Staying compliant in pharma

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Remaining compliant is one of the biggest challenges for pharmaceutical companies, but with help of epista IT and the AX for Pharma solution, it can be achieved easily

Pharmaceutical and life sciences companies across the world must comply with a range of strict regulatory requirements and guidelines to ensure that the quality and safety of pharmaceutical manufacturing facilities and healthcare products remain consistent worldwide.

For example, companies must comply with Good Laboratory Practice and Good Manufacturing Practice (GMP) guidelines, which outline the minimum manufacturing, testing and quality assurance requirements a pharmaceutical company must meet to ensure that their medical products are safe for human consumption. Other regulations mandate that pharmaceutical manufacturers must audit and validate all systems and software used to process electronic data, and provide electronic signatures and documentation to demonstrate regulatory compliance.

As the industry frequently updates or introduces regulations, it is essential that pharmaceutical companies have flexible and cost-effective enterprise resource planning (ERP) systems, which can be adapted quickly to ensure they retain control over operational processes and remain compliant.

Founded in 2009 and based in Denmark, epista IT is an independent consultancy that helps life sciences companies to select and implement suitable ERP systems, such as AX for Pharma. We then test the system to check it is working as planned and validate that it will enable the company to produce high-quality healthcare products in the most cost-effective and compliant way.

Built on the Microsoft Dynamics AX platform, AX for Pharma is an ideal integrated ERP solution for pharmaceuticals that want to standardise their operational processes, while lowering costs and remaining compliant with evolving industry regulations.

Not only does it offer a familiar user interface and integrate with various other Microsoft products, the solution also provides standard ERP, laboratory information management, manufacturing execution system and dispensing functionalities. In addition, AX for Pharma supports all of the functionality a company needs to comply with Good Automated Manufacturing Practice, GMP and electronic documentation requirements, such as the ability to create electronic signatures and approved vendor and manufacturer lists.

AX for Pharma is also one of the easiest ERP solutions to validate. As a commercial-off-the-shelf solution (Good Automated Manufacturing Practice 5 Category 4 software), it has been developed and extensively tested for standard use by any company in the industry and can be easily updated or extended in the future. Consequently, it takes less time for epista IT to validate the AX for Pharma system than it would if the company had deployed their own customised solution. This reduces implementation time, allowing pharmaceuticals to bring safer and higher quality products to market faster.

Klavs Esbjerg is the CEO and founder of epista IT, a validation partner of AX for Pharma