# USDM Life Sciences

# Unify Public Cloud for Microsoft Azure

## An innovative solution for continuous GxP compliance of regulated workloads on Microsoft Azure

Microsoft empowers life science companies to reimagine ways to bring together people, data, and processes to advance scientific innovation, get products to market faster, enable success with virtual teams, and improve operational and patient outcomes. Together, Microsoft and USDM Life Sciences enable regulated businesses to transform their GxP workflows in the cloud with USDM's Unify Public Cloud for Azure. Your business depends on every layer of your technology to comply with FDA and global regulations for software assurance. From your infrastructure to data centers to the platform layers and many business applications that power your productivity, Microsoft and USDM can ensure your operation is continuously compliant.

### USDM Solution

USDM's **Unify Public Cloud** solution provides expert compliance services, fast-start accelerators, and validation deliverables based on 20 years of life sciences solution delivery. Below are the features included with Unify Public Cloud.

| Services | Accelerators | Deliverables |
|---|---|---|
| • Annual Vendor Audit<br>• Infrastructure Qualification<br>• Cloud Application Validation<br>• Cloud Services Qualification<br>• IS Health Check | • Cloud Assurance<br>• Impact Assessments<br>• Procedures & Controls<br>• Change Management<br>• Qualification Package | • Qualification(s)<br>  • Qualification Plan<br>  • System Requirements<br>  • Configuration Specification<br>  • CQ / PQ<br>  • Qualification Report<br>• Assurance Report<br>• USDM Vendor Certification |

All these features come wrapped in USDM's Cloud Assurance™ subscription, to manage on-going updates, maintain your compliant-state, and decrease your compliance burdens. By providing a total, continuous, GxP compliant framework for your regulated workload, USDM helps you minimize regulatory risk and maximize productivity.

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# Unify Public Cloud for Microsoft Azure

## USDM Approach

USDM's approach to regulated workloads in the public cloud covers end-to-end technology solutions to reimagine your regulatory operations from a cost-center to an innovation hub. Our delivery model addresses SaaS (business applications), PaaS (cloud services), and IaaS (global infrastructure).

## Azure Assurance Architecture

The image below shows how Unify Public Cloud supports the compliance requirements of your Azure infrastructure and Microsoft cloud applications.

| | | | Services | Accelerators | Deliverables |
|---|---|---|---|---|---|
| **CUSTOMER** | • SharePoint Online<br>• Office 365 apps | **Business Applications** | • Cloud Application Validation<br>• Gap Assessment | • Cloud Assurance<br>• Best Practice Standards<br>• Compliant Configuration | • Validation Plan<br>• SRS/CS<br>• Test Scripts<br>• Validation Report |
| | • Azure DevOps<br>• Azure Data Lake | **Specific Build / Infrastructure for Commissioning a Service** | • Cloud Services Qualification<br>• Gap Assessment | • Best Practice Standards<br>• Compliant Configuration<br>• Impact Assessment | • Procedures<br>• Technical Configurations<br>• Assessment Tool(s) |
| | • Azure AD<br>• API Management<br>• Change Management<br>• Account / Access Management<br>• Provisioning of Cloud Servers | **Infrastructure and Platform Management** | • Initial Qualification<br>• IS Health Check<br>• Gap Assessment | • Initial Qualification Pack for Azure Platform (IaaS and PaaS) | • Qualification Plan<br>• SRS/CS<br>• Test Scripts<br>• Qualification Report |
| | | **Cloud Management** | | • Cloud Management Procedures<br>• Best Practice Standards | • Procedures<br>• Technical Configuration(s) |
| **AZURE** | • Foundational Services | **Virtual Infrastructure and Platform Services** | • Annual Vendor Audit<br>• Real Time Montioring<br>• Periodic Reviews<br>• Supplier Agreement<br>• Reviews | • Cloud Vendor (QMS) Quality Manager<br>• Best Practice Standards | • Vendor Assurance Report<br>• USDM Vendor Certification |
| | • Global Infrastructure | **Data Centers and Physical H/W** | | | |

# Unify Public Cloud for Microsoft Azure

**Azure Assurance
Architecture – How it Works**

The images below detail the phases and engagement for Unify Public Cloud for Microsoft Azure.

## Phases 1 - 3
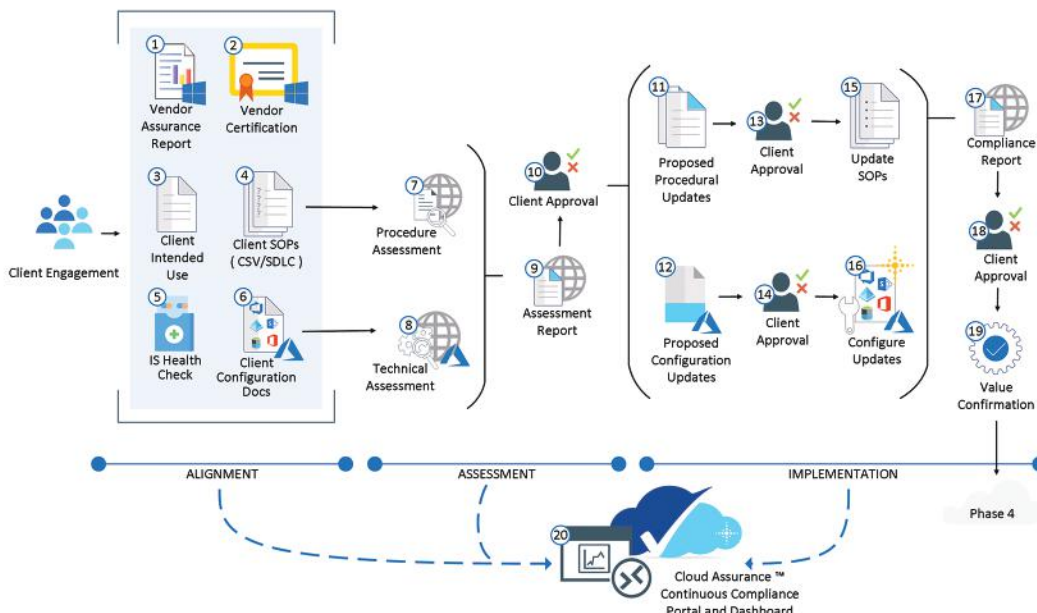


## Phase 4
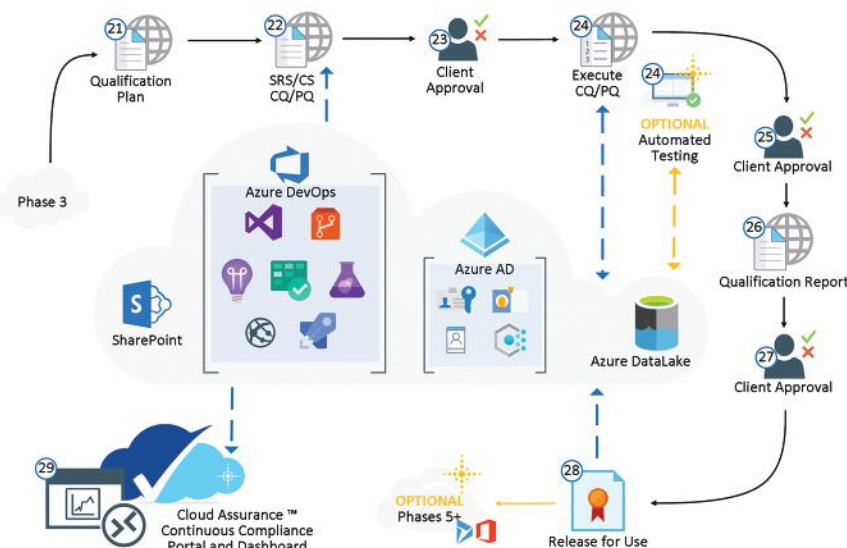


1. Upon signed Client agreement, USDM and Client will schedule a kick-off meeting where USDM will provide the Microsoft Vendor Assurance Report, and subsequent items 2-4, 6 will be exchanged.
2. USDM provides Client the Microsoft Vendor Certification
3. Client will provide USDM access to their system intended use.
4. Client will provide USDM access to their Software and Cloud compliance policies and SOPs (CSV/SDLC).
5. USDM works with Client to perform the IS Wellness Check utilizing the Cloud Assurance™ Accelerator.
6. Client will provide USDM access to their Configuration documents.
7. USDM performs compliance assessment of the provided procedures.
8. USDM performs technical assessment of the system configuration.
9. USDM drafts Assessment Report utilizing the Cloud Assurance™ Accelerator to summarize and document the results of the assessment activities.
10. Client approves Assessment Report.
11. USDM provides content for the proposed procedural updates.
12. USDM provide details of the proposed configuration updates.
13. Client approves proposed procedural content.
14. Client approves proposed configuration.
15. Client updates SOP with approved procedural content.
16. Client updates configuration per approved design. OPTIONAL USDM updates configuration per approved design.
17. USDM drafts the Compliance Report utilizing the Cloud Assurance™ Accelerator summarizing the results of all recommendations defined in the Assessment Report including the implemented procedural and technical updates.
18. Client approves Compliance Report.
19. USDM schedules and conducts Value Confirmation meeting with Client.
20. All Alignment, Assessment and Implementation activities and results are uploaded to the USDM Cloud Assurance™ Continuous Compliance portal. Client can view the USDM Cloud Assurance™ Continuous Compliance dashboard to visually track key performance indicators, metrics, and key data points to monitor the health of their Cloud Compliance.

21. USDM drafts the Qualification Plan utilizing the Cloud Assurance™ Accelerator
22. USDM works with Client to draft the System Requirements Specifications (SRS), Configuration Specifications (CS) and related Configuration Qualification (CQ) and Performance Qualification (PQ) utilizing the Cloud Assurance™ Accelerators
23. Client approves SRS/CS and CQ/PQ.  Client approval order may differ from depiction.
24. USDM manually executes the Configuration Qualification (CQ) and Performance Qualification (PQ) scripts on the Client environment. OPTIONAL USDM provides automated testing of CQ and PQ.
25. Client approves Test Results.
26. USDM drafts the Qualification Report utilizing the Cloud Assurance™ Accelerator to summarize and document the results of the qualification activities.
27. Client approves Qualification Report.
28. Client releases system for use. OPTIONAL Additional Workload Migrations to Cloud. Requires scoping based on impact assessments which can include Cloud Assurance™.
29. All qualification activities and results are uploaded real time to the USDM Cloud Assurance™ Continuous Compliance portal. Client can view the USDM Cloud Assurance™ Continuous Compliance dashboard to visually track key performance indicators, metrics, and key data points to monitor the health of their Cloud Compliance.

# Unify Public Cloud for Microsoft Azure

## USDM Advantages

By leveraging USDM's decades of life sciences expertise and accelerated cloud services, you can rapidly implement a GxP compliant framework for all layers of your cloud tech stack to generate true business value faster.

### Continuous Cloud Compliance

- **Reduce compliance risk** by leveraging USDM domain experience
- **Achieve continuous compliance** with USDM's framework and accelerators for Azure
- **Expand internal compliance knowledge** through increasingly complex projects

### Accelerated Cloud Journey

- Benefit from a **structured journey map and assessment** to identify strategic business initiatives made possible by Azure
- Fast-track your innovation with **a pre-packaged solution built-on life sciences best practices**
- Utilize a **flexible cloud adoption model** to migrate regulated workloads to Azure based on business priority
- **Scale as your business needs evolve**

### Realized Business Value

- **Speed up deployment and adoption** of Azure and Microsoft business applications
- **Cost-effective, bundled solution** to minimize barriers to compliance and innovation
- **Build value-creating activities with Azure**, decrease value-consuming activities

## Let's talk, schedule a consultation with our team today.

**USDM Life Sciences**
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