

USDM + Microsoft Partnership for Compliance

01 USDM Vendor Assessment

USDM conducts annual assessment of Microsoft for cloud compliance to quality processes, SDLC and release process.

Vendor Assurance Report

02 Release Management

Microsoft supports validation efforts with their ISO 9001 certified change management and release management process for each major and minor product release.



03 USDM Initial Qualification

USDM takes into consideration the annual Assurance Report and Microsoft's release management to complete the initial qualification based your intended use. FDA's CSA guidelines are used, saving additional time and cost.

Plan

Functional Risk Assessment

Configuration Qualification

Operational Qualification

Summary Report

04 USDM Continuous Assurance

USDM's Cloud Assurance subscription keeps the Infrastructure and application compliant with each release. USDM assesses the release notes and Microsoft's RVP results. The assessment and additional risk based test scripts are provided to the client. USDM utilizes proprietary tools to accelerate the assessment and compliance.

Annual Audit

Release Monitoring

Release Assessment

Release Scripts

Configuration Qualification


Operational Qualification

Cloud Assurance™



Managed service delivering
end-to-end GxP compliance
from implementation through ongoing
validation maintenance, including new
releases, for all your cloud applications.

- USDM best practices and automation **decrease** your implementation and validation time
- Delivered via **Computer Software Assurance** methodology
- **Onboarding, Initial Qualification and Continuous Compliance:**

Vendor Assurance Report	System Implementor	Initial Qualification	Continuous Compliance
<ul style="list-style-type: none">• Vendor Assessment	<ul style="list-style-type: none">• Configuration Specs• SIT• UAT 	<ul style="list-style-type: none">• Plan• Risk Assessment (SRS/RA)• Configuration Qualification• Operational Qualification• Summary Report	<ul style="list-style-type: none">• Annual Vendor Assurance Report• Continuous Monitoring• Release Assessment• Test scripts for High Risk GxP changes

UPC Cloud Assurance™ Maintenance Core

USDM will help manage your platform updates to ensure continuous compliance

Task	Responsibility	
	USDM	CUSTOMER
Annual Vendor Assurance Report	✓	
Continuous Release Monitoring	✓	
Analysis of release notes and impact assessment of core functionality	✓	
Test scripts for High Risk GxP core functionality based on assessment	✓	
Impact assessment of customer specific use cases		✓
Test scripts for High Risk GxP customer specific use cases		✓
Managing change control process		✓
Configuration		✓
Resolving technical issues		✓

UPC Cloud Assurance™ Maintenance Premium

All the support of **Core**, plus **customer specific** support for your continuous compliance

Task	Responsibility	
	USD M	CUSTOMER
Annual Vendor Assurance Report	✓	
Continuous Release Monitoring	✓	
Analysis of release notes and impact assessment of core functionality	✓	
Test scripts for High Risk GxP core functionality based on assessment	✓	
Impact assessment of customer specific use cases	✓	
Test scripts for High Risk GxP customer specific use cases	✓	
Managing change control process		✓
Configuration		✓
Resolving technical issues		✓