PHARMACEUTICAL INDUSTRY
IT QUALITY, COMPLIANCE AND SECURITY

Owning your data is the fundamental backbone of any life science company. It is of the utmost importance for pharmaceutical manufacturing companies to have the strictest controls over the Intellectual Property (IP) of their drug product. The quality and security of this data, along with its compliance with industry regulatory requirements is paramount.

Our IT Quality, Compliance, and Security experts help you reduce risk, maximize security, and preserve data integrity. As pharma industry specialists, our consultants boast skillsets in both technical IT and regulatory requirements. Additionally, they are backed by a robust set of systems to support clients effectively and efficiently in quality, compliance, and security.

Pharma IT/PLG supports pharmaceutical manufacturing clients with the following services:

1. **Computer System Validation (CSV):** We perform validation projects to ensure that the client's software or system performs as intended. Our consultants are certified in CISSP, CISA, GDPR, CISM, ISO 27001, GAMP, EU Annex 11, and more. We are also experts in the V-model, Quality in Data Migration, User Requirement Specifications (URS), System Management SOPs, *and much more.*

2. **Qualification of Infrastructure:** We have experienced consultants who can ensure your laboratory and manufacturing facilities are GMP compliant by qualifying your IT Infrastructure. Pharma IT can help you design, build, qualify, and execute an IT infrastructure solution that is reasonable, secure, risk-mitigated, compliant, and tailored to your needs.

3. **Data Integrity:** Our consultants are data integrity experts with several years of experience in the field and can assist you in establishing a sound data integrity practice. With grounding in the ALCOA++ principles, we can provide gap analyses, training, policy and SOP development, mapping of processes and systems, and process optimization.

4. **Data Protection Officer:** This is a specific role where the expert consultant is responsible for protecting your data and ensuring EU-GDPR compliance. They work on data mapping, gap analysis, and enhancing the security of your data. This includes ensuring general risk management through the appropriate technical and organizational measures, executing recurring training & internal audits, cooperating with supervisory authorities, and monitoring regulatory developments to ensure compliance.

5. **Security Management:** This entails a list of services inclusive, but not limited to Risk Assessment, Business Impact Assessment, Data Privacy Impact Assessment, Software Vendor Audit and Cybersecurity Program Acceleration Assistance.

Why Choose Us as a Pharmaceutical Industry Security Partner

■ EXPERTS

Pharma IT's experts have the knowledge and experience working in the IT and Regulatory fields to support clients with multiple services in Quality and Security services. Coupled with PLG's global footprint and extensive resources, we can assist your company in a host of geographies.

■ AGILITY AND FLEXIBILITY

Pharma IT has systems already designed and running to ensure your data is well protected while remaining compliant. We also cater to your specific needs to the unique nature of how you would like to manage your data.

■ SCALABILITY

Pharma IT/PLG would consider not only your current needs by designing systems that can grow alongside your company. We believe in the longevity of our designs to maintain consistency as a hallmark of greatness.

To learn more, please visit Pharma IT's website: https://pharmait.dk/services/it-quality-compliance-security/

Contact us at the following address: sales@productlifegoup.com

START-UP CLOUD SOLUTIONS

Every start-up is concerned about the following two terms: incubator and accelerator. They entail partnerships with Labs, Contract Research Organizations (CROs), Venture Capitalists and many other partnership types to speed up the development of a product. It is the most common route used, but what if there was something your start-up could have that would give you the edge over your competitors? Ideally, you already have it. It is your clinical data and Intellectual Property (IP).

The Start-up Cloud Solutions include:

EDMS | QMS | Training Management | eTMF | eCRF | DocuSign | Safety

PLG and Pharma IT can help you ensure that your IP and clinical data remains your own, is intuitively stored and digitally organized, and can be leveraged to keep your company growing. We do this by offering our cloud technology data management services as part of our Start-up Cloud Solutions. Instead of buying, owning, and maintaining your own physical IT Infrastructure, you can take advantage of our cost-efficient cloud solutions to harness the power of digitalization while protecting your data..

The Advantages of Cloud Technology over its Legacy counterpart?

COST: The systems require no physical infrastructure to be installed by the client and are already set up and configured. This provides cost savings to the client as implementation, maintenance and updates are all faster with limited downtime. Included in the cost would be Pharma IT's dedicated IT department to help manage your data, reducing your need for internal staff.

COMPLIANCE: Our systems come GxP validated, to meet the standards and best practices of the industry. A yearly compliance review is done with reports submitted to the client to ensure your implementation remains compliant.

CONTROL: The main advantage of cloud-based technology is that they act as an interface for your data and provides full control to the client to define access and use. This ensures full ownership of the client to the company's assets and keeps your IP safe.

SCALABLE: While you may be a start-up today, you will be a full-fledged company in the future. That's why our systems boast low to no implementation costs and can scale as you do. You pay on a per user basis, so you'll never have more or less than you need.

AUTOMATION: Cloud technology is integrated with Machine Learning as opposed to Legacy options, which are slow to implement improvements. Machine Learning allows users to automate recurrent and tedious tasks. This in turn saves you time and money and reduces your staffing costs.

Choosing the Correct Cloud Computing Partner

■ PROVEN EXPERTISE & EXPERIENCE

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/biotech-it-accelerators/
Contact us at the following address: sales@productlifegoup.com