Achieve GxP Compliance with Microsoft Power Platform and Dynamics 365

A prescriptive guide to accelerating your GxP compliance journey

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SUMMARY

Executive Summary

Moving from theory to practice is almost always a challenge and moving from the theory of Good Practice (GxP) to implementing in the cloud with Power Platform is no different. This paper is an effort to help organizations adopt Power Platform as an enabler in their GxP efforts and be confident in their ability to demonstrate adherence to the regulatory goals and requirements of their particular field.

Regulatory goals aim to ensure that businesses in regulated industries manufacture products that are safe to use and meet stringent quality standards during the production process. Computerized systems that use GxP processes require validation of adherence to GxP requirements. Businesses and the FDA consider computerized systems qualified when the business can demonstrate the systems can fulfill all the relevant and applicable GxP requirements. Businesses achieves GxP qualification by using the following steps: 1) Platform Qualification, 2) Documentation of Qualification, 3) Power Platform Landing Zone Build/Verify, 4) Governance Policy Design and Document, 5) Design SOP for Verification, 6) Application Verification and Validation, 7) Pilot, 8) Build new app with SOP or Validate Existing app. These can broadly fall into three categories of activities: quality management, risk management, and validation.

DEFINITIONS

Terms and Definitions

GxP

'Good Practice' (GxP) governs many of processes mentioned above. The 'x' in GxP represents multiple fields of applicability — clinical (GCP), manufacturing (GMP), distribution (GDP), laboratory (GLP), agriculture (GAP), etc. There is no single global regulatory entity or administration nor body of precise instructions for these fields; each country has its own guidelines and regulators — though some requirements are similar if not identical from country to country. GxP regulations within the United States include those requirements outlined in the US Food and Drug Administration (FDA) CFR Title 21 Part 11. The European Union's guidelines are in EudraLex Volume 4 — GMP Guidelines, Annex 11 (briasmitatms & Mazzoli, Good Clinical, Laboratory, and Manufacturing Practices (GxP), 2024).

Quality Management

Quality management is the process of ensuring products and services meet the specified requirements and expectations of the customers and regulators. Quality management involves the business defining the quality policy, objectives, and responsibilities, establishing the quality processes and procedures, implementing the quality controls and measures, and conducting quality audits and reviews.

Risk Management

Risk management is the process of identifying, analyzing, evaluating, and mitigating the potential risks that may affect the quality, safety, and efficacy of the products and services. Risk management involves the business defining the risk criteria, methods, and tools, performing the risk assessment and treatment, monitoring and reviewing the risk performance, and communicating and reporting the risk information to relevant stakeholders.

Qualification and Validation

Qualification is normally reserved for use with equipment, utilities, instruments and the like. Validation is normally reserved for use with and about processes (Yeotikar, 2022). The intent of both is to support demonstrating that the items/process under test meet the specified requirements and perform as intended to expectations of the customers and regulators. Validation involves the business defining the validation scope, strategy, and plan, executing the validation activities and tests, documenting the validation results and evidence, and maintaining the validation status and records. When validation requires underlying equipment (e.g., a cloud service offering like Power Platform), it also requires qualification of that equipment.

Microsoft has published a whitepaper for using Microsoft Dynamics 365 while adhering to GxP best practices and regulations. This document compliments that whitepaper by sharing different patterns leveraged by customers when validating applications that require GxP governance.

Demonstrate GxP Compliance with Power Platform and Dynamics 365

Microsoft Power Platform and Microsoft Dynamics 365 offer tailored solutions for digitizing critical processes, such as drug development, development documentation, and regulatory compliance activities and forms. Microsoft delivers both as Software as a Service (SaaS) — with a consequent shared responsibility model that, to some, makes demonstrating GxP adherence hard. The reality is it makes such demonstrations different, but not inherently harder.

As a function of the cloud shared responsibility model, businesses inherit some administrative, technical, and physical security controls from Microsoft — specifically those controls relevant to the Microsoft Data Centers and extensively documented in their various security framework attestations. Even with such inheritance, businesses are still responsible for the elements of their processes within their facilities and operating environments (e.g., facilities, network infrastructure, cloud-application controls/configuration). Shared responsibility matrices document who is doing what, and does not relieve firms from having their own technical and administrative controls in place.

By demonstrating GxP Compliance with Power Platform and Dynamics 365, business can realize a host of benefits. The automation capabilities of Power Automate prove instrumental in expediting workflows, automating approvals, and enhancing operational efficiency in regulated industries. Other tools such as Power Business Intelligence (Power BI) can perform dynamic data visualization and reporting to empower these companies to monitor research and development data, compliance metrics, and performance indicators. This and other monitoring then foster data-driven decision-making. Adding to the tool kit, companies can leverage Copilot Studio to deploy chatbots for streamlined interactions, from clinical trial inquiries to pharmacovigilance reporting.

Quick Steps for Qualifying the Platform and Validating Solutions

With scene setting complete, let us work through the steps of GxP qualification and validation. The numbered steps have their own numbered section for explication.

1. Platform Qualification
2. Documentation of Qualification
3. Power Platform Landing Zone Build/Verify
4. Governance Policy Design and Document
5. Design SOP for Verification
6. Application Verification and Validation
7. Pilot Verification (and Validation)
8. Build New App with SOP or Validate Existing app

1. Platform Qualification

Microsoft enterprise cloud services undergo regular independent third-party SOC 1 Type 2 and SOC 2 Type 2 audits and have earned certification under ISO/IEC 27001 and ISO/IEC 27018 standards. Other certifications contribute to platform qualification like NIST 800-53 used by the Federal Risk and Authorization Management Program (FedRAMP). Although these regular audits and certifications don't specifically focus on FDA regulatory compliance, their purpose and objectives are similar in nature to those of CFR Title 21 Part 11 (briasmitatms, Mazzoli, & Vukos-Walker, 2024). These certifications serve to help ensure the confidentiality, integrity, and availability of data stored in Microsoft cloud services. Our qualification approach is also based on industry best practices, including the International Society for Pharmaceutical Engineering (ISPE) GAMP series of Good Practices Guides and the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Good Practices for Computerized Systems in Regulated GxP Environments.

Some examples of capabilities that facilitate Platform Qualification are below.

Dataverse

Microsoft Dataverse provides businesses and application developers a data store for information of interest. Standard and custom tables within Dataverse provide a secure and cloud-based storage option for your data. Tables let you create a business-focused definition of your organization's data for use within apps. If you're not sure whether tables are your best option, consider these benefits (Peart, Kumar, Deore, atikmapari, & Coulter, 2024):

- **Easy to manage** – Both the metadata and data are stored in the cloud. You don't need to worry about the details of how they're stored.
- **Easy to secure** – Data is securely stored so that users can see it only if you grant them access. Role-based security allows you to control access to tables for different users within your organization.
- **Access your Dynamics 365 Data** – Data from your Dynamics 365 applications is also stored within Dataverse, allowing you to quickly build apps that use your Dynamics 365 data and extend your apps with Power Apps.
- **Rich metadata** – Data types and relationships are used directly within Power Apps.
- **Logic and validation** – Define calculated columns, business rules, workflows, and business process flows to ensure data quality and drive business processes.
- **Productivity tools** – Integration with SharePoint, Power BI, Teams, and Excel increases productivity and ensures data accessibility.

Data Availability

One of three legs of the traditional triad of information security is availability, with the others being confidentiality and integrity. Power Platform and Dynamics 365 assures 99.9% availability in Microsoft's Service Level Agreement (SLA) for Microsoft Online Services. Additionally, Microsoft's Business Application Platform (BAP) provides Business Continuity and Disaster Recovery (BCDR) capabilities to all production type environments in Dynamics 365 and Power Platform SAAS applications (Erickson, et al., 2023). Being confident in the ability to have access to information is an essential component of GxP qualification.

Activity Logging and Auditing

Microsoft designed the Dataverse auditing features to meet the external and internal auditing, compliance, security, and governance policies that are common to many enterprises. Dataverse auditing logs changes made to customer records in an environment with a Dataverse database. To enable user access auditing (log access) or activity logging (Read logs), auditing must be enabled at the environment level (Liew, et al., 2024). Of course, there are additional tools and capabilities needed for Qualification — not least of which are the people, processes, and technologies that will consume the logged information and make meaningful decisions based on that information.

Release Wave Updates

Within every process, there is a requirement to ensure it and its supporting technologies are kept up to date in the face of changing threat environments. Within the Power Platform environment, Microsoft does so with what it calls 'release waves.' These generally become available twice a year. Business environments automatically receive these mandatory updates as the release wave is a mandatory update--businesses cannot postpone the updates. These updates are essential for maintaining system integrity and security of the platform and any application(s) built atop the platform (Mathur, et al., 2024).

2. Documentation of Qualification

Cross-walking existing documentation for the audits and certifications discussed above contributes to satisfying the demands of qualification. Customers of Microsoft must retrieve the documentation from the Microsoft Service Trust Portal to support the assertion of Qualification. With this body of evidence (BOE) in hand qualification is not a foregone conclusion — the business still has its own people and process components to the effort. Indeed, the shared responsibility model is essential in every effort to demonstrate the security of cloud service offerings (CSOs).

3. Power Platform Landing Zone Build and Verify

Power Platform environments are containers that administrators can use to manage apps, flows, connections, and other assets, along with permissions to allow organization members to use the resources. GxP Application Lifecycle Management requires the definition of three environments: development, test, and production. To simplify solution management, a best practice is to have project specific development environments. Test and Production environments can be shared by many projects (briasmitatms, Mazzoli, & Vukos-Walker, 2024).

Building the business' landing zone and verifying its configuration and appropriate use of Microsoft and other tools/capabilities are necessary precursors to being able to build qualified applications. In many respects, the Power Platform is the foundation of the building effort, with the landing zone being the first course of blocks upon the foundation. With those elements complete, application makers can erect the rest of the house and all the applications they need within their environment.

Data Loss Prevention (DLP)

Part of verifying the landing zone's capabilities is to ensure it employs DLP at a level that assures applications deriving from the zone will inherit the protections of sensitive data. The use of some form of DLP is essential to qualify their applications, capability, or other processes — so implementing in a manner and location that reduces workload and likelihood of error is a wise course of action. Organizations can use the hosting Azure environment as well as Power Apps to create and enforce DLP policies. Those policies define the consumer connectors that enable the sharing of specific business data with specific users/consumers. A common practice is to ring fence GxP environments to connect only qualified applications (Ferland, et al., 2024). To enable organizational citizen developers at scale, businesses consider creating a prequalified package of connectors.

Monitoring and Request Mechanisms

Manage environment requests with COE Toolkit: Environment Request Management

The environment request components consist of two apps:

1. Admin - Environment Requests app for admins to view and approve environment and connectors requests. Share this app with other admins and assign them the Power Platform Admin SR security role.
2. Maker - Environment Request app for makers to request environments and connectors. Share this app with your makers, and assign them the Power Platform Maker SR security role. See also Set up environment request components - Power Platform | Microsoft Learn

Monitor Environments with COE Toolkit: Set up the Power BI Dashboard

The Power BI dashboard provides a holistic overview with visualizations and insights into resources in your tenant: environments, apps, Power Automate flows, connectors, connection references, makers, and audit logs. Telemetry from the audit log is stored from the moment you set up the Center of Excellence (CoE) Starter Kit, so you can look back and identify trends over time. See also Set up the Power BI dashboard - Power Platform | Microsoft Learn

Manage backlog with COE Toolkit: Innovation Backlog Components

Use the Innovation Backlog app to ask users to submit ideas for apps and flows that need building and describe pain points with the current process. As users describe the process, they will provide information about personas involved, tools used, and measures for improvement. This information is then used to calculate an ROI and complexity score. See also Set up Innovation Backlog components - Power Platform | Microsoft Learn

4. Governance Policy Design and Documentation

No matter where an organization decides to host its GxP qualified processes, there is a uniform requirement to set policy, and procedures. In many ways, this is akin to the truism that an organization should write what it does and do what it writes. The documentation services as guideposts to internal audiences and simultaneously illustrates to external assessors that the organization has specified its expectations. Part of setting up a governance structure that leads to rapid qualification is setting up the right roles with the right permissions for the right people.

Governance requirements are wide-ranging, and of course consist of technical and administrator requirements and their areas of overlap. Among the access control, device control, operational system checks areas of emphasis, there is one that tends to get overlooked in the excited flush of access to new supporting technology — that "persons who develop, maintain, or use electronic systems have the education, training, and experience to perform their assigned tasks" (FDA, 2003). The roles below represent overhead that, if ignored, will lead to undesirable outcomes.

Typical Roles for Governance, Operations, and Maintenance

Each organization has a need for people to fulfill common roles and functions. The roles titles and functions vary and depend on the size and complexity of the organization — business owner, tenant administrator, environment administrator, maker, and quality assurance analysts are fairly typical.

Business / Process Owner

- Responsible for defining Application Lifecycle Management (ALM) standard(s) for the enterprise
- Responsible for defining Data Loss Prevention (DLP) policy(ies) for the enterprise
- Responsible for defining the quality standard for the application(s) for the enterprise

Tenant Administrator

- Responsible for assigning licenses to applications, processes, and interactive users

- Responsible for environment request process(es)
- Responsible for implementing the Application Lifecycle Management (ALM) standard(s)
- Responsible for implementing the Data Loss Prevention (DLP) policy(ies)
- Responsible for developing and implementing the Standard Operating Procedure (SOP) for Service and Validation

Environment Administrator

- Responsible for implementing the development, stage, and production environments
- Responsible for implementing the ALM process
- Responsible for configuring logging and other security services
- Responsible for restoring environment, among other tasks, as necessary

Maker

- Responsible for documenting application behavior(s)
- Responsible for documenting quality controls for the application
- Responsible for building the application
- Responsible for testing the application in pre-production and production contexts
- Responsible for documenting test results
- Responsible for adhering to the ALM process

Quality Assurance Analyst

- Responsible for evaluating application behavior in the context of the production system
- Responsible for ensuring completeness of application and test documentation

Electronic Signature

An essential element of the Governance structure is the characterization of acceptable electronic signatures. There are several options to fulfill electronic signature requirements, including using a third-party eSignature solution or extending the platform with a customer component/plug-in to fulfill the required functionality. Some of the popular third-party solution that have out of the box integration with Power Platform are:

- **DocuSign eSignature** - https://appsource.microsoft.com/en-us/product/web-apps/docusign.docusign-azure-offer and DocuSign + Microsoft: Better Together
- **Adobe Acrobat Sign** - https://appsource.microsoft.com/en-us/product/web-apps/adobe.adobe_acrobat_sign_saas and Microsoft PowerApps and Flow E-Signatures | Adobe Acrobat Sign

5. Design SOP for Verification

Repeatability and low variability are key expectations in any GxP related qualification and validation effort. To achieve verification, an assurance that developers build applications correctly, it is important for the business to establish standard operating procedures (SOP) that lead to consistent outcomes.

Standardized development processes (e.g., standardized use cases, coding style, documentation style, embedded documentation, tool chain use, integrated security testing) are an essential component to being able to claim that SOPs are leading to consistent application builds. Of course, validating that the application is doing what it is supposed to do, correctly, is a different discussion and covered below.

SOPs are, like the role discussion above, are a frequently discounted element of having a development team that supports the need to generate functional software and supports the requirement to be able to prove security. It is a rare developer that likes to write how they do their job, likes to abide by what others have written, and live under strictures that do not frequently make their immediate lives easier.

6. Application Verification and Validation

Once the organization has established its verification SOP, putting it into effect is key to being able to demonstrate security of a GxP process. An application's verification and validations plan must identify the applications purpose, design, life cycle, and testing plan. The verification component of the plan ensures, ideally through automation, that the application is adhering to the design specifications. The validation component of the plan should clearly define process controls and technical controls that are in place to ensure objective evidence that software specifications conform to user needs and intended uses, and that the software and supporting systems consistently fulfill their particular requirements.

Microsoft provides tools to assist with the creation of an application verification plan. One tool within the Power Application toolkit to help with that is the Metadata Diagramming tool. Visual representation of metadata can be useful, especially when you are trying to describe the relationship between entities in the system. Organizations can use the Metadata Diagram tool to read the Organization web service metadata and generate entity relationship diagrams from that data (Hecke, Daly, & Deore, 2023). Another capability readily available is the Solution Layering approach that Microsoft advocates — and has been taught in Computer Science classrooms for decades —

modularity and reuse. After verifying a particular layer is functioning as designed and well (verification), we reduce the need to test it in the future. In this context, the Power Platform refers to that as 'Solution Layers' which are part of the Application Life Cycle Management (ALM).

Application Life Cycle Management (ALM)

Managed solutions are used to deploy to any environment that isn't a development environment for that solution. This includes test, user acceptance testing (UAT), system integration testing (SIT), and production environments. Managed solutions can be serviced (upgrade, patch, and delete) independently from other managed solutions in an environment. As an ALM best practice, managed solutions should be generated by a build server and considered a build artifact (shmcarth, et al., 2022).

Application Pipelines

Pipelines in Power Platform aim to democratize application lifecycle management (ALM) for Power Platform and Dynamics 365 customers by bringing ALM automation and continuous integration and continuous delivery (CI/CD) capabilities into the service in a manner that's more approachable for all makers, admins, and developers (Burke, et al., 2024).

Solution Layers

When envisioning an application as a series of layers that accomplish different tasks we know that each layer must pass information to those above or below it. At the bottom of this solution layer is of course the system layer.

The system layer contains the entities and components that are required for the platform to function. With a few exceptions, solution components use a "top wins" behavior where the layer that resides at the top determines how the component works at app runtime. This layering approach helps speed development of Power Apps, as well as allows customization of standard behaviors as necessary (Peart, Deore, Steinmetz, & Vivek, 2022).

How Managed Solutions are Merged

The processes that Microsoft Dataverse uses to merge customizations emphasize maintaining the functionality of the solution. Although every effort is made to preserve the presentation, some incompatibilities between customizations might require that the computed resolution change some presentation details in favor of maintaining the customization functionality. Major areas to focus on are (shmcarth, et al., 2023):

- **Form Customizations** - One way to avoid form merging is to provide new forms for any Dataverse entities.

- **SiteMap Customizations** - Only the differences are included in the managed solution. These differences include items that are changed, moved, added, or removed.
- **Option Set** - A managed solution usually updates or adds options for option sets that are already in the environment, for example, the Category or Industry option sets for an account. When a managed solution modifies the options available in an option set, all the options defined in the managed solution are available in the environment.
- **Security Role** - Don't use a custom Solution to modify predefined security roles. These updates will be removed when the predefined roles are updated by the system. Create a copy of the predefined role and manage the copied role in your custom solution.

The validation of the application(s) as noted above requires dedicated effort. It requires a repeatable process(es) by which the developer can demonstrate fulfillment of the design's purpose(s) and fulfillment of the validation plan. Developers can frequently achieve this through the development and use of acceptance criteria and being transparent to 3rd party consumers about the contents and results of the acceptance testing. Validation also requires a repeatable and effective process(es) by which the developer can demonstrate security throughout the life cycle of the application — inclusive of what happens to collected data upon decommissioning of the application.

7. Pilot Verification (and Validation)

With governance policy in place, SOPs for application development in place, SOPs for verification in place, and a Power Platform Landing Zone built, it is time for a dry run with a non-critical application. With such a pilot, organizations can design and build a prototype application in its development environment, move it to its test environment, and practice moving it to the production environment. The intent of this prototype application is less focused on the particular problem(s) the application is trying to solve than ensuring the surrounding context leads to a well-built application. If the developer intends on using this Pilot as a throw-away prototype, skipping or minimizing the validation of the application is appropriate. If, as is often the case, the throw-away Pilot gets morphed into long-term use, the developer must complete the entirety of the application's verification and validation plan.

8. Build New App with SOP or Verify and Validate Existing App

We have reached the last step in helping an organization make use of Power Platform and Dynamics 365 in their GxP efforts — building the applications to support their processes! It is important to test an application using Microsoft Power Apps Test Studio or something similar to it.

Test Studio

Power Apps Test Studio is a low-code solution to write, organize, and automate tests for canvas apps. In Test Studio, you can write tests using Power Apps expressions or use a recorder to save app interaction to automatically generate the expressions. You can play written tests back within the Test Studio to validate app functionality, and also run the tests in a web browser and build the automated tests into your app deployment process (Deore, Maniar, Vivek, & Aengusheaney, 2023).

Of course, after developing the application, migrating it to the test, user acceptance (as applicable) and production environments is a critical task. Pipelines is the capability to help make that task simpler.

Conclusion

It is completely possible for a business to jump straight into requirements elicitation and coding when working to automate processes, but doing so will rarely lead to being able to successfully demonstrate GxP Qualification and/or Verification.

This Power Platform GxP Accelerator instead offers a solution for pharmaceutical organizations seeking efficient GxP compliance. To be successful, we have suggested a series of activities to pursue that culminates in an application that can, defensibly, satisfy qualification and verification requirements.

By leveraging insights from this whitepaper and Microsoft's Dynamics 365 GxP best practices, organizations can navigate GxP regulations effectively, ensuring innovation, efficiency, and the delivery of high-quality products and services.

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