

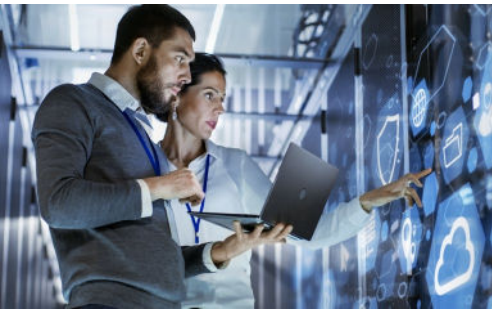
# Pharma IT

A ProductLifeGroup Company

## Cloud Services



The advancement of technology is leading to a paradigm shift in the life sciences industry. Companies are gravitating towards Cloud-based services to manage their business. As with any new technology, initial adoption is costly and only implemented by some of the industry's larger companies. However, with the growth of the industry, the cost is becoming significantly reduced, allowing access to small and mid-sized companies



Pharma IT and PLG have partnered with two cloud software providers to execute a system where clients can quickly and easily slot in their data and start managing their projects. These cloud-based solutions are GxP-validated and tailored for the pharma, biotech, and MedTech industries.

Ennov is our offering for Electronic Document Management (EDMS), Quality Management System (QMS) and Training Management (TMS), Clinical Information Management (CTMS/eTMF), and Regulatory Information Management (RIM/IDMP, eCTD).

Argus and/or HALO PV is our prime choice for Pharmacovigilance and Safety. Both systems have been rigorously tested for compliance against best practices and industry standards. Our expert IT team is also available to train and maintain these systems and your data.



# TWO PILLARS of the Pharma IT Cloud

## ENNOV

EDMS, QMS, Training, RIM, IDMP, Dossier Publishing, CTMS, eTMF etc.



## ARGUS SAFETY and HALO PV

Full PV management.



■ This digital transformation suite is designed to integrate and manage regulatory content. The platform provides a solid foundation due to its intuitive implementation and configuration, flexibility, secure and stable technology, and single repository solution. This Unified Compliance Platform supports and enriches the pharmaceutical product life cycle by enabling the coordination of Quality, Clinical, Regulatory and Commercial data.

■ Argus Safety and HALO PV are a multi-faceted pharmacovigilance software which facilitates pharmaceutical companies to optimise global compliance, faster integration of risk management and enable better safety decision-making. Argus Safety with HALO PV can support data extracts and business process management processes currently not supported within Argus Safety. You can manage, ICSR, PSMF, drug safety processes, Signal reporting, Literature search and many more safety responsibilities. These tasks can be automated with machine learning and AI enhancements. This reduces the amount of manual effort required for tedious and repetitive tasks.



# ADVANTAGES of Pharma IT Cloud-Based systems over Legacy systems

## Cloud-Based System



## Legacy System



### Implementation Time and Method

The system is pre-configured to industry best practices, enabling immediate implementation and lowered transition time.

Uses Software as a Service (SaaS) model, which uses Cloud Technology to deploy, fix and update the system configurations.

It can take anywhere between 3 to 6 months for the implementation of software with licenses and additional time for the transition of the company's data.

Configuration locked to End User Specifications.

### Compliance

The system has already been GxP validated, and Pharma IT maintains system compliance over time.

Software must be tested for compliance.

### Scalability

With our system, you pay per user and can scale your solution over time.

Cloud computing allows for maximum scalability, no matter the number of users or quantum of data being managed.

License costs are generally based both on modules and the number of users.

The need for Physical IT resources and internal staff are another limiting factor in scaling up data storage and management.

### Cost and Overall Benefits

Factors to improve cost-benefit:

- Low, to no, up-front implementation costs
- The system comes GxP-validated
- IT infrastructure is Cloud Computing
- Rapid system deployment and training
- IT expertise is provided by Pharma IT
- Extremely low cost to scale
- Cloud computing allows for faster implementation, maintenance and updates.

Considerations likely to add additional cost:

- Must have IT infrastructure in place
- Must have IT experts present as an additional cost
- Legacy software requires time to test, implement, configure, maintain and update
- Scalability requires additional physical and software resources
- Compliance with the system must be determined before setup

# WHY CHOOSE Pharma IT & PLG as your Cloud Solutions partner?

## EXPERTISE

■ **Pharma IT** was founded in Denmark in 2016, focusing on pharma, quality, and IT. Since then, our company has grown to provide services across the drug development life cycle. Our IT Applications team includes experienced IT consultants and bright young talents, who can support you with all IT Applications processes. We can tailor our services to meet your needs and budget.

■ **PLG** is a global life sciences solution provider with expertise in multiple disciplines. In collaboration with our partners at Pharma IT, PLG can support the quality of the information your company produces. Our global reach also allows us to leverage a broad range of external expertise.



## AGILITY

Pharma IT/PLG the IT systems come GxP validated and are already implemented. It is essentially a "plug-and-play" system in which companies can slot in their information and begin working. This rapid deployment method saves the client from any down time and subsequent loss and enables a fast return on investment.

To learn more, please visit Pharma IT's website:  
<https://pharmait.dk/services/pharma-it-cloud/>



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