



# USDM Cloud Assurance™



SharePoint M365 Qualification and  
Cloud Assurance



**700+**

**Clients Globally**

8 of Top-10 Pharma  
15 of Top-20 Med Dev  
200+ Emerging

**200+**

**Cloud  
Assurance  
Subscribers**

**20+**

Years Regulatory  
Compliance  
Experience

At USDM Life Sciences, our purpose is to bring clarity and action to the interplay of technology and regulations to help biotech, pharma, and medical device companies deliver trailblazing outcomes.

Google



Microsoft



box

ORACLE®

Veeva

DocuSign®

okta

salesforce

SERVICEMAX

servicenow

ptc



# Business Challenges We Solve

- ✓ Time vs. Cost Pressure
- ✓ Compliance Burden
- ✓ Keeping up with Cloud Vendor
- ✓ Scale GxP Use Cases
- ✓ Future-Proof IT and Quality Decisions
- ✓ Finding The Right Talent



# Our Customers

## PHARMA



## MEDICAL DEVICE



## BIOTECH



## AND MORE





# SharePoint M365 Customers





# USDM's Strategic Framework

Connecting **technology, people, and processes** to **deliver trailblazing business outcomes**



USDM Cloud Assurance™

- Vendor Audit
- Implementation/qualification
- Automated Testing
- Continuous Compliance
- IS Health Check

- Superior Program Management
- Organizational Change Management and Adoption

- CSA Assessment
- CSA Education/Training
- IaaS/PaaS Compliance Framework
- Compliance/qualification Framework for AI platforms and ML/DL Models

- Innovation Roadmap
- GxP Compliant Bots
- Data Management
- Data Science & Analytics
- Artificial Intelligence
- Cognitive Services

**Insights**

**Business Process**

**People**

**Technology + Compliance**



# SharePoint M365 Services

- Cloud Assurance™
  - Annual Microsoft 365 Audit, Initial Qualification, Continuous Release Management
- Organizational Change Management
  - End-User Training and Communications
- Data Migration Assistance
- FastTrack Implementation Assistance
- Technical Design, Implementation, and Configuration Services
- Content Governance
- Post Go-Live Configuration & Change Management



# 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 qualification 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 on the 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





# SharePoint M365 Qualification & Continuous Compliance

Core ER	Premium ER	Premium ERES
<b>Core</b> for Electronic Records	<b>Client Specific</b> for Electronic Records	<b>SharePoint + DocuSign</b> for ERES
<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-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>
2-3 months	3-4 months	1-2 months



# SharePoint M365 – License Scope

## SharePoint M365

- Enterprise E5
- Enterprise E3
- Business Basic
- Business Standard
- Business Premium

## Identity and Access Management

- Azure AD P2 via M365 Enterprise E5
- Azure AD P1 via M365 Enterprise E3
- Azure AD P1 via M365 Business Premium
- M365 Business Basic + Azure AD add-on
- M365 Business Standard + Azure AD add-on

## Basic Auditing with 90-day retention

- Microsoft 365 Business Basic
- Microsoft 365 Business Standard
- Microsoft 365 Business Premium

## Advanced Auditing up to 10-year retention

- M365 Enterprise E5
- M365 Enterprise E3 + M365 E5 Compliance add-on
- M365 Enterprise E3 + M365 E5 eDiscovery and Audit add-on



# Microsoft 365 Auditing

## Basic Audit



### Log and search for audited activities:

- Enabled by default
- Thousands of audited events
- 90-day audit record retention
- Access by GUI, cmdlet, and API

## Advanced Audit



### Advanced Audit capabilities:

- Longer retention of audit records
- Custom audit retention policies
- High-value, crucial events
- Higher bandwidth access to API

## qualification of SharePoint for GxP Content Management Solution

**Turning Point Therapeutics needed GxP document storage integrated with electronic signature capabilities.** They already used SharePoint for non-GxP document storage, but their audit trail would not be maintained indefinitely by Microsoft.

**USDM integrated DocuSign as a GxP compliant e-Signature solution with SharePoint.** USDM developed training material for the employees to drive adoption of the new system and created a PowerShell script to export audit trail documentation to a secure location.

**Turning Point optimized their existing technology and minimized IT expense while adding GxP functionality.** There was decreased time and cost to validate SharePoint Online and increased system adoption and speed to use with organizational change management (OCM) training.



# USDM Cloud Assurance™



A managed service subscription that offloads the **initial qualification/qualification and ongoing compliance maintenance** your company must undergo with every new release.

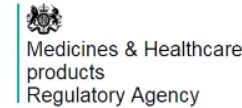
USDM absorbs this workload and delivers **end-to-end GxP continuous compliance** saving you significant time and money while increasing your utilization of the technology for regulated use cases.

- USDM best practices and automation **decrease implementation and qualification time**
- Delivered via **building block CSA methodology**
- **Onboarding, Initial Qualification / qualification and Continuous Compliance:**

Vendor Assurance	Technical Services*	Initial Qualification/qualification	Continuous Compliance
<ul style="list-style-type: none"><li>• Vendor Audit</li><li>• Vendor Assurance Report</li><li>• Vendor Functional Compliance Assessment to Unified Compliance Matrix - ERES</li></ul>	<ul style="list-style-type: none"><li>• Design</li><li>• Implementation</li><li>• Configuration</li><li>• FastTrack</li><li>• Automated Execution</li></ul>	<ul style="list-style-type: none"><li>• Plan</li><li>• Functional Requirements with Risk Assessment</li><li>• Configuration Specification</li><li>• Automated Configuration Verification</li><li>• Automated Functional Qualification</li><li>• Automated Summary Report with Trace Matrix</li></ul>	<ul style="list-style-type: none"><li>• 12 months of continuous compliance for core functionality</li><li>• Annual Vendor Assurance Report</li><li>• Continuous Monitoring</li><li>• Release Assessment</li><li>• Regression Testing</li><li>• Test Scripts for High-Risk Regulated Changes</li></ul>

# Regulatory Expertise

USDM has 20+ years of focus on regulated life sciences industries and employs former agency staff that help write some of these laws





# Cloud Assurance Maintenance Core

USDM will help manage your vendor updates to ensure **continuous compliance** of the core functionality

Task	Responsibility	
	USDM	CUSTOMER
Annual Vendor Assurance Report	✓	
Continuous Release Monitoring	✓	
Analysis of release notes and impact assessment of core functionality	✓	
Automated regression testing of core functionality	✓	
Automated testing of new GxP functionality	✓	
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		✓



# Cloud Assurance Maintenance Premium

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

Task	Responsibility	
	USDM	CUSTOMER
Annual Vendor Assurance Report	✓	
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Analysis of release notes and impact assessment of core functionality	✓	
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Impact assessment of customer specific use cases	✓	
Automated of customer specific use cases	✓	
Managing change control process		✓
Configuration		✓
Resolving technical issues		✓





# Cloud Assurance Optional Services

USDM can help you get the **maximum ROI** from your technology

Task	Details
<b>Standard Operating Procedures (SOP) Development</b>	Develop system SOPs, such as Use and Operations, Change Control, and Computer System qualification
<b>Organizational Change Management (OCM) Training and Communications</b>	Develop end-user training materials and presentation, including email communications to increase awareness of system value and drive end-user adoption
<b>Single Sign On (SSO) Integration</b>	Develop requirements and testing for system integration with SSO
<b>Data Migration</b>	Develop data migration plan and test scripts for migrating data from legacy systems
<b>Other</b>	If you have additional needs, we can support most technical services to support your objectives



# USDM Cloud Assurance™



SharePoint M365 ERES

SharePoint Document Management +  
DocuSign eSignatures





## SharePoint M365 E5 ERES + CA Document Management + eSignatures

USDM best practice Configuration Specification for Part 11 / Annex 11 compliance allows you to **rapidly configure SharePoint M365 E5** for site collection, secure with **Azure Active Directory P2**, 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.

USDM ready to use **SharePoint M365 E5 / DocuSign Standard Operating Procedures** ensure compliance and essential tasks are performed according to approved procedures.

12 months included of **USDM Cloud Assurance™** ensures your validated SharePoint Online M365 E5 and DocuSign, and maintains **continuous compliance** through all releases, patches, and changes.



Use  
Case

# SharePoint M365 E5 RAPID Ready for GxP Use

## Gaps in GxP Document Management

Customer needed to solve for GxP document management gaps in their quality processes and was exploring eDMS and eSignature solutions.

## Existing SharePoint Environment Configured to Meet GxP Needs

Customer engaged USDM to select GxP ready vendors. Instead, USDM implemented Part 11 compliant eSignatures with **Azure Active Directory** and **DocuSign** that enabled compliant document management processes in the customer's existing SharePoint environment.

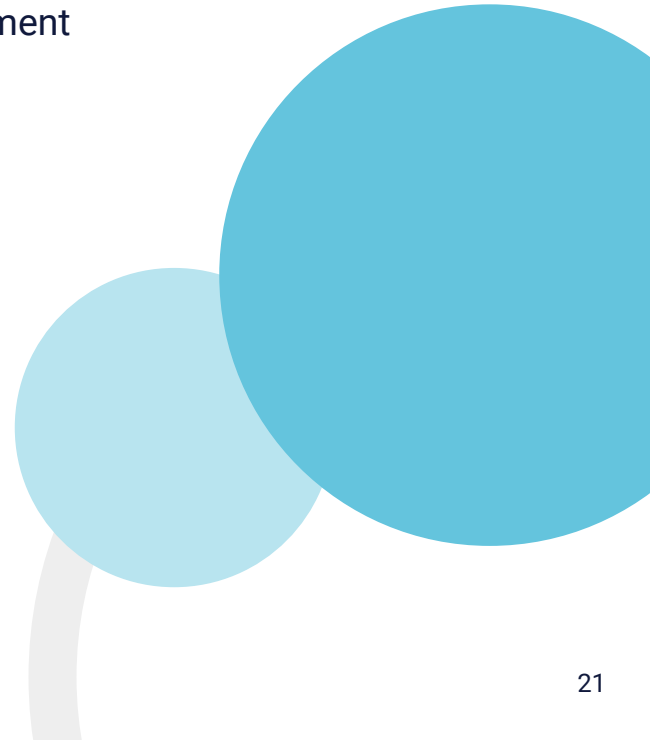
## Increased Use and Maximized ROI of SharePoint

USDM helped customer get greater use of SharePoint by expanding GxP and Non-GxP usage. Customer saved money by utilizing their MACC funds and not having to add additional applications to their tech stack to meet their regulatory requirements. Customer also expanded Azure use by storing more documents and data in Azure.



# SharePoint M365 ERES

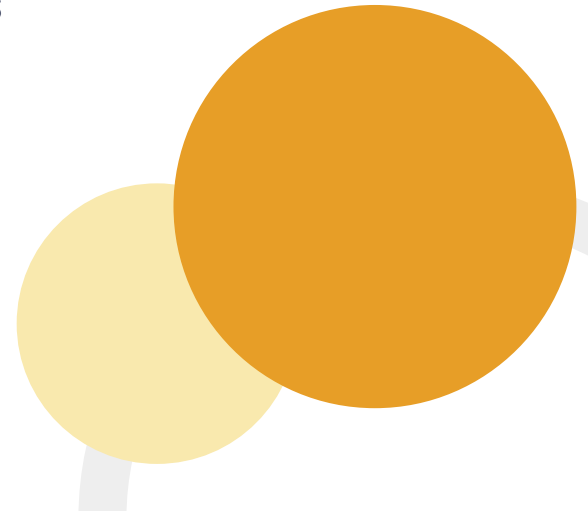
- Defensible annual M365 & DocuSign Vendor Assurance Reports for the FDA
- M365 E5 & DocuSign Part 11 and EU Annex 11 Technical Assessment
- Configuration Specification
- Automated Configuration Verification
- Automated Execution Core Test Scripts
- Automated Summary Report with Trace Matrix
- SharePoint M365 E5 / DocuSign Admin SOP
- SharePoint M365 E5 / DocuSign User SOP
- SharePoint M365 E5 / DocuSign E-Signature Usage Policy
- 12 months of USDM Cloud Assurance™ continuous compliance for core SharePoint M365 & DocuSign functionality





# SharePoint M365 ERES – Benefits

- ✓ Add on to SharePoint Online M365 E5 license
- ✓ Transactable with MACC
- ✓ Reduce time vs. cost pressure
- ✓ Fast-track qualification and requalification efforts
- ✓ Reduce QA / IT compliance burden and workload
- ✓ Keep up with cloud vendor releases
- ✓ Continuous automated cloud compliance
- ✓ Scale GxP use to maximize ROI on technology





# USDM Cloud Assurance™

Ensuring a continuously compliant tech stack

## Applications / SaaS



## Platform Services / PaaS



## Environment / IaaS





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Configuration		✓
Resolving technical issues		✓





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# Why Cloud Assurance

- ✓ Essential component for **continuous compliance**
- ✓ All the functionality, **none of the compliance headaches**
- ✓ Trusted solution by **200+ Life Science organizations**
- ✓ **Faster implementation and integration** to maximize ROI
- ✓ **Scalable technology solutions** to grow with your business and establish your compliant IT foundation
- ✓ Extensive digital transformation services including **people and process changes**

# Thank you!



**First Last**

Title

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