Streamlining pharma operations

MASSIMO CRUDELI: AX FOR PHARMA

Accuracy and quality control are key priorities for pharmaceutical companies, and these can be achieved easily with an integrated enterprise resource planning solution like AX for Pharma

Pharmaceutical and life sciences companies want to manufacture high quality products in the most streamlined, cost-effective and compliant way possible. In the past, these companies relied on separate enterprise resource planning (ERP), laboratory information management system (LIMS) and manufacturing execution system (MES) to manage the processes involved in producing and distributing medications. However, supporting numerous vendors and IT is expensive, while manually entering data into multiple systems can lead to incorrect or duplicated data. And in an industry where ensuring products are safe for human consumption is a key priority, accuracy and quality control are critical.

Many pharmaceutical companies are now switching to solutions that provide integrated ERP, LIMS, MES and weighing and dispensing functionalities to streamline operational and quality control processes.

Built to integrate seamlessly with the Microsoft ERP, AX for Pharma is the only solution Certified for Microsoft Dynamics AX 2012 for the pharmaceutical and life sciences industry. Via its Advanced Quality Management and Weighing & Dispensing modules, AX for Pharma helps companies to manage everything from weighing ingredients, to maintain production and laboratory equipment; from tracking how long temperature-sensitive products have been out of a temperature-controlled warehouse, to creating a 'regulated product list per country' to monitor the quantity of medications that have been shipped to certain countries.

Weighing and dispensing ingredients precisely is a critical part of the manufacturing process. Although most pharmaceutical companies manually weigh materials according to strict guidelines, human error can creep in when lab technicians have to fill in paper documents or enter data into separate MES, LIMS and ERP systems. Although small, these errors can have costly repercussions during the production stage, potentially rendering the medicine non-compliant or risking patient safety.

AX for Pharma's Weighing & Dispensing module integrates with electronic scales and barcode devices to help technicians accurately calculate and dispense the required quantities of active ingredients and fillers or compensating ingredients for each medication. It also allows them to select materials according to the First Expired, First Out method. This provides manufacturers with a high level of control and visibility over work-in-progress materials to ensure that they are manufactured in compliance with industry regulations.

Global legislation also demands that companies can accurately track and trace each individual product unit as it passes through the supply chain, from the initial weighing and dispensing phase, to the manufacturing and final distribution stages. Using a complete integrated ERP, LIMS and MES system – like AX for Pharma – pharmaceutical companies can easily track each single batch, single container and sample, and automatically print labels. Lab technicians can also access an archive of batch disposition codes, which would help them to isolate or block specific batches or sub-batches, such as those with damaged containers.

Using an integrated solution also leads to significant cost savings when implementing, validating, operating and maintaining the system. Plus, it's more cost-effective, easier and quicker to train every employee to use a single, standard solution with the same interface, operating tools and menus, than it is to teach each department how to use a different system.

AX for Pharma supports all of the functionality a company needs to comply with Good Automated Manufacturing Practice, Good Manufacturing Practice and electronic documentation requirements. These include the ability to create electronic signatures and approved vendor and manufacturer lists. As a commercial-off-the-shelf solution, the software has also been extensively tested for standard use by any company in the industry, making it quick and easy to update, extend and validate in future.

To date, more than 20 pharmaceutical and specialised chemical companies worldwide have reaped significant benefits by adopting AX for Pharma. For example, one large, multi-national company previously used at least ten Microsoft Excel spreadsheets to calculate costs every quarter, which took weeks of work for very skilled, high level managers. Now the company has replaced the spreadsheets with AX for Pharma, it only takes a few hours to complete these calculations.

Meanwhile, another multinational company was using three separate ERP systems in the US, another in the UK and a third in Germany. Not only was it expensive to maintain all of the systems and train employees when they transferred to different offices, it was also time consuming to input the same data into each individual system. By replacing its multiple systems with AX for Pharma, the company has reduced the number of errors made during the manufacturing and shipment processes.

Soon, we will release a preconfigured pharmaceutical tool based on AX for Pharma, which will run in Microsoft Azure and accelerate the implementation and validation processes. Meanwhile, new functionalities and modules in the AX for Pharma roadmap will enrich our solution and help our customers to streamline their operations. For example, companies will be able to manage the vendor qualification process in the ERP system. We will also make significant investments to capitalise on new opportunities to help our customers improve supply chain and clinical trial operations when they are using AX for Pharma. ◎

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