Cloud Assurance for SharePoint

GxP Validation and Continuous Compliance Subscription

USDM Life Sciences

20+	**700+**	**200+**	**20+**
Years Regulatory Compliance Experience	**Clients Globally** 8 of Top-10 Pharma 15 of Top-20 Med Dev 100+ Emerging	**Cloud Assurance Subscribers**	**World-Class Technology Partnerships**

Microsoft · Google · Veeva · box · DocuSign · COMPLIANCEQUEST Quality . Compliance . Collaboration . Communication

aws · servicenow · ORACLE · SERVICEMAX · ptc · okta · salesforce

DOMAIN KNOWLEDGE

- Pharma, Med Dev, Biotech experience
- Global Regulations
- Life Sciences GxP use cases and best practices
- One-stop-shop for compliance and technology

DIGITAL TRANSFORMATION

- IS Health Check / Strategy and roadmap planning
- Cloud Assurance™ enables continuous compliance
- SaaS, PaaS, IaaS validation and implementation
- Unleash the value of your data

USDM's SharePoint Solutions

➢ USDM Cloud Assurance continuous compliance subscription

➢ Validation and Program Management

➢ Annual Vendor Audit

➢ Content Governance

➢ Data Migration

➢ End-User Training and Communications (OCM)

➢ Post Go-Live Configuration & Change Management

➢ Unify Public Cloud for Azure

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 **significantly decrease your implementation and validation time**

- Delivered for **Computer System Validation** or **Computer Software Assurance** depending on preferred methodology

- **Onboarding and Initial Validation** includes:

|		
VENDOR AUDIT	PART 11 & ANNEX 11 ASSESSMENT	VALIDATION PLAN
USER REQUIREMENTS & FUNCTIONAL SPECIFICATION	RISK & IMPACT ASSESSMENTS	IQ/OQ/PQ PROTOCOL & TEST SCRIPTS
TRACEABILITY MATRIX	USE & ADMINISTRATION SOPs	VALIDATION SUMMARY REPORT

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Cloud Assurance™ Maintenance

USDM will manage your vendor updates to ensure **continuous compliance**

Features	Deliverables
Vendor Changes	✓ Manage all cloud vendor's release cycles
Impact Assessments	✓ Impact assessments based on release notes of core system ✓ Impact assessments for customer-specific use cases (OQ/PQ) ✓ Updates to customer validation documents ✓ Quarterly Business Process Improvement meetings for increased ROI
Test Execution	✓ Test execution of core system ✓ Test execution of customer-specific use cases (OQ/PQ) ✓ Reports and analyses

Various subscription packages available

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IS Health Check

- Complimentary to USDM customers

- Indicates your state of regulatory compliance and IS efficiency

- Maturity Model is defined at 6 levels with scores from 0-5

- Designed for the purpose of scoping and planning a more detailed strategy and roadmap

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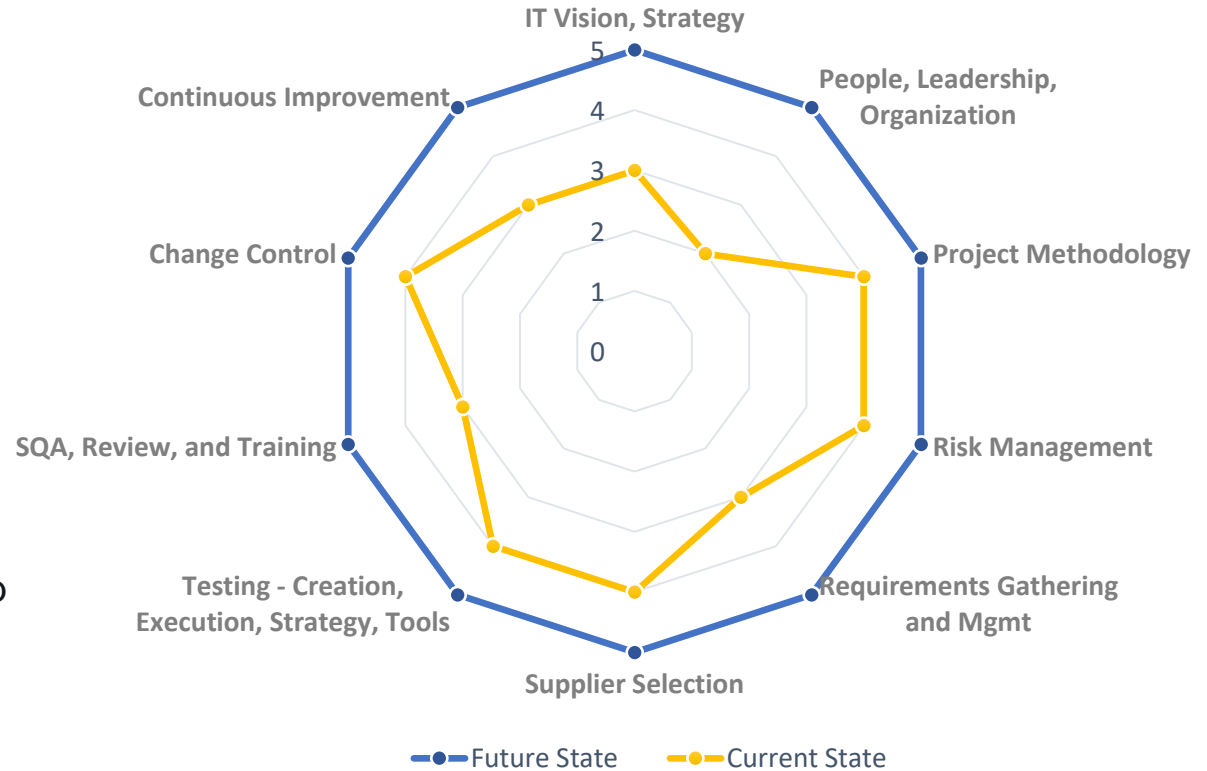
Organizational Change Management

PLAN

- Develop and deploy an OCM Strategy and Communication Plan
- Develop the communications calendar and timeline
- Develop a project plan to coordinate activities, track progress, and communicate key messages from stakeholders

EXECUTE

- Publish a communications and training calendar
- Communicate change and business deadlines/ milestones with all stakeholders
- Create OCM materials; emails, articles, literature, and events
- Co-develop training materials

TRAIN

- Co-lead the development and review of a training plan, documents, and schedules
- Co-lead the implementation of the training program and perform a training needs assessment to determine optimal training delivery

MAINTAIN

- Ongoing support and resistance management
- Survey and results
- Steady state support

USDM Training and Communication Program

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Why Cloud Assurance for **SharePoint Online**

> ❝ *My billable time is an asset my company wants maximized. Validation is important, but it's the lost opportunity cost of me spending my time on compliance verses other priorities where I can return greater value.* ❞

- ✓ Leverage your IT investment for GxP compliant content management

- ✓ Trusted solution by 200+ Life Science organizations

- ✓ Significantly reduce validation effort

- ✓ Maintain ongoing SharePoint cloud compliance

- ✓ Enables faster implementation of new SharePoint features

- ✓ Scalable vendor solutions to grow with your business and establish your compliant IT foundation

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The USDM Strategy Framework

Connecting **technology, people**, and **data** in **new ways** for **real-time insights** to **improve business outcomes**

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

- CSV/CSA Assessment
- CSA Education/Training
- Azure DevOps Compliance Framework
- Compliance/Validation Framework for AI platforms and ML/DL Models

Insights

- Superior Program Management
- Organizational Change Management and Adoption

Business Process

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

People

Technology + Compliance

Thank you!
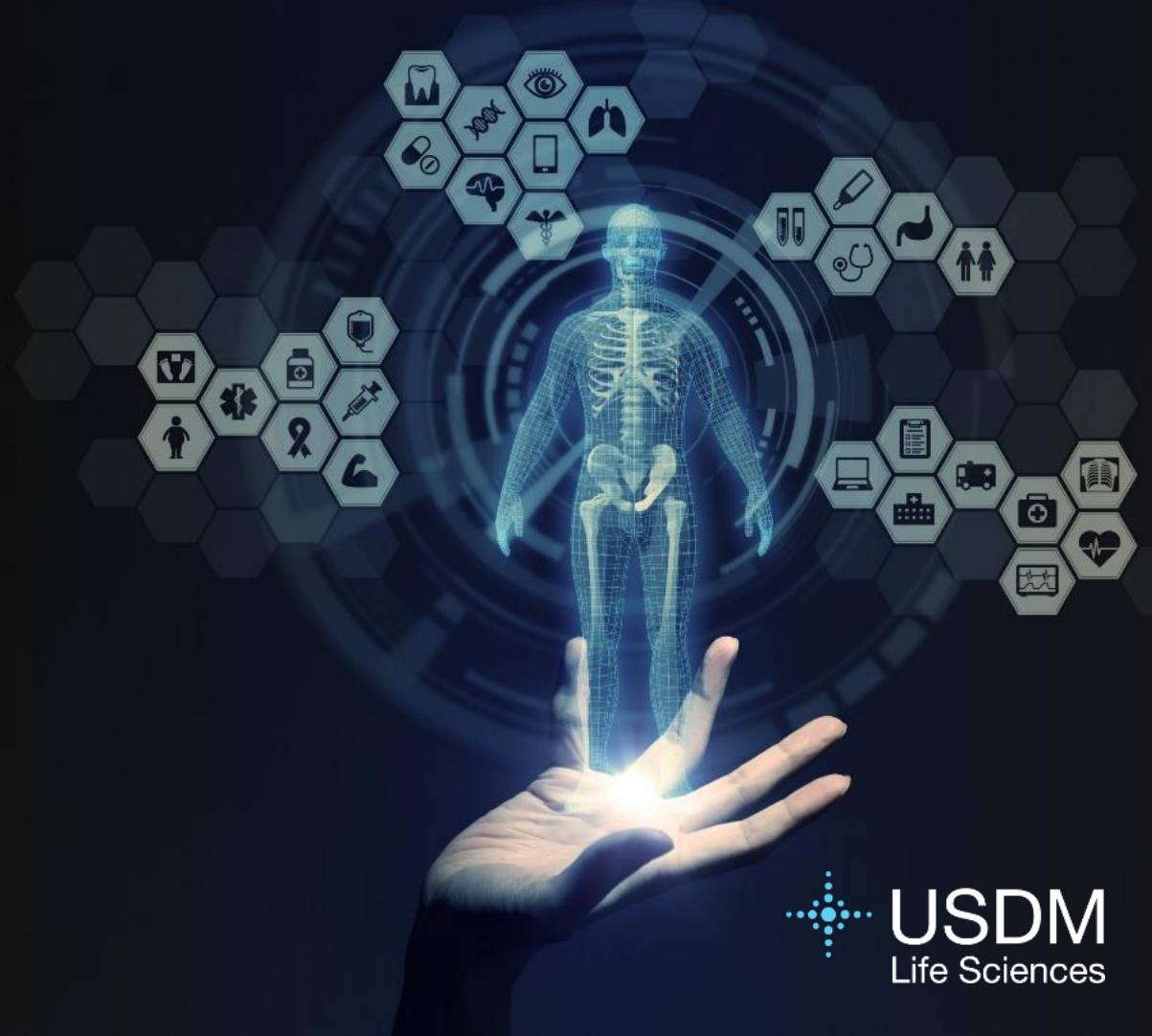
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Learn More

Unify Public Cloud for Azure is in innovative solution to achieve a GxP compliant Azure tech stack.

It addresses SaaS (business applications), PaaS (cloud services), and IaaS (global infrastructure).

All packaged in USDM's Cloud Assurance subscription to manage ongoing updates and decrease your compliance burdens.

On-Demand Webinar
[Click Here](#)

Product Datasheet
[Click Here](#)

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