

Why pharmaceuticals should choose the cloud



MASSIMO RUOSI: AX FOR PHARMA

Using cloud-based enterprise resource planning systems can help life sciences companies achieve security, privacy, transparency and compliance

Held back by cumbersome legacy IT infrastructures that are complex, expensive and inefficient to run, many pharmaceuticals are struggling to respond to the dynamic shifts in drug supply and demand driven by globalisation, increasingly complex supply chains, the growth of personalised medicines, and cost and price pressures. Stricter regulations and requirements, as well as the need for drugs to be tracked across the entire supply chain to address the increasing risk of counterfeit products, are also highlighting the need for better control in manufacturing and distribution processes.

To alleviate the operational and supply chain challenges, a growing number are turning to

cloud-based enterprise resource planning (ERP) systems. Cloud-based ERP platforms give pharmaceuticals the tools they need to streamline processes, increase efficiency and reduce costs, while ensuring patient safety, product quality and data integrity. Plus, they facilitate rapid on-demand scalability and significantly lower costs because pharmaceuticals are no longer paying to install and maintain large and expensive IT infrastructures that need updating regularly.

AX for Pharma for Dynamics 365, for example, meets the full range of ERP needs of pharmaceuticals, with integrated systems for laboratory information management, manufacturing execution in modules like Basic Pharma, Advanced Quality Management, Weighing and Dispensing, and Advanced Warehouse Management. The solution also leverages Microsoft platforms to support additional modules for managing specific processes, such as procurement, inventory, clinical trials, plant maintenance, administration, sales and more.

By running all these modules and storing all the associated data on AX for Pharma's cloud-based platform, pharmaceuticals can quickly gain complete control over their entire manufacturing, warehouse and distribution, and supply chain processes. Users can also build dashboards to gain instant access to data about how their business is performing against key performance indicators and corporate goals. For example, they can see information about the supply chain, products, customer interactions and sales, allowing them to pinpoint critical issues,





spot opportunities for process optimisation, and make faster and more informed decisions. Plus, they can view metrics about their quality control systems and processes, so they can drive continuous improvement in how they manufacture and distribute their drug products.

While many pharmaceuticals have been quick to realise the cost and operational benefits of using solutions like AX for Pharma Dynamics 365 to migrate their ERP systems to the cloud, there's one set of systems that have largely remained on-premises: Good Practice Standards (GxP).

GxP is a set of guidelines and regulations that are designed to ensure pharmaceutical and life sciences companies adhere to strict quality standards throughout the drug research, manufacturing, control, storage and distribution processes to ensure that they create safe drug products that

meet their intended use. Some of the standards include Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Practices

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and regulatory requirements such as FDA 21 CFR Part 11 Electronic Records, Electronic Signatures, and EudraLex Volume 4 – Annex 11 Computerised Systems.

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safety and meeting regulations, hence moving these GxP systems to the cloud has long been considered as a significant data security and compliance risk. However, braving the leap into the cloud could actually help companies to create a safer and more efficient model for driving innovation, while protecting customer and business-critical data, ensuring quality control and maintaining regulatory compliance.

Cloud platforms like Microsoft Azure, for example, have been designed to help companies achieve security, privacy, transparency and compliance at any scale. Microsoft Azure has multiple built-in governance technologies, data encryption methods, protocols and algorithms, which are regularly audited and verified for effectiveness by independent third-party assessors. Together, these features ensure that the data in GxP systems remains confidential and is protected from breaches.

For additional reassurance about the security of GxP systems in the cloud, pharmaceuticals can develop a well-defined strategy and robust governance model. Doing this enables companies to identify any potential risks associated with

hosting their GxP applications on the cloud and then implement appropriate processes or security measures to mitigate them before the migration takes place. It also gives them the opportunity to ensure that they will have access to proven data back-up and recovery procedures to minimise the impact of any security breaches. In addition, they can update their own internal IT and quality procedures to ensure they are adapted for using cloud-based applications. Plus, they can train the personnel responsible for managing and maintaining cloud-based solutions. By doing this, and thoroughly assessing the cloud service provider's platform, processes and controls, they can ensure that the system they choose is designed for optimum performance and resiliency, and that all virtual infrastructure components and services are maintained in a qualified state.

AX for Pharma's mission is to help pharmaceutical and life sciences companies implement exceptional cloud-based and on-premises IT solutions to manufacture, control and distribute any type of pharmaceutical product. ■

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