Regulated GxP Workloads in the Public Cloud

Accelerate innovation, improve employee experience, and build operational agility

USDM Life Sciences

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About **Our SMEs**

Vishal Sharma

VP of Digital Trust and Transformation

USDM Life Sciences

Vishal has more than twenty years of experience in the life sciences industry, providing consulting services in the areas of strategic planning, business process automation, quality and compliance management, content management, cloud adoption, data analytics (AI/ML/DL), project management, and application development.

John Petrakis

VP of Cloud Assurance

USDM Life Sciences

John has thirty years of global industry experience in business transformation, delivering solutions that address regulatory and quality pressures. John has led all aspects of strategy development and delivered value for pharmaceutical, biotech, medical device, and healthcare companies through application development and maintenance, ERP, advanced analytics (RPA/AI/ML), cloud compliance, and cybersecurity.

Executive **Summary**

Life sciences companies have historically lagged in their cloud and emerging technology adoption due to burdensome regulatory requirements and risk-averse cultural beliefs. However, the global pandemic has forced regulated companies to rapidly shift from a Cloud-First strategy to a Cloud-NOW strategy and adopt new operating models to maintain business continuity and enhance their workforce experience to accommodate remote employees globally.

Much of this shift to the cloud has come in the form of business applications that enable capabilities like secure workflows, electronic signatures, audit trails, and access to digital content management to ensure employees can continue to collaborate remotely. Yet real business value comes in the ability to link, share, and analyze data in new ways, both within the organization and increasingly from outside through partners, customers, and suppliers. Cloud platforms are instrumental in breaking down silos of data from business applications and other areas of an organization's technology stack to integrate workflows, making data scalable, available, and accessible without sacrificing security and compliance to drive innovation across the enterprise.

Further, the cloud can offer life sciences companies access to new tools and technologies in areas outside of the core competencies of traditional life science organizations. These include areas such as artificial intelligence (AI), machine learning/ deep learning (ML/DL), natural language processing (NLP), and robotic process automation (RPA) to more tailored product innovations for the life science sector. These new cloud capabilities are already enabling ground-breaking life sciences companies to confront both process and data challenges that were impossible just a few years ago. Beyond merely enhancing process integration and data analytics challenges, cloud computing can be a key component of any sizeable digital transformation effort in any life sciences organization.

Until now, there has not been an accessible, packaged solution for GxP workloads inclusive of infrastructure management and control, cloud services management, and business applications. Workloads refers to any GxP related business process and regulated data (i.e., security, strict controls, governance, data management, etc.). While some rigid solutions based on traditional computer system validation (CSV) models exist, they do not address the challenge of operating in a very dynamic public cloud environment and are cost prohibitive to maintain.

Today's regulated business workloads require a new level of flexibility and scale to handle the needs of life sciences business. In this white paper, we will introduce a new solution – USDM Unify Public Cloud™ – for continuous compliance of regulated workloads on the public cloud that is accessible, scalable, and designed to address global infrastructure (IaaS), cloud service platforms (PaaS), and business application software (SaaS).

Challenges of Regulated **Workloads in the Public Cloud**

Life sciences companies have had to operate in highly regulated environments for decades. These regulatory challenges affect all areas of the value chain. USDM's Unify Public Cloud solution can help reduce most of these compliance burdens.

Research & Development
Siloed and legacy infrastructure

Clinical Trials
Stringent regulatory requirements

Manufacturing & Distribution
Track-and-trace compliance through supply chain and quality events

Post Market Surveillance
Product safety and product recalls

Customer/ Patient
Data security risk

Security & Compliance

Often the business justification for a public cloud solution begins in an individual department that requires insights that can only be gained through advanced analytics and AI. As the individual department begins to explore the ever-growing pool of regulated data, how to access it, and how to extract the insights, the conversation expands to other departments that hold the keys to the data or may have a similar use. As the volume and velocity of regulated data from various sources continues to grow, so will the need for cross-enterprise, cross-platform, and cross-partner collaboration to gain insights from the data.

As such, a compliant public cloud platform will be required to meet the needs of a data-driven, insight-driven culture. Through the compliant cloud solution, this data-driven transformation and other cloud transformation opportunities are possible, e.g., making data scalable, available, and accessible to pursue research projects, faster and collaboratively.

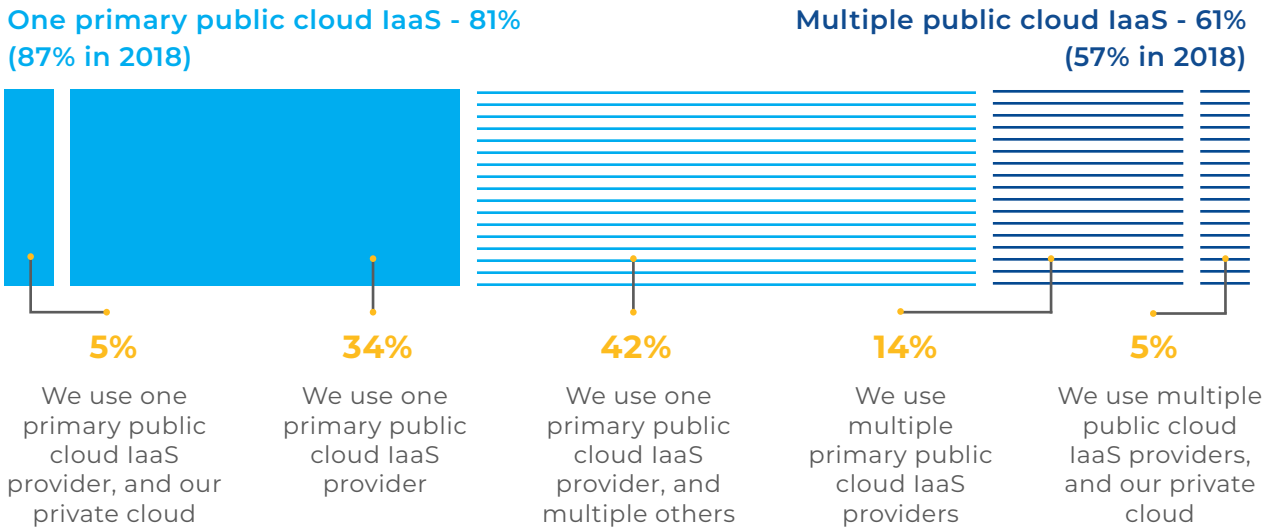
Fears of FDA 483 observations and warning letters, cybersecurity hacks, and harming patients have fueled oppositional beliefs and risk-averse cultures to resist cloud adoption and more innovative solutions through available technologies. Business processes have been developed over many years to try and avoid regulatory punishment versus striving to innovate and get higher quality products on the market faster with the use of technology. Even when an organization is open to the idea of a cloud or hybrid-cloud approach to improve business processes, the solutions available often only address the business application layers of their tech-stack. They rarely address the high-touch platform and infrastructure layers from a public cloud perspective.

Further concerns with how to manage cloud updates and keep up with the pace of innovation from SaaS vendors to maintain a continuous state of compliance have amplified this hesitation to adopt cloud technologies. Finally, the ever-evolving challenges of time versus cost versus quality pressure will always be there, and life sciences organizations must move faster than ever before to beat their competitors to market. While all these historical challenges have made the journey to the public cloud slower to adopt versus non-regulated industries, there is tremendous opportunity happening in the life sciences today to encourage real digital transformation – modernize, transform, and innovate.

The following are few considerations to keep in mind when developing a structured journey map to move regulated workloads to the cloud and extract value from your data to drive intelligence.

- Adoption will only move as fast as your slowest stakeholders. You must consider the Organizational Change Management (OCM) requirements to drive adoption.
- Even if an organization commits to an *all-in* cloud-first strategy, everything will not move at once. You must have a well-defined strategic IT roadmap to guide your journey.
- Crawl, walk, run—plan to build your compliance teams' experience through increasingly complex projects.
- Policies, procedures, and training must be modernized for Infrastructure as Code (IaC) to move data center management and provisioning with velocity and trust (Guckenheimer, 2020). Policies are being leveraged by organizations to optimize costs. Automated cloud cost optimization policies can save time while ensuring organizations monitor their environments consistently to eliminate waste. Larger organizations are increasingly replacing cumbersome and inadequate manual processes with automated ones.
- Cloud use often goes hand in hand with adopting DevOps processes. Organizations will frequently choose to implement configuration management tools that allow them to standardize and automate deployment and configuration of servers and applications.
- Once you determine your approach to using public cloud IaaS services, it is critical that you plan accordingly.

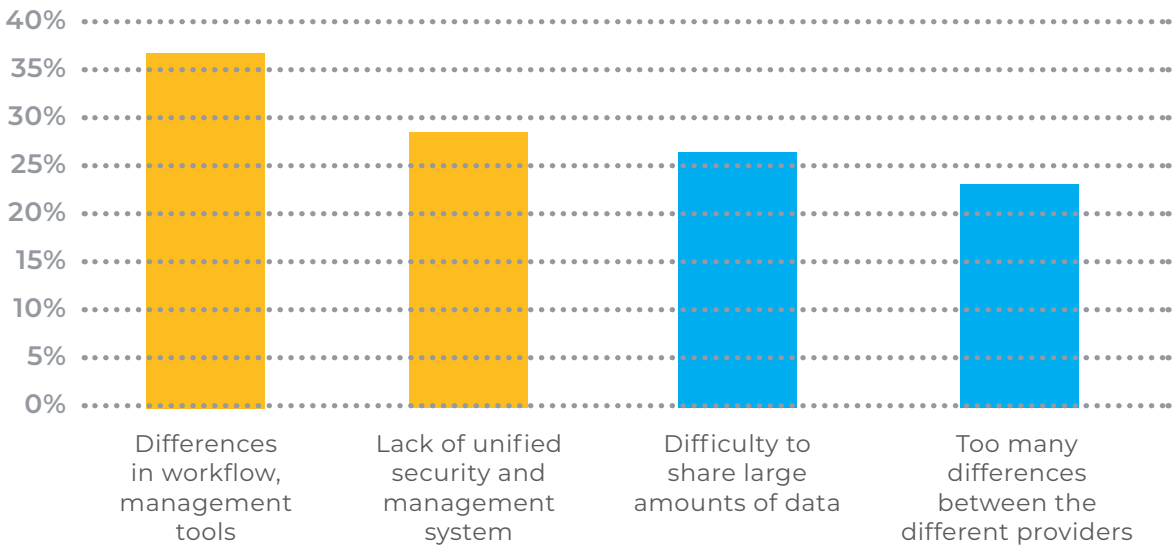
Characterizing Company's Approach to Using Public Cloud Iaas Services



(IDG, 2020)

The multi-cloud environment will continue given the drivers – specific cloud services, avoidance of vendor-specific lock-in, cost reduction, and regulatory requirements. Cloud vendors continue to offer new and innovative services at an ever-increasing pace, and life sciences are a target-rich market. While there are many advantages to a multi-cloud architecture, there are challenges to recognize and consider in the journey.

Top Challenges with Using Multiple Public Cloud IaaS Providers

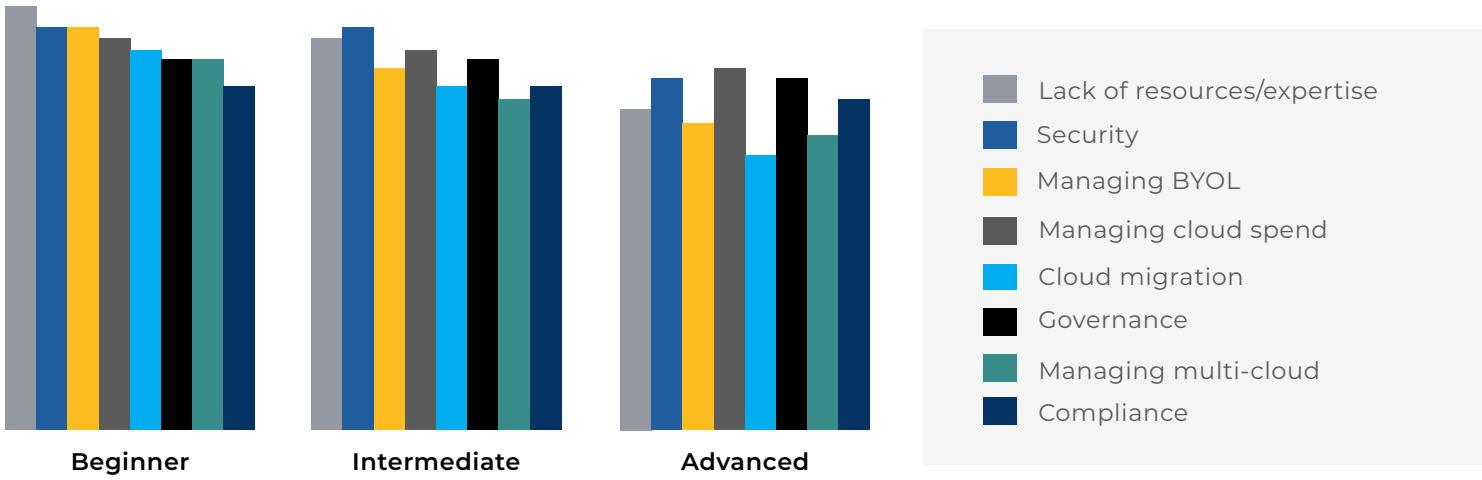


(IDG, 2020)

Companies that are early in their cloud journey often struggle with resources and expertise. While cloud migration and managing multi-cloud environments may become more manageable as an organization matures and gains experience – security, governance, and compliance are still significant challenges at any stage of an organization's journey. And controlling cloud spend remains a challenge for even the most advanced companies.

Cloud Challenges by Maturity

% of all respondents



N=750 (Flexera, 2020)

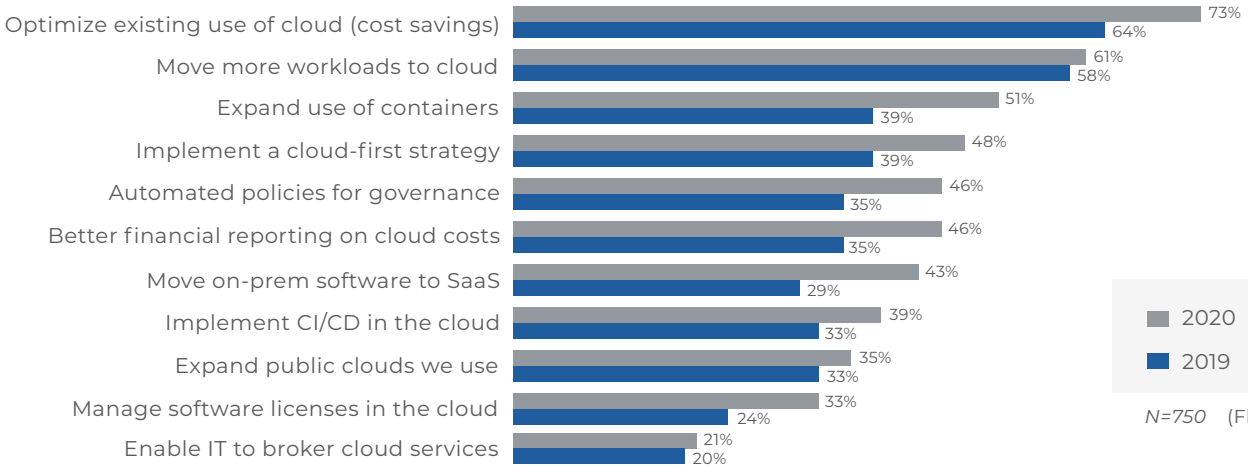
Trends
in Life Sciences

Today, life science businesses must operate outside of their digital walls. Constant M&A activity in the industry requires organizations to defragment their operations and data to share information more seamlessly. Contracted research and manufacturing operations require system access and integration that must happen in facilities and sites across the world in real-time. Considering COVID-19 and the urgency to discover a vaccine, clinical trials rely on the capabilities offered by the cloud more than ever.

Even competitors are compelled to join hands in R&D efforts in the race for new therapies and vaccines. A global product launch takes hundreds of employees to orchestrate marketing, sales and supply chain activities across the world in a connected, harmonious way. These requirements for life sciences businesses to operate outside of their digital walls are forcing the adoption of cloud services faster than ever. It is not merely about a cloud-first strategy; it is about Cloud-NOW!

Top Cloud Initiatives YoY

% of all respondents



N=750 (Flexera, 2020)

Migrating workloads can save money and drive agility. As organizations move more workloads to the cloud, they can retire the technical debt associated with maintaining and operating traditional data centers. Container usage can also help control costs because they allow more efficient use of infrastructure. Consequently, they offer a more cost-effective way to deploy workloads in the cloud.

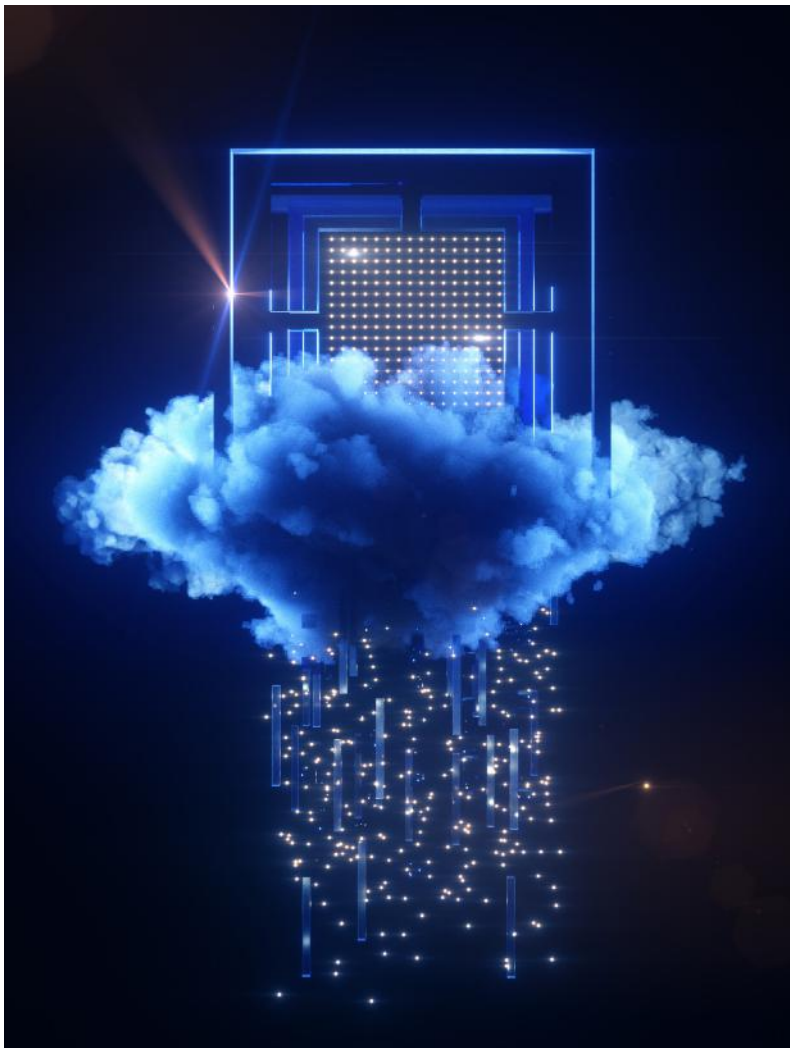
Cloud Initiatives by Maturity

BEGINNER	INTERMEDIATE	ADVANCED
1. Migrating more workloads to cloud (65%)	1. Optimizing existing use of cloud (70%)	1. Optimizing existing use of cloud (77%)
2. Optimizing existing use of cloud (54%)	2. Migrating more workloads to cloud (65%)	2. Migrating more workloads to cloud (60%)
3. Cloud-first strategy (52%)	3. Expanding use of containers (49%)	3. Better financial reporting on cloud (51%)
4. Expanding use of containers (48%)	4. Cloud-first strategy (48%)	4. Cloud-first strategy (51%)
5. Better financial reporting on cloud (46%)	5. Automated policies for governance (44%)	5. Automated policies for governance (51%)

N=750 (Flexera, 2020)

As we recently learned with the COVID-19 pandemic, workplace technology makes or breaks productivity. Earlier this year, CTOs had to halt progressive company initiatives to spend months acquiring and provisioning laptops for thousands of employees. Now the global workforce must be able to work remotely and have digital access anywhere, anytime. This mobility and accessibility requirement is becoming table-stakes to stay in business. As regulated companies enable remote employees and move to the cloud, this transition takes time and cannot happen all at once. This creates a need to interoperate with legacy processes, applications, and data in a hybrid model while transitioning to a cloud-led approach.

As life science companies forge new partnerships to improve market access by working with more regulatory bodies, cyber threats and regulations continue to grow. This increases the compliance burden; hence, frictionless security and scalability provided by public cloud infrastructure can be instrumental for the successful migration of regulated workloads in the public cloud. The looming fear of data leakage by working with more partners and contractors is also expediting the transition to the public cloud due to its massive investments in infrastructure security and compliance that is beyond reach for any individual organization. Cloud enhances overall data security by removing data from old on-premises servers lacking the latest security updates, and allows more reliable security controls to be implemented that meet data integrity and governance requirements.



Use Cases & Opportunities **for Innovation**

For the early adopter in life sciences, we are beginning to see significant progress using the public cloud in GxP use cases.

A top pharma USDM customer, who is using the Microsoft Azure platform, is using AI chatbots to support GxP content in their clinical trials. USDM developed a Master Assurance Plan (MAP) that distinguished GxP, non-GxP, and Software as a Medical Device (SaMD) to differentiate between formal testing and informal testing to meet global regulatory requirements. By helping the customer build a continuously compliant infrastructure framework, they were able to scale AI chatbots (intelligent agent) for GxP uses.

Top Growing Cloud PaaS Services

% of enterprise respondents

PLACE	SERVICE	2019	2020	GROWTH
1	IoT	29%	35%	21%
2	Container-as-a-Service	48%	56%	17%
3	Machine Learning / AI	35%	41%	17%
4	Data warehouse	50%	56%	12%
5	Serverless	43%	48%	12%

N=554 (Flexera, 2020)

"Sanofi is looking to create value from data in new ways. This could involve selling analytics, creating new therapeutics built on data insights, offering new recommendations and solutions for healthcare systems based on its data, enabling virtual healthcare, and even managing population health. These types of innovations will also likely challenge the traditional pharmaceutical business model. Perhaps these services will be offered on a subscription recurring-revenue model, globally, at scale and across many diseases", says Ameet Nathwani, Chief Medical Officer and Chief Digital Officer, Sanofi.

"Companies like Takeda and Roche are already starting to offer digital health services and platform technologies that facilitate health interventions, help doctors make better diagnoses, and expand what constitutes a treatment choice," says Phillipe Barillion, Head of Insights and Analytics, Takeda. "Core pharma business models will change in the era when everyone is connected to devices and will be able to access their own data and take charge of their own wellness and healthcare."

The Broad Institute has increased the speed at which it analyzes human genomes by 400% after moving its inhouse genome sequence and analysis onto the cloud (Eyeforpharma, 2020). Eli Lilly recently hired a new chief data and analytics officer, tasked with creating a data culture. Although Lilly already had a science-driven culture, the company was traditionally less focused on big data and AI. The organization has realized successes by partnering with early adopters and forming cross-functional teams with diverse backgrounds. It has developed a "marketing approach" for analytics and AI to help create advocates and ambassadors. While these initiatives are still early, they show signs of significant progress (Harvard Business Review, 2020).

We are witnessing a few other trends in pioneering life sciences companies, where cloud infrastructure is providing a way to free siloed data trapped inside the various operating affiliates, divisions, and subsidiaries around the globe. Bringing disparate data sets together faster means being able to link, synthesize, analyze, and share data externally with less friction and without sacrificing compliance.

Data externalization is also helping large multinational research projects pursue breakthroughs between pharma, clinical research organizations, academic institutes, hospitals, and other stakeholders. A cloud-based data management infrastructure that enables all stakeholders to share data easily with strict security, access controls, and compliance protocols is a vital prerequisite for participation in the global quest for finding new therapies and vaccines. A cloud-based data lake infrastructure also allows life sciences companies to move massive amounts of GxP data for real-time analysis and insight that can be operationalized to drive high-impact business outcomes. Cloud also provides a scalable and flexible infrastructure to create a data hub where real-time data from edge devices can be streamed for patient monitoring and improved health outcomes.

> Companies spend huge amounts of **time and money** on **analytics and AI technologies.** Yet, they don't invest in **data-oriented cultures.**
> - Tom Davenport (Harvard Business Review)

Without a data-driven culture, organizational performance lags. NewVantage Partners Research shows the vast majority (91% of companies surveyed), cite people and process challenges, not technology, as the most significant barriers to becoming data-driven. Unfortunately, the research also shows that companies are not improving, and many are getting worse. This is discouraging, since companies without a data-driven culture make inferior decisions, engage in less innovation, and lose talent to competitors. A McKinsey study found that organizations are 65% to 70% less likely to be high performers if they don't have a C-suite data leader, broadly accessible data, and rapid testing and learning from failures.

"Where there is growth, most of it is in the cloud," said Stephen Minton, Program Vice President in IDC's Customer Insights and Analysis group. "Overall, software spending is now expected to decline as businesses delay new projects and application roll-outs, while there is a fundamental link between employment and spending on things like software licenses and campus networks. On the other hand, the amount of data that companies must store and manage is not going anywhere. Increasingly, even more of that data will be stored, managed, and increasingly also analyzed in the cloud" (IDC, 2020).

Unify Public **Cloud**

USDM has developed an innovative solution for continuous compliance of regulated GxP workloads in the public cloud called Unify Public Cloud. This solution addresses SaaS (business applications), PaaS (cloud services), and IaaS (global infrastructure). Unify Public Cloud includes a package of expert compliance services, prepackaged accelerators, and defensible validation deliverables.

- **Expert Compliance Services** - an Annual Vendor Audit, Infrastructure Qualification, Cloud Application Validation, Cloud Services Qualification, and an IS Health Check
- **Fast-Start Accelerators** - Impact Assessments, Procedures and Controls, Change Management, and Qualification Package
- **Defensible Validation Deliverables** - Qualification(s), Qualification Plan (System Requirements, Configuration Specification, CQ/PQ, Qualification Report), USDM's Assurance Report, and Vendor Certification

By leveraging USDM's life sciences expertise and accelerated cloud services, customers can rapidly implement a GxP compliant framework. Our approach covers end-to-end technology solutions for your entire tech stack to reimagine your regulatory operations from a cost-center to an innovation hub. The image below shows how Unify Public Cloud supports the compliance requirements for your business applications, cloud services, and global infrastructure.

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

FDA **Outlook**

USDM has been supporting regulated life sciences companies for more than two decades and has unmatched domain expertise. We work closely with the FDA and even have former FDA employees on staff that helped draft some of the regulations we follow today.

The FDA is shifting away from the traditional ways of doing computer system validation (CSV). In their Case for Quality initiative, the FDA will be releasing a new guidance called Computer Software Assurance for Manufacturing, Operations, and Quality System Software (CSA). This guidance will be released later this year, and the FDA has clearly stated that this fresh approach can and should be used now in regulated environments.

The FDA has also expressed its belief that the use of modern IT, automation, and data solutions throughout the system life cycle can provide significant benefits to drive enhanced quality and safety. The FDA is well aware that other industries utilizing automation have shown a substantial gain in enhancing quality and safety, thereby reducing risk as compared with non-automation, and is encouraging this progress in all areas of life sciences.

USDM has been following the FDA's new CSA guidance closely and built the Unify Public Cloud solution with a true risk-based approach that focuses more on testing the right things and minimizing documentation. Further, the new CSA guidance allows for life sciences companies to utilize their cloud vendor assurance activities to reduce their internal testing and documentation burdens.

With a defensible and modern CSA approach to validation and qualification, USDM customers can trust that the Assurance Report and Vendor Certification included in the Unify Public Cloud solution will minimize their compliance burden.

In **Conclusion**

Be it Microsoft, Google, Amazon, Oracle, or any other cloud platform available today, the public cloud offers a wide range of tools, templates, and accelerators to access and migrate data and ultimately analyze the data to fuel the decisions across the organization. Due to the scalability, accessibility, speed, and unleashing of advanced data analytics – plus the urgent work-from-home mandate driven by COVID-19 – life sciences businesses are moving to the cloud NOW.

The key is to make sure your cloud strategy considers the critical convergence of people, process, and technology to enable a data-driven culture that makes better decisions with the support of advanced analytics and AI. Real digital transformation is more than a technology decision. It is about reinventing your business - changing how you operate, transforming your culture, and changing how you innovate.

Eyeforpharma. (2019). Unlock Pharma's Value through Cloud Technology.

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IDC. (2020, May). IDC Lowers Forecast for Worldwide IT Spending to a Decline of 5.1% in 2020, but Cloud Spending Remains Relatively Resilient.

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UNIFY PUBLIC CLOUD
for Microsoft Azure

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An innovative **GxP compliance solution** to **accelerate your regulated workload** on Microsoft Azure Cloud

Unify Public Cloud 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

Benefits
of Unify Public Cloud

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

Let's Talk

Schedule a consultation with our team today

Contact USDM Life Sciences
888.231.0816 | usdm@usdm.com

Contact Us

USDM Life Sciences
535 Chapala Street
Santa Barbara, CA 93101
+888-231-0816

USDM Europe GmbH
The Squaire 12 - Am Flughafen
60549 Franfurt am Main
Germany
+49 69-95932-5459

usdm@usdm.com
www.usdm.com

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Any comments relating to the material contained in this document may be submitted to the contact info above.

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