USDM Life Sciences

Google

Google Cloud Platform for Life Sciences and Health Technology

How to integrate a holistic compliance framework across your entire cloud tech stack

Executive Summary

Creating software for life sciences or health tech is an exciting endeavor, but when it accounts for and aligns compliance throughout the entire development process, that's when you know you've exceeded the "It Factor" with your first-in-kind piece of software.

The thing is, though, when it comes to introducing a new software application in the cloud—for example, an application with validation and security built-in, process automation, or chatbots—it's a fundamental change that requires your cloud service provider to perform and maintain many of the compliance and security activities. That kind of change to compliance management is hard.

Giving up this control of your on-premises environment by moving to the cloud may peg the needle on your risk aversion meter. However, Software-as-a-Service (SaaS), Platform-as-a-Service (PaaS), and Infrastructure-as-a-Service (IaaS) are the tech-stack building blocks that ensure you are creating a quality product with data security and patient safety at the forefront.

Google Cloud for Healthcare & Life Sciences is evolving the care paradigm, advancing research at scale, and allowing the industry to innovate and transform, and USDM Life Sciences (USDM) is providing an integrated compliance framework to enable this innovation in Google Cloud quickly.

Cloud technology paves the way to innovation and transformation

Adapting to change may not be part of your company's or your quality team's DNA. Whether it's the fear of "losing control" of an on-prem environment or getting out of your comfortable Waterfall method of working, we are beginning with the end in mind by building compliance into your application and making compliance the output of this new way of working.

We are helping you integrate compliance from the start, slash your validation efforts, and accelerate your speed to market. We are diminishing your overhead costs while enhancing your data and product compliance.

You've got regulated user stories and apps to build. USDM has a holistic compliance framework. Google Cloud Platform (GCP) enables your innovation.

> A user story is a one or two-sentence description of a software feature from the user's perspective. For example, "As a <user role>, I want <goal> so that <benefit>."

A Cloud Compliance Vision

The Google Cloud Platform has the technology to bring your ideas to life. Whether your business is early in its journey or well on its way to digitalizing your IT systems and developing your own applications, GCP has the compute engines, storage capacity, artificial intelligence (AI) and machine learning, and database solutions to help you with your next breakthrough idea.

USDM has a built-for-compliance framework that fits right into your agile DevOps processes to capture quality artifacts as they are created and cover end-to-end continuous compliance of your technology. With USDM's Unify Public Cloud (UPC) solution, you can transform your regulated operations from a bottleneck to innovation by building in compliance and automating Software Quality Assurance (SQA) in your IaaS, PaaS, SaaS—and anything your DevOps can imagine.

You might think that using an Agile strategy in a regulated environment is a bit of an oxymoron, but it isn't as absurd as you might think. All industries have similar business demands for focused productivity and rapid delivery, and these demands usually move them to an Agile approach to project management and software development. Regulated life sciences and health technology industries have these same business pressures, with the added requirement of patient safety. A built-for-compliance Agile framework ensures software quality, safety, and security are a part of the development process rather than something QA tests for prior to release. By implementing artifact capturing, continuous verification, and release validation activities within the Agile lifecycle, you build in quality and manage the regulatory risk, allowing you to concentrate more of your time and resources to further innovations.

The partnership between Google and USDM makes your next-level innovation possible for your compliant technology. Agile, compliance, and validation are integrated in each individual sprint as well as the final run-through of the application.

> DevOps encompasses the practices, tools, and cultural philosophy that automate and integrate the processes between software development and IT operations teams. It emphasizes team empowerment, cross-team communication and collaboration, and technology automation. This lays the groundwork for USDM's framework and toolset.

> Agile is an iterative approach to project management and software development that helps teams deliver value to their customers faster. Instead of waiting until product launch, an agile team delivers work in small increments. Requirements, plans, and results are evaluated continuously so teams can respond quickly to changes.

USDM Audit of Google

Life sciences and health tech companies are ultimately responsible for ensuring that their technology meets patient safety, data privacy, security, and compliance requirements; however, regulatory bodies realize the importance of the connection between the system owner and the cloud service provider. Some go as far as to say that if vendor documentation is in place and of good quality, it can and should be leveraged as documented evidence that the software core functionality (and layers of the tech stack) has been verified and qualified.

The conditions for leveraging a vendor's qualification documentation are clear and detailed:[1]

- System owner has a thorough knowledge about the vendor's quality system and qualification activities, which will usually be obtained through an in-depth assessment/audit.
- An assessment/audit has been performed by qualified staff, with sufficient time spent on the activities and with cooperation from the vendor.
- An assessment/audit has gone sufficiently deep into the activities, and that a suitable number of examples for relevant activities have been looked at and documented.
- The assessment/audit report determined the vendor's qualification documentation to be satisfactory or that shortcomings can be mitigated by the system owner - e.g., that the system owner is performing part of the qualification.
- System owner has detailed knowledge about the qualification documentation and can navigate in it and explain the activities as if they had performed the activities themselves.
- When required during an inspection, the audit and qualification documentation is made available to the inspectors in a timely manner, irrespective of whether it is provided by the system owner or the vendor.
- Both the system owner and the vendor establish full configuration management for TEST and PROD environments.
- System owner can fully account for any differences between the vendor's TEST environment and the system owner's PROD environment.
- System owner can justify any differences between these environments.
- The system owner performs a Configuration Qualification (CQ)/Performance Qualification (PQ) of the system.

[1] https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/qa-good-clinical-practice-gcp

As part of USDM Cloud Assurance™, USDM performed an independent, qualified third-party audit of Google Cloud services that included the design, development, testing, qualification, and maintenance methodologies of Google Cloud Infrastructure.

USDM's vendor audit addressed these leverageable items, including (but not limited to) the vendor's quality system framework, software development methodology, and software qualification processes and artifacts. The audit also dove deeper into the vendor's configuration management, documentation and records management, security, training and education, and provided an overview of the quality management system (QMS) with respect to system development, system configuration and implementation, and ongoing support.

The results of the audit were compiled into a comprehensive Google Vendor Assurance Report and reference document that summarizes the audit, cites all source material reviewed during the audit activities, and provides direct links to all publicly available content.

> "Google is committed to meeting and exceeding customers' stringent due diligence requirements. USDM's assessment of Google Cloud processes, policies, and operations bolsters trust in our environment, helping customers accelerate and complete their risk, security, and compliance responsibilities."
>
> *- Andrea McGonigle, General Manager, Healthcare & Life Sciences Partnerships & Strategic Initiatives, Google Cloud*

The Magnitude of Global Regulation

The regulatory landscape for life sciences and health tech companies is vast and can become more complicated with every innovation.

- The European Union's Annex 11 covers the use of computerized systems as part of Good Manufacturing Process (GMP) regulated activities, application validation, and IT infrastructure qualification.
- The FDA has cybersecurity guidance for off-the-shelf software and how Quality System Regulation applies to cybersecurity maintenance activities.
- Many countries have followed the lead of the EU's General Data Protection Regulation (GDPR) regarding data and personal privacy rights.
- The Federal Risk and Authorization Management Program (FedRAMP) provides a risk-based approach for the adoption and use of cloud services.
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) ensures that safe, effective, high-quality medicines are developed, registered, and maintained.
- The International Organization for Standardization (ISO) describes the best way of doing something like making a product, managing a process, and delivering a service.

And that is just to name a few. It is safe to say, that is a lot to get a handle on.

Your regulatory landscape is unique to your business just as compliance regulations are highly specific to your products and the countries where you do business.

USDM's Unified Compliance Matrix™ (UCM), on the other hand, may be used to manage the complexity of your specific regulatory landscape, including data privacy, security, and patient safety regulations, among others. The UCM is a proprietary automated tool designed by USDM to determine the global regulatory requirements that govern your quality management practices. UCM provides the corresponding technical and procedural controls and assesses your organization's compliance to these business needs.

Google Cloud Platform helps life sciences and health tech companies like yours meet quality and security objectives and makes it easier to achieve your UCM requirements by managing your compliance obligations in the cloud. It is the cornerstone of account controls, compliance audits, and customer certifications for regulated systems. Products and capabilities include electronic records and signatures, data retention, identity and access management, data security and audit trail, data ownership, physical security, network security, and application security.

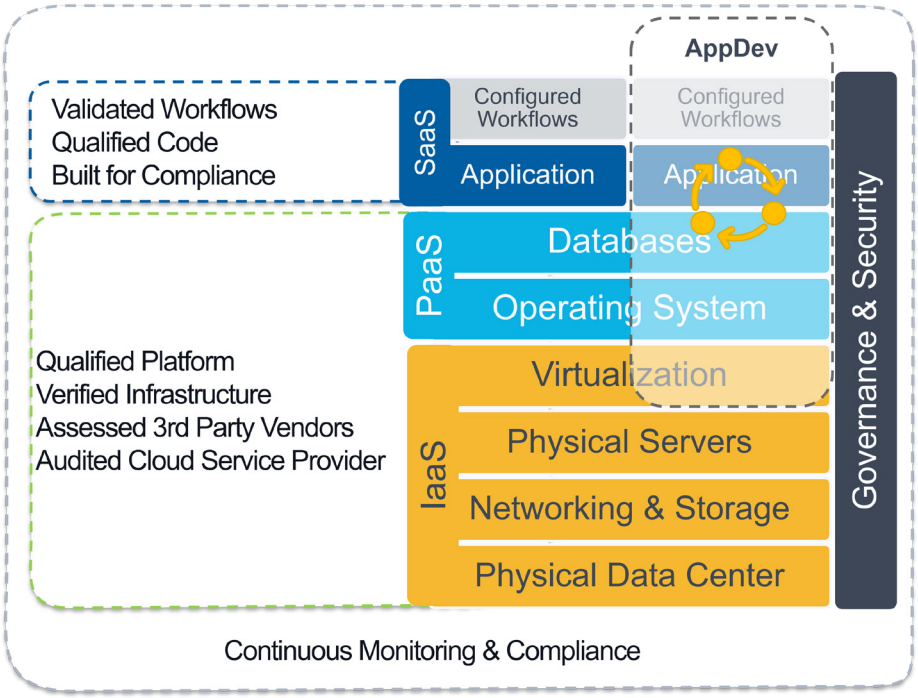
USDM Framework Details: How It Works

Successful vendor and team relationships have many components and a well-defined communication plan. Working with transparency, agreeing on upfront goals, cross-checking key milestones, adopting common quality and risk management strategies, and establishing guardrails are vital in creating and maintaining a strong partnership among teams throughout the life cycle of the project.

Traditional on-prem validation occurs when your application is on a physical server in a room that you control. In addition to your application's intended-use and compliance testing, on-prem validation traditionally qualifies the hardware and software components; confirms the application design and architecture; tests disaster recovery, backup, and restoration; and verifies the minimum requirements for the server, networking, and storage for each application.

Ultimately, you are testing for quality after the fact. However, in the UPC framework for compliance, we help you implement the framework, leverage the vendor audit, and capture your compliance artifacts as they are created during the AppDev process, which allows you to right-size your compliance effort.

You can leverage the USDM comprehensive vendor audit of your cloud service provider documents to confirm the Software Development Life Cycle (SDLC), and ensure your cloud infrastructure is secure, available, continuously monitored, maintained, and supported.



Use Case 1 – DevOps Framework for Process Automation

A compliance framework for DevOps is ideal when you have a business and technical need for automating the process of developing and deploying code in a regulated environment.

A regulated DevOps framework increases the frequency and quality of deployments to meet customer and business needs while automating compliance and security. It also enables a UCM compliant software delivery pipeline.

Common Challenges

Regulated companies wanting to build out a framework in their agile development operations tend to face similar challenges:

- They lack standardized security and compliance processes and policies across the enterprise.
- There is no formal SDLC, computer system validation (CSV) method, or standard operating procedures (SOPs) governing their development operations.
- They lack regulatory compliance expertise and don't know how to use the DevOps process to meet validation requirements.
- They are plagued with time-consuming internal approval processes for regulated activities that slow down agile operations.
- They need QA artifacts integrated in their Continuous Integration/Continuous Development (CI/CD) pipeline.
- They need regular monitoring to know if ongoing work meets their regulatory goals but lack the know-how to deliver this monitoring capability.

Along with these challenges comes the need for understanding your organizational readiness and maturity before you start to build an integrated QA DevOps framework. This readiness assessment will ascertain the level of maturity for your people, processes, and technology in order to focus on speed, value, and quality (including your Unified Compliance Matrix and regulatory needs).

Use Case 2 – Software Application with Validation Built In

Imagine leveraging technology to make processes and communication more efficient around the world. In real time, regulators could access and review data sitting in the cloud. Pharmaceutical companies would no longer have to redo the same work for separate regulators. Data standards allow you to move information around in shared formats and you can bring data together to generate insights.

Accumulus Synergy had this vision to exchange information between a biopharma company and its regulators. Instead of the traditional method of static information and documents, they envisioned access to a cloud environment that offers up-to-date data with the assurance of data privacy and cybersecurity.

Accumulus must meet vendor requirements of sponsors and health authorities and validate the SaaS platform to prove the software and systems are performing according to specifications and intended use.

To deliver critical therapies to the world, Accumulus partnered with Google to build a global information exchange platform and USDM to build global regulatory compliance into the application. Together, Accumulus, Google, and USDM are creating one platform that encompasses technology, process, collaboration, and quality. Expertise, innovation, and teamwork created a first-in-kind software that has compliance and unusually high cybersecurity built in from the beginning.

> "Our vision is game-changing, but collaborating with the Health Authorities, USDM, Google, and the biggest pharma companies in the world has culminated into an unprecedented, first-in-kind global platform that will help bring therapies to patients faster and more efficiently. This teamwork and innovation inspire us."
>
> *-Dominique Lagrave, Regulatory Operations Strategic Innovation Leader, Accumulus*

Features and functionalities from third-party apps were used in a new and different way and USDM is qualifying the tech stack based on the changes. These pieces, along with custom code, are the building blocks that meet various regulations and predicate rules as defined in their Unified Compliance Matrix. USDM also developed the Accumulus software validation methodology and strategy.

Quality, compliance, security, and data privacy are core to the Accumulus mission and values. USDM performed risk assessments on features and functionality, assessed the user story and the bigger picture, and is writing and automating the test scripts to prove that the building blocks were qualified and ready for user acceptance testing (UAT) and production. These elements of the Computer Software Assurance (CSA) methodology have saved time and effort by leveraging the existing vendor audit report and capturing the quality artifacts as they were created.

Shortening the time between having a medicine and getting it to patients is possible. Enabling this continuous data-driven review leads to real-time data submissions and that is bringing the future of real-time, iterative drug development within reach.

Use Case 3 – AI Chatbots Support GxP Content for Clinical Trials

Cloud technology is critical to the success of life sciences companies and IT organizations, yet moving a heavily regulated system to the cloud can cause concern for quality leaders.

USDM helped a Top 10 global pharmaceutical company create a validated DevOps framework to use artificial intelligence (AI) chatbots that provide automated assistance with regulated content at their clinical sites.

The customer lacked the experience to use DevOps tools in a regulated environment and had no formal SDLC, CSV, or SOPs governing their regulated development processes. USDM developed a Master Assurance Plan (MAP) that distinguished regulated, non-regulated, and Software-as-a-Medical Device (SaMD) data to differentiate between required artifacts and formal, informal, and ad-hoc testing to enable the customer to meet global regulatory requirements.

USDM also helped the company with an AI pilot program and built a continuously compliant platform to scale AI bot use for faster innovation. This included developing a governance structure and workflows to support regulated and SaMD use cases and educating their teams on best practices for DevOps pipelines to meet global regulatory requirements.

FAQ: People, Processes, and Technology

IT and QA leaders are inundated with decisions related to capabilities, cloud-first technology, cloud compliance, and making the most of their data, and that's barely scratching the surface. When it comes to integrating a holistic compliance framework across your entire cloud tech stack, here are some of the most frequently asked questions.

People	
How do we align our IT and Dev teams and our QA and Validation teams?	Start by identifying the tools you need for your development and validation processes, then determine how you will create the process in the technology. Collaborating on these aspects requires that you move beyond the basics of writing documents; you want the technology to enable you to do anything you need it to do. Agreeing on the technology and understanding the process flow is key to aligning your IT and Dev teams.
How do you properly onboard and train your people to understand the agile ways of working?	It is critical to document and define SOPs and processes, but you need to distinguish between training and actually driving adoption and understanding. There needs to be a cultural transformation. For example, implement daily standup meetings, enable daily and weekly communication, and commit to demonstrations that show your teams how things could and should work. The only way that you can move quicker or more efficiently in this framework is that people truly understand the ways of working and how those ways are different.

Processes	
How do we integrate the tools into our GxP processes in an agile way?	Define your quality guardrails, then implement tools that support them. For example, communication among team members is a guardrail. It prevents individual teams (e.g., security, application development, QA, compliance) from working in a silo for too long. You can implement a communication tool like Microsoft Teams or Slack to maintain a traceable history of communication about a project.
How do we collect GxP records throughout the process?	From Slack to SpiraTest, the right supporting tools ensure that the artifacts can be captured without derailing the innovators from innovating. At minimum you should have systems to capture issues, bugs, changes, requirements, product backlog with electronic approvals, software releases, test cases, test execution, and defects. You don't necessarily need these applications or any new software, but you need to set up your tools to support your process and establish traceability from your ideas through changes through release to end users.

Technology	
How do we create the process in the technology?	Technology supports well-defined quality guardrails (like user stories, requirements, risk assessments, level of detail, required information and traceability, definition of done, and testing activities) then adds stage gates and approvals where needed to capture the compliance artifacts as they are created. The goal is to build in and capture quality as we go, not to compile and test for quality at the end of the process.
What tools and technology do we need to think about as part of this framework (vs. just writing documents)?	Functionality for tools you might use as part of the framework include: • DevOps • Issue tracking • Agile Project Management • Requirements Management • Automated Testing • Monitoring

Conclusion

As life sciences companies continue to take advantage of Google Cloud Platform features and functions across SaaS, PaaS, and IaaS, there is a natural expansion of SaaS apps and system integration to develop and evolve more innovative and complex business solutions. These cloud-based solutions are necessary to keep up with the ever-expanding volume and velocity of regulated data that drive business insights and decisions. These are the very solutions that impact quality, patient safety, and profitability. New business models are being developed to leverage the non-traditional use of regulated data.

Use of the cloud, evolving solutions, and new business models are dependent on an agile compliance framework; therefore, UPC, the built-for-compliance framework, must become an integral part of DevOps. Only then can a continuous state of compliance be ensured.

Developing a software application with compliance built in is complex and there are many facets. Still, you may be wondering if this can be done in-house. To ensure that it's done right, you need to bring in strategic partners to ensure and verify that your development process and software app really is compliant.

Google has the technology to help customers configure secure, compliant workloads. USDM has the proven methodology for compliance in the cloud. We know that CSA fits well into the Agile methodology. We have shown that this compliance approach to software development works.

About USDM Life Sciences

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. We help our customers use cutting-edge technology to increase their speed to market while ensuring continuous compliance and patient safety. The world's leading technology companies trust USDM to ensure their technology is adopted effectively, powerfully, and in compliance. Thousands of life sciences companies choose USDM to bring the future of work into the present.

About Google Cloud

Whether your business is early in its journey or well on its way to digital transformation, Google Cloud can help you solve your toughest challenges. Google Cloud for Healthcare & Life Sciences evolves the care paradigm, advances research at scale, and empowers everyone in your organization to innovate and transform.

When regulated companies need third-party tools with specialized functionality to build complex applications, GCP has a large network of approved partners to choose from.

Contributors

Stepheni Norton,
Director of Product Management,
Digital and Cloud Solutions,
USDM Life Sciences

John Petrakis,
Vice President of Cloud Assurance,
USDM Life Sciences

Kim Hutchings,
Head of Alliances and Digital
Transformation, USDM Life Sciences

Shweta Maniar,
Director, Healthcare & Life Sciences
Solutions, Google Cloud

Andrea McGonigle,
General Manager, Healthcare & Life
Sciences Partnerships & Strategic
Initiatives, Google Cloud

Contact Us

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

usdm@usdm.com

www.usdm.com

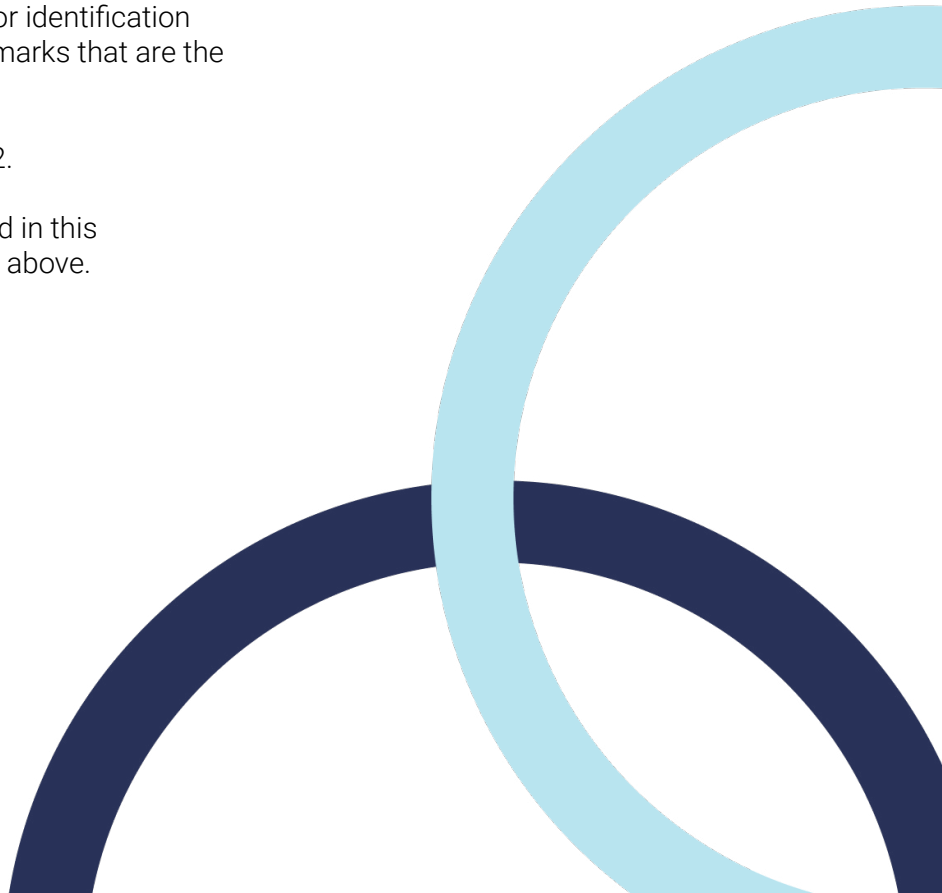
COPYRIGHT © 2022 USDM Life Sciences. All rights reserved.

No part of this publication may be copied, reproduced, printed, distributed, or published, in whole or in part, by any means, electronic, mechanical, photocopying, recording, or otherwise, without the express consent of the copyright owners.

USDM Life Sciences℠, USDM℠, and USDM Cloud Assurance™ are trademarks/service marks of USDM Life Sciences. All other trademarks/service marks are the property of their respective owners. All other brand, company, and product names are used for identification purposes only and may be trademarks/service marks that are the sole property of their respective owners.

Published by USDM Life Sciences, January 2022.

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



USDM Life Sciences

Google