentation on testing by the ISV supporting compatibility with each update.

5. Evaluation of Functionality (Positive Testing)

The customer is responsible for all changes moved into their production SaaS environment. Therefore, it is important to obtain comfort and document any validation activities before agreeing to each update. Testing of each update should be defined to validate the end-to-end business process with the following considerations:

• What is being updated as part of the standard release
• Customizations and integrations unique to the customer’s production environment
• Impact on update to processes with higher risk to the organization both operational and compliance

The customer should also perform appropriate required testing (based on the Risk Assessment by the customer) to validate actual results meet expectation and adequate testing has taken place prior to migrating the update into production.

Additionally, the customer should consider performing end-to-end process validation of net new or significantly enhanced functionality prior to migrating the update into production.

6. Evaluation of Functionality (Negative Testing)

Performing appropriate functionality testing is important to evaluate unexpected results are not produced with the updates, as applicable. This can include attempting to transact or update data that should not be updatable or perform functions that should be disabled per a customer’s business process or engineering environment.

7. Evaluation of Internal Controls

An evaluation of change on your business process is important to determine that internal controls function as expected, remain relevant to be triggered as part of the normal course of business after changes have been applied, or have been adjusted appropriately and tested prior to migrating the update to production.

8. Evaluation of End-to-End Impact (Regression)

Companies are responsible for assessing the impact the change has on their entire business process. Performing a full risk-based validation of impacted functionality, per the customer’s validation methodology is recommended.

Changes to the environment that update functionality or apply new functionality can also introduce new ways to transact or apply changes to the production environment. Companies need to test changes to identify this functionality, assess who should be granted the access, and how it may impact the company's segregation of duty and sensitive access control environment.

Tools and Services to Enable Compliance for Dynamics 365 for Finance and Operations Updates

One Version introduces a solution to the Microsoft Dynamics 365 for Finance and Operations SaaS update model to give customers the opportunity to update their environment with the latest hotfixes, improvements, and new functionality. As part of the One Version process, Microsoft issues service updates to its customers eight (8) times within the calendar year and requires that customers apply at least two (2) updates per year. While the tooling and validation programs that Microsoft provides can enable customers to take updates on a more regular basis, such as soon as they are made available, up to eight (8) times a year; One Version also permits an organization to manage their updates at their own, controlled pace of change to allow for time to document and perform compliance with regulatory requirements. This places the customer at the center of its journey and adoption of changes on the Microsoft Dynamics 365 for Finance and Operations environment. Customers are given the opportunity to “pause” up to three (3) consecutive updates (up to six months) through the Update Settings in their Microsoft Dynamics Lifecycle Services (LCS) project. Based on a customer’s industry and seasonality of the business (e.g., Retail) or unique customer circumstances (e.g., IT/Engineering resource constraints, unique IT blackout periods, or special projects), customers may choose to reduce the number of updates per year based on their business requirements. As each update may introduce significant new or enhanced capabilities, customers have the option to opt-in to these new features with the Feature Management capability when they are ready.

As a part of the development of the One Version process, Microsoft developed the following tools and services to enable customers the flexibility and opportunity to utilize the SaaS model of staying consistent with up to date versions of Dynamics 365 for Finance and Operations, while still maintaining the compliance requirements that regulated organizations require:

Safe deployment rings

As part of Microsoft’s Quality Assurance (QA) program, each software update progresses through a series of rings. This starts with internal Microsoft deployments and progresses to system integrators and customers requesting early access before full deployment. At each stage, both the version and the update process are exercised, as they will be in general availability. Telemetry is collected at each stage with the update moving to the next stage only with successful results. Microsoft has also committed the service updates being backwards compatible, which is included as part of this QA process. With safe deployment rings, service updates are expected to work with the existing customizations or additional ISV code implemented.
Enabling new features

To help customers manage the risk and potential impact on their production environment, customers control when new capabilities that change business processes or user experiences are enabled for their deployment. As part of One Version, the ability to manage new features will be added. This feature gives customers the opportunity to implement each update and schedule a larger evaluation of functionality (see 5 and 6 in section above) for new features being turned on at a time of the customer’s choosing through their normal change management process.

Update audit history:

As every organization needs to ensure the right level of controls are in place to audit when updates have been applied, within LCS customers are able to see a complete view of when updates were applied and by whom. Validation sign off status is also captured as part of the update history. Maintenance operations performed on the environments by Microsoft are logged and visible within the customer’s LCS project. To aid managing changes to the system several information features are available in LCS. This includes a notification of new updates in the Action Center and through email. Upcoming updates are also shown through the Notification Bar and a What’s New link describes the changes including a detailed description of fixes.

Impact Analysis Tool

The Impact Analysis Tool can be used in the execution of the Impact Assessment and the Risk Assessment (see 2 and 3 in section above) to give the customer a visual representation of the detailed release plans provided by Microsoft, and the creation of a customized visualization based on how the customer uses their production environment. Using the tool, the customer can assess what functionality they are using within their Dynamics 365 for Finance and Operations production environment, and if that functionality is being impacted by the update being evaluated. Using this information, the organization can identify the appropriate testing scripts to execute based on risk and impact. Use of the Impact Analysis Tool may provide a means to more clearly articulate ‘when’ and ‘where’ a change has financial vs. food and drug (FDA) process vs. normal business operation impact thereby informing the degree and extent of testing procedures. The use of the Impact Analysis Tool should be checked with the organization’s regulatory audit function to confirm completeness of the impact assessment.

Regression Suite Automation Tool (RSAT)

To help increase efficiency and enable the customer’s evaluation of functionality (see 5 and 6 in section above) and Evaluation of End-to-End Impact (see 8 in section above), Microsoft has released an automated testing tool, the RSAT, to evaluate the monthly updates in customer’s test environment before implementing the updates in production. To design and build the testing scripts used by the RSAT, a level of upfront time investment is required; however, with the use of automation testing, efficiencies can be realized in future updates, enabling the organization to be agile, but also compliant with regulatory testing and documentation requirements. In addition, a robust and automated regression suite of tests validates that key functionality is tested efficiently for each release.
Release Validation Program

Releases in One Version are validated in a shadow of the customer’s production environment for those who opt into the program, and the suite of RSAT tests are run as part of the internal deployment ring validation. This validates the regression test covers the core functional changes, as well as unique customizations to customer’s environment. Overall this makes it simpler to show that regulated functionality remains in a validated state, and gives customers added comfort that updates will be ready for their production environment.

Summary of Change Management with Microsoft One Version

While companies explore the benefits of SaaS solutions within their environment, it is important to keep in mind the responsibility for assessing the changes that they implement into their SaaS production environment for impact on regulated data, controls, and processes. With a combination of defined processes and procedures for change management, and tools that Microsoft has provided to its customers, regulated companies can take advantage of SaaS benefits while meeting their compliance obligations.
Appendix

- Microsoft Dynamics 365 Release Notes are published months prior to each April and October update to help customers and partners plan for new capabilities: [https://docs.microsoft.com/en-us/business-applications-release-notes/](https://docs.microsoft.com/en-us/business-applications-release-notes/)


- Microsoft Azure GxP Guidelines: [https://gallery.technet.microsoft.com/Azure-GxP-Guidelines-ab1b98d9](https://gallery.technet.microsoft.com/Azure-GxP-Guidelines-ab1b98d9)

Contacts page

PricewaterhouseCoopers LLP (PwC) and Microsoft Corporation have formed a strategic alliance to help companies engaged in enterprise transformation projects that use Microsoft Business Applications technology. With this alliance, PwC is the first major service partner recognized by Microsoft's Dynamics Group as a Global Business Transformation Partner, which allows it to build business transformation services around the Dynamics 365 suite of applications.

Under the agreement, PwC consultants will advise our clients and provide implementation assistance to clients who select Dynamics 365 together with other Microsoft technologies, including Microsoft Dynamics 365 for Finance and Operations (enterprise resource planning (ERP)), customer relationship management (CRM), and business intelligence (BI) solutions, as part of a business transformation project.
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