USDM
Life Sciences

Cloud Assurance for Azure

An innovative solution to accelerate your regulated workload with **Azure**

USDM Life Sciences

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   aws   box

ORACLE   Veeva   DocuSign   okta

salesforce   SERVICEMAX   servicenow   ptc

Our Customers

PHARMA	MEDICAL DEVICE	BIOTECH	AND MORE

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
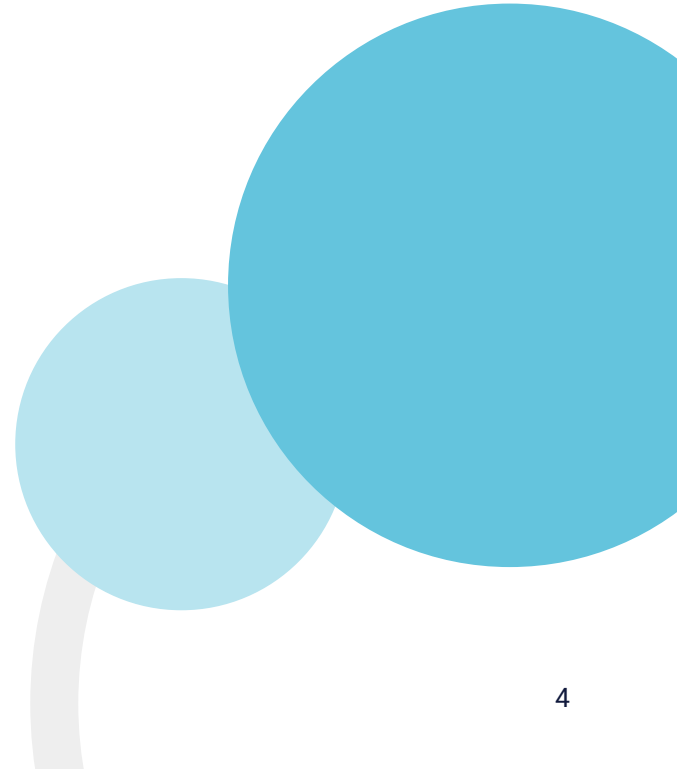
USDM's Strategic Framework

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

USDM Cloud Assurance™

- Vendor Audit
- Implementation/Validation
- 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/Validation 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

Public Cloud Possibilities

Turn compliance into a **strategic competitive advantage** with USDM's Cloud Assurance

	Research & Development	Clinical Trials	Manufacturing & Distribution	Post Market Surveillance	Customer / Patient
OLD	Siloed and legacy infrastructure	Slow, costly, low success rate + stringent regulatory requirements	Track-and-trace compliance through supply chain and quality events	Product safety and product recalls	Data security risks
NEW	De-Risk and advance R&D with AI/ML tools that work across diverse data sets to **accelerate and improve drug development**	Improve and augment clinical trials with real-time data and biometrics to **enhance intelligence, insight and accuracy**	Optimize manufacturing with ML, business insights, and highly secure IoT tech to **modernize manufacturing**	Proactively, securely monitor volumes of real-world data, distributed across disparate sources with **compliance and security built-in**	**Improve patient value**, adherence and engagement by drawing integrated data and actionable insights from drugs, devices, and software

Advanced Analytics and AI transforming the industry (market valued at 1.1B in 2019, 4.9 B by 2025). You need a compliant tech-stack solution to enable new busines processes, workloads, and data acceleration.
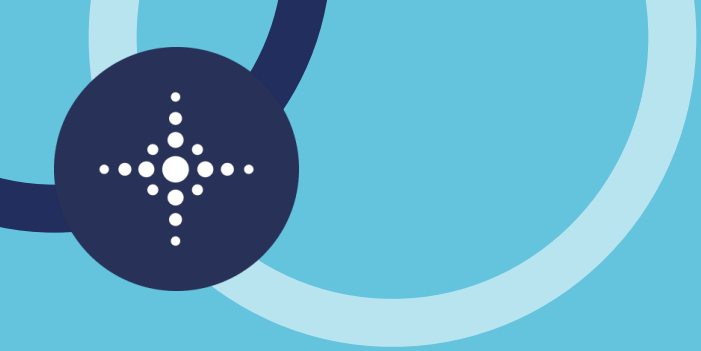
Azure Assurance

Services, accelerators and subscriptions to help you land and expand your regulated workloads on the cloud

New to the Cloud	Already in the Cloud
Assess & Plan	
Readiness Assessment	Compliance Assessment
Implementation Plan	Remediation Plan
Design & Implement	
Procedural Control	Procedural Updates
Technical Configuration	Technical Remediation
Compliance	
Initial Qualification	Gap Qualification
Continuous Compliance	
Cloud Assurance™	
Optimize and Transform	
Migrate Analyze AI / ML Orchestrate Innovate	

Cloud Compliance Simplified with GxP Technologies
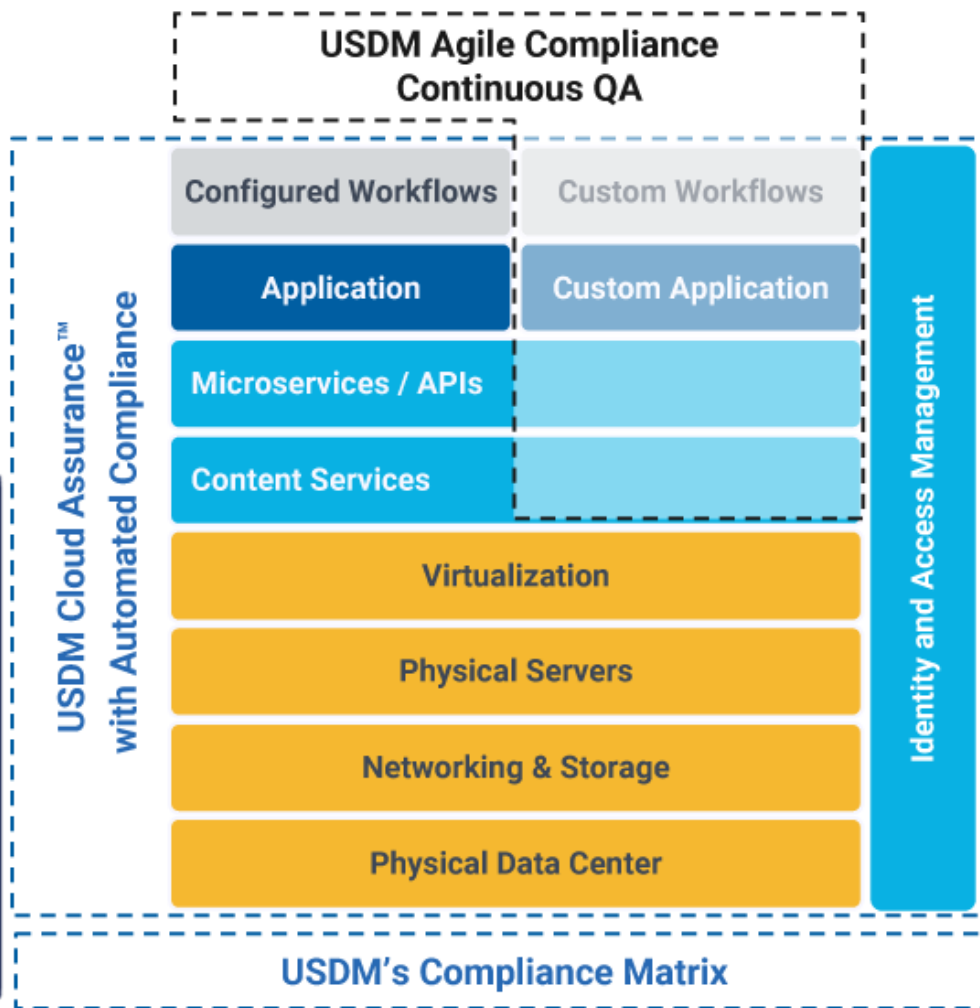
Cloud Assurance for Azure

- Rapid implementation, validation, and maintenance to enable a continuously compliant tech-stack (SaaS, PaaS, IaaS)

- Faster delivery through accelerators built on life sciences best practices

- Bundled solution to minimize and control cloud expenses and resources

- Security and compliance built-in

- Flexible cloud adoption model to migrate your GxP workload

- Unlocks the value of your data made possible with Azure

Value Generated from Rapid Cloud Adoption

Application Productivity

Business Agility

Application Costs

Infrastructure Resources & Cost
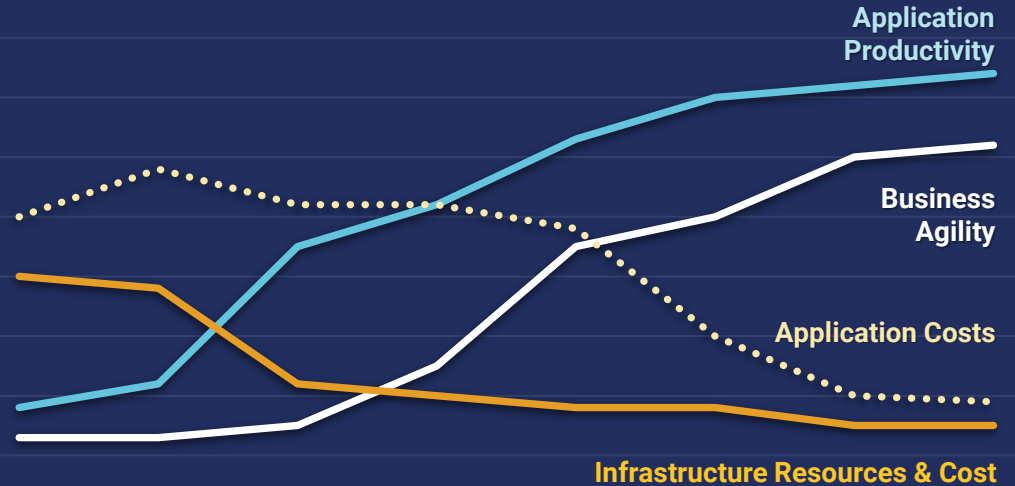
Continuous Cloud Compliance

50-80% faster delivery	**30-50%** less infrastructure costs	**25-75%** efficiency gains

Cloud Assurance™

↓ **Effort** ↓ **Risk**

Release feature configuration

Automated Configuration Management & Regression Testing
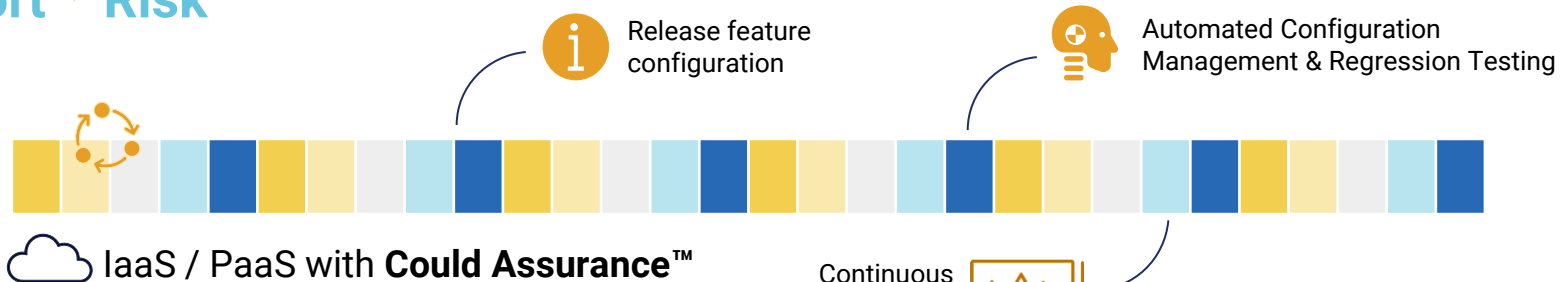
IaaS / PaaS with **Could Assurance™**

Continuous monitoring

Configure for Targeted Release, set for Automated Compliance

Continuous monitoring

Automated Configuration Management, Release Testing & Regression Testing

Cloud Assurance - Automated Compliance
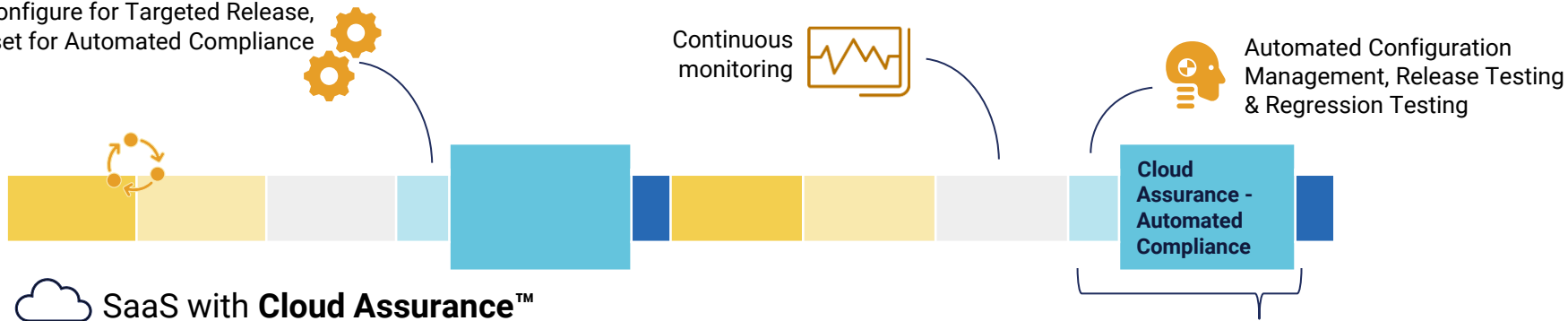
SaaS with **Cloud Assurance™**

Targeted Release Window vendor set 1-2W gap before general release

USDM Cloud Assurance™

A managed service subscription that offloads the **initial qualification / validation 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 validation time**

- Delivered via **building block CSA** methodology

- **Onboarding, Initial Qualification / Validation** and **Continuous Compliance**:

Vendor Assurance	Technical Services*	Initial Qualification/ Validation	Continuous Compliance
• Vendor Audit • Vendor Assurance Report • Vendor Functional Compliance Assessment to Unified Compliance Matrix - ERES	• Design • Implementation • Configuration • FastTrack • Automated Execution	• Plan • Functional Requirements with Risk Assessment • Configuration Specification • Automated Configuration Verification • Automated Functional Qualification • Automated Summary Report with Trace Matrix	• 12 months of continuous compliance for core functionality • Annual Vendor Assurance Report • Continuous Monitoring • Release Assessment • Regression Testing • Test Scripts for High-Risk Regulated Changes

Case Study

Azure DevOps Framework

Pilot Program for AI Chatbots

Customer wanted to develop chatbots that could be used to provide automated assistance with GxP content at their clinical sites.

DevOps Framework for GxP Requirements

Lacked knowledge on how to use DevOps tools to meet GxP validation requirements. No formal SDLC governing Azure DevOps. No DevOps specific CSV and SOPs.

Continuously Compliant Framework

USDM developed a Master Assurance Plan (MAP) that distinguished GxP, non-GxP, and SaMD to differentiate between formal and informal testing to meet global regulatory requirements and built a continuously validated Azure infrastructure to scale AI bot use.

USDM Cloud Assurance™
Ensuring a continuously compliant tech stack

Applications / SaaS	Platform Services / PaaS	Environment / IaaS
DocuSign® okta	box ORACLE	Google Cloud
tracelink SERVICEMAX	salesforce servicenow	Microsoft Azure aws
ptc	Azure Active Directory Microsoft 365	
SharePoint Azure DevOps	veeva	

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	✔	
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	✔	
Automated of customer specific use cases	✔	
Managing change control process		✔
Configuration		✔
Resolving technical issues		✔

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Cloud Assurance
Optional Services

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

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

IS Health Check

- 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
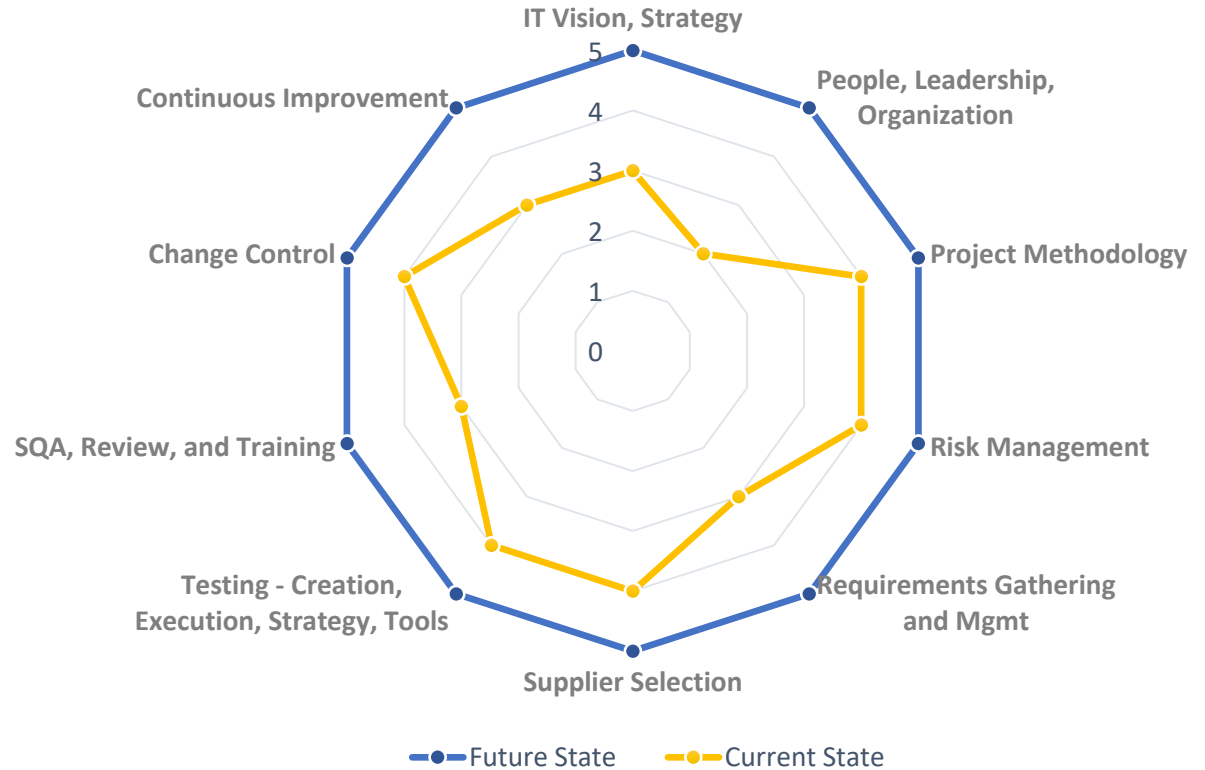
Why Cloud Assurance

- ✓ 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**

Amplified Benefits

- Cloud Assurance benefits increase as your organization matures

- Drive **greater speed, efficiency, and cost savings** by outsourcing the release management of more GxP systems

- Compliance-as-a-Service gives your team **more capacity** and enables **radical innovation**

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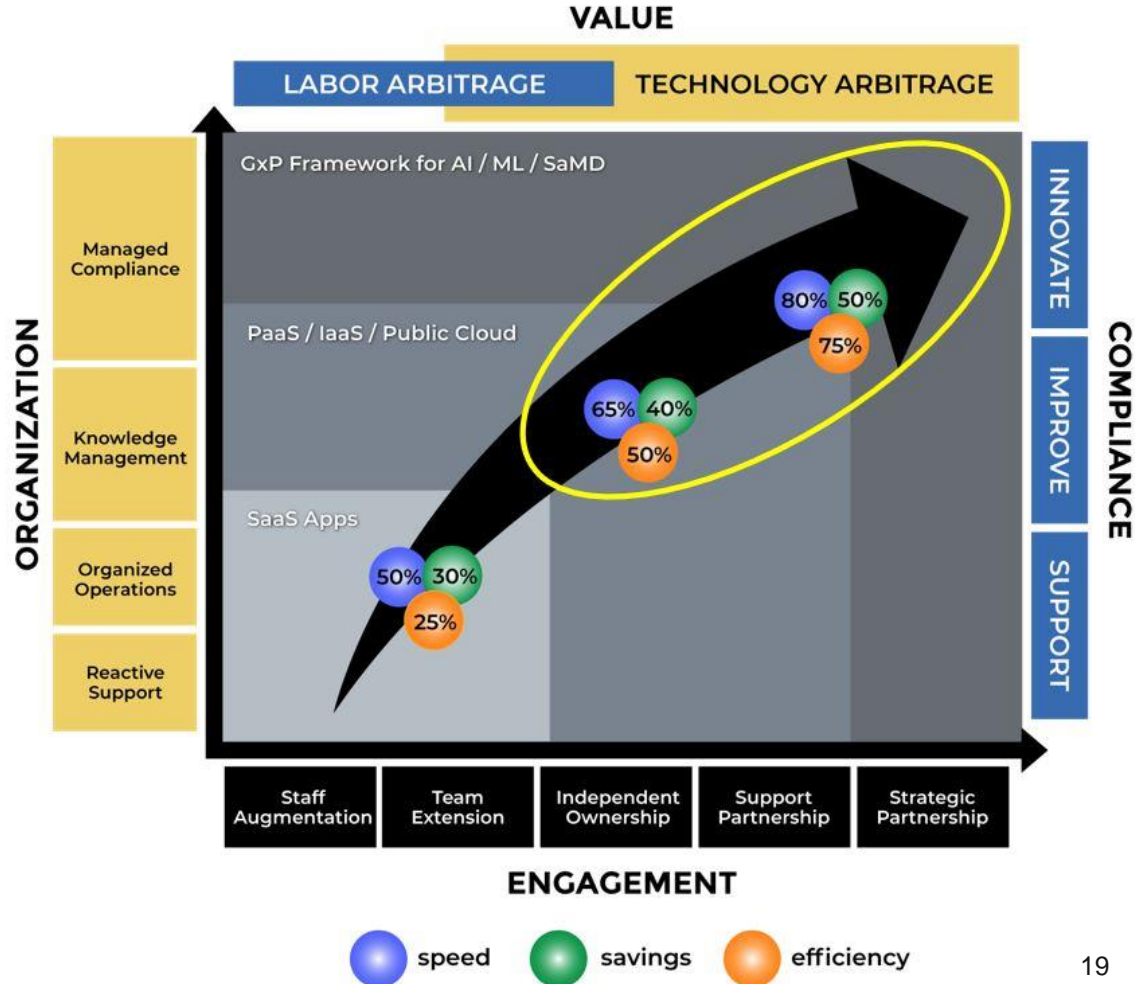
Why USDM

Better business outcomes through simplicity, scalability, and security

	Traditional	USDM
Cost	$$$$	$$
Complexity	High	Low
Coverage	Siloed Point Solution	Bundled SaaS, PaaS, IaaS
Deployment	Waterfall Months/Years	Agile 3 months
Flexible/ Scalable	10%	100%
Continuous Compliance	0%	100%

Cloud Assurance Advantages

- By leveraging USDM's life sciences expertise and accelerated cloud services, you can rapidly implement a GxP compliant framework.

- Reduce your compliance risk and achieve continuous cloud compliance with USDM's framework and accelerators for Azure

- Accelerate your cloud journey by identifying strategic business initiatives made possible with Azure

- Speed deployment and adoption of Azure and Microsoft business applications with prepackaged solutions built-on life sciences best practices

- Flexible cloud adoption model to migrate regulated workloads

- Cost-effective, bundled solution to minimize barriers to compliance and innovation

- Build value-creating activities, decrease value-consuming activities

Thank you!

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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.

Microsoft

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 risked 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