

USDM can optimize your existing SharePoint M365 application to include the management of GxP-regulated content. Utilizing USDM's best practices and automation will significantly decrease your implementation and validation efforts of SharePoint M365. Further, USDM's Cloud Assurance managed subscription will maintain compliance with all your SharePoint M365 releases so you can keep innovating in a continuously compliant state.

## USDM + Microsoft Compliance Partnership

### 01 USDM Vendor Assessment

USDM conducts an annual assessment of Microsoft for cloud compliance to quality processes, SDLC, and release process. Microsoft Azure and Microsoft 365 are Cloud Assurance Certified technologies.

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 considers the annual Assurance Report and Microsoft's release management to complete the initial qualification activities based on your intended use. GAMPs building block methodology and FDA's Computer Software Assurance (CSA) guidelines are used, along with automated compliance testing, saving greater time and cost.

### 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 and provides the assessment and additional automated risk-based test scripts. USDM utilizes proprietary tools to accelerate the assessment and compliance activities.

Plan

Annual Vendor Assurance Report

Functional Requirements with Risk Assessment

Continuous Monitoring

Configuration Specification

Release Assessment

Automated Configuration Verification

Regression Testing

Automated Functional Qualification

Test Scripts for High-Risk Regulated Changes

Automated Summary Report with Trace Matrix

## SharePoint M655 Release Management

USDM's Cloud Assurance subscription will help manage your vendor updates to ensure your SharePoint M365 environment stays in a **continuous state of compliance**, and you can focus on utilizing new functionality. Below are various options to meet your business needs.

Core ER	Premium ER	Premium ERES
<b>Core for Electronic Records</b>	<b>Client Specific for Electronic Records</b>	<b>SharePoint + DocuSign for ERES</b>
<ul style="list-style-type: none"> <li>• M365 Vendor Assurance Report</li> <li>• SharePoint M365 E5 Functional Assessment</li> <li>• Plan</li> <li>• <b>Core Functional Requirements with Risk Assessment</b></li> <li>• <b>Core Configuration Specification</b></li> <li>• Automated Configuration Verification</li> <li>• Automated Functional Qualification</li> <li>• Automated Summary Report with Trace Matrix</li> <li>• 12 months of USDM Cloud Assurance continuous compliance for Core SharePoint M365</li> </ul>	<ul style="list-style-type: none"> <li>• M365 Vendor Assurance Report</li> <li>• SharePoint M365 E5 Functional Assessment</li> <li>• Plan</li> <li>• <b>Client-Specific Functional Requirements</b></li> <li>• <b>Client-Specific Risk Assessment</b></li> <li>• <b>Client Specific Configuration Specification</b></li> <li>• Automated Configuration Verification</li> <li>• Automated Functional Qualification</li> <li>• Automated Summary Report with Trace Matrix</li> <li>• 12 months of USDM Cloud Assurance continuous compliance for Core and Client Specific SharePoint M365</li> </ul>	<ul style="list-style-type: none"> <li>• M365 &amp; DocuSign Vendor Assurance Reports</li> <li>• SharePoint M365 E5 &amp; DocuSign UCM-</li> <li>• ERES Functional Assessment</li> <li>• Plan</li> <li>• <b>ERES Functional Requirements with Risk Assessment</b></li> <li>• <b>ERES Configuration Specification</b></li> <li>• Automated Configuration Verification</li> <li>• Automated Functional Qualification</li> <li>• Automated Summary Report with Trace Matrix</li> <li>• SharePoint M365 E5 / DocuSign Admin SOP</li> <li>• SharePoint M365 E5 / DocuSign User SOP</li> <li>• DocuSign E-Signature Usage Policy</li> <li>• 12 months of USDM Cloud Assurance continuous compliance for Core SharePoint M365 &amp; DocuSign</li> </ul>
<b>2-3 months</b>	<b>3-4 months</b>	<b>1-2 months</b>

### SharePoint M365 + DocuSign eSignature Ready for GxP Use

- USDM best practice Configuration Specification for Part 11 / Annex 11 compliance allows you to rapidly configure SharePoint M365 E5 for site collection, secure with E5 Azure Active Directory, and use [DocuSign](#) for workflows and electronic signatures
- USDM automated verification and qualification testing relieve your testing effort while providing the documented summary and traceability evidence you need for compliance
- Utilize our SharePoint M365 Standard Operating Procedures (SOPs) to ensure tasks are performed according to approved procedures
- USDM Cloud Assurance ensures your validated SharePoint M365 environment maintains a continuous state of compliance through all releases, and changes

**MACC Eligible!**  
Use your Microsoft Azure Consumption Commitment (MACC) on USDM's Cloud Assurance subscription.

**Increase the return on your technology investments. Contact USDM today.**



Phone US: +1 (888) 231 0816  
Phone UK: +44 (0) 7818 428014  
Email: [usdm@usdm.com](mailto:usdm@usdm.com)  
Website: [usdm.com](http://usdm.com)

COPYRIGHT © 2022 USDM Life Sciences.  
All rights reserved.