Managed IT Services for the Pharmaceutical Industry – Why Regulatory Experience is Essential



Managed IT services can transform IT from being a resource, productivity, and risk burden to being a facilitator of growth, enhanced competitiveness, and positive transformational change. That said, pharmaceutical companies are not like companies in other industries. Considerations such as regulatory compliance, patient safety, and the value of your intellectual property (to name a few) mean it is essential you work with a managed IT services provider that has direct regulatory experience.

A managed IT services provider with regulatory expertise will deliver all the same services of a standard provider, but those services will be delivered in a way that is aligned with your operational and compliance requirements.

This will be explored further in this blog, but it is also beneficial to highlight the advantages of managed IT services in the pharmaceutical industry.

The Benefits of Managed IT Services in the Pharmaceutical Industry

The largest multinational pharmaceutical corporations can put in place very large IT teams to look after most IT requirements in-house. Outside of the largest corporations, however, the question of managing your IT infrastructure is more complex, as it is very difficult to put in place sufficient internal resources.

The regulatory burden is still the same, though, whether you are a small or medium-sized pharmaceutical company or the very largest multinational corporation. Furthermore, even the largest corporations require expert third-party support, particularly given the global nature of the pharmaceutical industry.

The benefits of managed IT services for the pharmaceutical industry include:

- Reduces IT costs while ensuring IT expenditure is predictable.
- Ensures you have the IT skills you need when you need them.
- Continuous optimisation of IT infrastructure and performance.
- Improves cybersecurity with <u>expert protection</u>.
- Reduces operational downtime because IT systems are well maintained and continuously monitored.
- Allows your team to focus on your business rather than trying to solve IT problems or deal with IT challenges.
- Get fast resolutions to issues when they arise from an expert team in your time zone and region.
- Reduces risks related to IT, from security and disaster recovery to ensuring your IT infrastructure is future-ready.

Why is regulatory expertise essential in a managed IT services provider? Here are 10 benefits of working with an IT company that has pharmaceutical industry experience.

10 Advantages of Regulatory Experience in a Managed IT Services Provider

1. Regulatory Requirements Across Multiple Jurisdictions

FDA regulations, EU regulations, and regulations in other jurisdictions are complex. They also have a direct impact on the selection, installation, configuration, use, maintenance, and decommissioning of IT systems. Therefore, <u>extensive regulatory knowledge</u> and experience are essential for managed IT services in the pharmaceutical industry.

2. Industry Standards and Best Practices

Knowledge of regulations also requires a detailed understanding (and practical experience) of pharma industry standards and best practices, including <u>GAMP5</u> and <u>21 CFR Part 11</u>.

3. Validating Computer Systems

In the pharmaceutical industry, it is not enough to simply select, customise/develop, install, and start using software and other technologies. Validation is also essential, so it's important to work with a managed IT services provider with experience in maintaining computer systems in a compliant and validated state.

4. Software and Systems

The learning curve can be steep for software and systems designed specifically for the pharmaceutical industry. Therefore, it is beneficial for your managed IT services provider to have direct knowledge of the systems and solutions commonly used in pharmaceutical

environments. The <u>LIMS</u> and <u>CDS systems</u> that are often used in pharmaceutical laboratories are good examples.

5. IT/OT Convergence

The ongoing digitalisation of production and business processes in the pharmaceutical industry is increasing the convergence of IT and OT (operational technology). As a result, it is beneficial if your managed IT services provider has experience in the integration of IT and OT as well as the challenges, limitations, and opportunities of IT and OT convergence.

6. IT Quality Management Systems

Your managed IT services provider can make a significant contribution to improving your IT Quality Management System. Experience in this area is advantageous.

7. Data Integrity

It is also beneficial for managed IT services providers to have expertise in optimising data integrity, both in general and also for a range of reasons specific to the pharmaceutical industry. This includes traceability, compliance, product safety, operational oversight, and performance optimisation.

8. Cybersecurity

Cybersecurity is important for companies in all industries, but the reality is that pharmaceutical companies are regarded as high-value targets by many hacking organisations. Experience in optimising cybersecurity within the pharmaceutical industry will be beneficial to your organisation.

9. Pharmaceutical Manufacturing and Operational Requirements

It is also helpful if your managed IT services provider has experience and knowledge of the day-to-day operational requirements, sensitivities, and priorities of companies in the pharmaceutical industry. Examples include confidentiality requirements, IP security, physical security, cleanroom controls, health and safety, and production uptime.

10. Industry 4.0 Objectives, Strategies, and Priorities

Implementing Industry 4.0-related technologies and solutions is a key priority for many pharmaceutical companies. As those solutions can involve IT, it's beneficial if your managed IT services provider has knowledge of the Industry 4.0 objectives, strategies, and priorities that are common in the pharmaceutical industry.

Managed IT Services Provider with Regulatory Experience

Westbourne IT works with a range of pharmaceutical companies providing managed IT services, as well as a range of related services. We work with both large companies and small, so we can use our experience and knowledge to support your IT infrastructure. We offer fully customised managed IT services to pharmaceutical companies, so please get in touch with us today to discuss your requirements.