

GxP Cloud Benefits

- Streamlined and centralized regulatory compliance
- IT Infrastructure:
 - GxP qualified
 - HIPAA compliancy
- Global Tier 3 / Tier 3+ ISO, SSAE, SOC compliant datacenters
- Data integrity assurance
- IT operational burdens eliminated
- GxP applications hosted on qualified cloud platform
- Enhanced business agility and resiliency via simplified IT
- Future proofing via maintenance and upgrade simplicity in the GxP cloud
- Improved adaptability to change via enhanced IT elasticity
- Avoid costly IT overprovisioning with pay-as-you grow pricing and rapid scalability
- Data retention concerns eliminated with scalable, secure storage
- Compliant backup, restore and disaster recovery options for additional IT peace-of-mind
- CloudMigrate service for easy transition to the cloud
- Reassign IT CAPEX funds to OPex and R&D

We Are Ready. Are You Ready?

Odyssey VC (OVC) and Egenera combine to deliver a compliant GxP Cloud Platform

The internet is replete with research studies and surveys extolling the benefits of cloud computing. For good reasons -- cloud has become ubiquitous.

But, getting to the cloud for highly regulated businesses such as those in the pharmaceutical and life sciences industries is seen as a significant challenge.

Fortunately, the good news is that there is an accelerated move by regulated companies to actively address these challenges through the utilization of competent industry partners. This is enabling rapid adoption of cloud technologies within these highly regulated industries.

The caveat is that there are still many critical mandatory activities to be addressed before cloud benefits can be realized. Odyssey Validation Consultants (Odyssey VC) and Egenera have the experience and expertise to ensure the challenges are addressed so that you can begin reaping the benefits of cloud sooner, rather than later.

Cloud - Use IT to grow your business, not slow your business.

When it comes to the information technology (IT) resources needed to facilitate organizations operating in the highly regulated Life Sciences sector, investment has traditionally been channeled to on-premise infrastructure and human capital to provide the IT resources required to compete effectively. This model is both time and capital intense.

With cloud, capital no longer needs to be earmarked for IT infrastructure. Egenera's Xterity Cloud Services enable you to secure the compute, storage, and networking performance required to grow your business, without incurring upfront capital expenses.

Rapid cloud onboarding via trusted advisor validation consultants simplify the regulatory maze

*"I am always looking into new mechanisms to enhance our ability to utilize new technologies in the deployment of compliant GxP Systems. My IT strategy is focused on the move to cloud platforms capable of supporting applications subject to regulatory oversight," said **Emmett Nolan, IT manager at Aspen Pharma Trading Limited.** "As such, I have found that the GxP Cloud offering and supporting Lifecycle Management Services offered by OVC in conjunction with the technical performance of Egenera is an excellent fit for us."*

Getting there - from here.

Egenera's highly skilled cloud support team is available 24x7x365. This always on technical support, combined with enterprise class hardware hosted in world class datacenters enables us to focus on IT system level regulatory requirements, compliant processes, system availability, security, etc. With 16+ years enterprise class IT solution experience, we're structured to ensure our 99.99% system uptime service level agreement (SLA) is achieved.

Odyssey VC delivers industry leading consultancy and engineering services packaged in a comprehensive GxP Lifecycle, which is underpinned by GAMP 5 and is executed under the guidance of the Project Management International (PMI) methodologies. This methodology is at the core of how Odyssey VC and Egenera combine to offer a very powerful integrated GxP Cloud Infrastructure and Lifecycle Management solution.

GxP Cloud is a journey – be sure you have a credible co-pilot

One of the main benefits of GxP cloud is that it enables businesses to focus on strategic goals instead of IT. This benefit can only be realized if your cloud partners have the experience and technologies that enable you to rapidly onboard in the cloud, in a **regulatory compliant / audit ready** manner.

Unfortunately, the cloud service provider (CSP) market is a minefield of commodity cloud vendors who don't have all of the puzzle pieces. Regardless of their "marketing" speak and associated collateral, many of the large CSPs provide nothing more than "some assembly required" GxP documentation. At the end of the day, companies are on their own with many CSPs, but not with Odyssey VC and Egenera.

Why partner with Odyssey VC and Egenera?

- We deliver **results**, not just services – compliant/audit ready cloud migration strategy & execution
- We engage in **long term** valuable relationships with **dedicated** and **reusable resources**
- We leverage GxP Ready, world-class Tier 3/Tier 3+ data centers strategically located **around the globe**
- Through our innovative approach we are at the forefront of **delivering solutions to companies in heavily regulated industries** to ensure that they will continue to do business into the future in an ever evolving digital marketplace
- The Odyssey VC GxP Cloud Platform delivers fully compliant cloud services to regulated companies in the life sciences sector and in the connected health/IoT space, ensuring data integrity in an audit ready environment. **OVC has worked closely with international regulatory authorities to develop its GxP cloud offering to ensure it meets and exceeds the requirements in this space.**

About Odyssey VC:

Odyssey VC consults to a broad range of regulated global companies in the Life Sciences sector. Odyssey VC's unique offering is a combination of Xterity's managed cloud infrastructure engineered as a GxP Cloud Platform combined with industry leading Computerized System Validation Lifecycle Management Services. Odyssey VC's extensive computerized system validation experience ensures the delivery of consistent, best-in-class, audit-ready-systems that allows customers to efficiently do business in a highly regulated, competitive environment.

Odyssey VC's customers:

Odyssey VC typically partners with Life Science companies, operating in a highly regulated environment, who require their GxP computerized systems be fit for purpose, fully validated and in an audit ready state. Agile, market leading and future proofed companies are actively moving to cloud services to maintain their competitive advantage while minimizing costs. Odyssey VC's senior consultants have over 15 years' experience in all aspects of computerized systems lifecycle management and have completed work for large pharma companies including **Pfizer, Amgen, Alexion, Aspen** and others. In addition, due to the growth in IoT and in particular IoT for connected health, Odyssey VC and Egenera offer fully compliant GxP cloud-based solutions for 'Connected Health' Start-Ups requiring a scalable platform.

Egenera and Odyssey Validation Consultants combine to do the GxP Cloud heavy lifting so you can achieve the same levels of compliance in the cloud that had only been possible with costly, complex on-premise solutions.

For additional information please contact us at:

Odyssey Validation Consultants

Unit 6 Block D, The Waterways,
Sallins, Naas, Co. Kildare, Ireland (W91 DN60)
Phone: +353 (0) 45 820 246
Fax: +353 (0) 45 834 205
Email: info@ovc.ie

Egenera, Inc.

80 Central Street
Boxborough, MA 01719 USA
Phone: 978.206.6300
Fax: 978.206.6436
Email: info@egenera.com