# Ensuring cost-effective compliance

Andrea Ruosi, CEO of AX for Pharma, tells us why pharmaceutical and life science companies should adopt integrated commercial-off-the-shelf solutions to manage production processes

BY REBECCA GIBSON

Managing life sciences and pharmaceutical companies is complicated; processes must comply with strict requirements, while products must be safe for human consumption. To ensure this, companies must manage inventory via an enterprise resource planning (ERP) tool, automate laboratory workflows and manage quality control via a laboratory information management system (LIMS), and use a manufacturing execution system (MES) for controlling weighing and dispensing processes, production and plant maintenance. However, these systems often run separately, creating a disjointed IT infrastructure that is difficult to manage and expensive to maintain.

"Employees must use multiple applications and typically need to create manual workarounds to manage processes outside of the systems' capabilities, such as weighing and dispensing," says Andrea Ruosi, CEO of AX for Pharma. "This introduces human error, potentially increasing costs."

Companies usually need to customise standard MES and ERP systems to ensure they can meet the specialised needs of the pharmaceutical industry.

"Companies must pay every time they update a customised solution and then retest and revalidate the entire system to prove it still meets industry laws," Ruosi explains. "Doing this to multiple systems supported by different vendors can be prohibitively expensive, especially with old software that's no longer supported by the provider."

The solution, advises Ruosi, is to implement a commercial-off-the-shelf (COTS) platform that integrates ERP, LIMS and MES functionality, and can be validated quickly to streamline operations and ensure compliance with evolving regulations, while reducing costs and accelerating time to market.

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"COTS tools have been extensively tested for general use within the specialised pharmaceutical industries, so they can easily be scaled according to business needs and they're much cheaper to maintain," he remarks. "For example, our AX for Pharma solution is built on Microsoft Dynamics AX, so it's automatically updated and revalidated whenever Dynamics AX is. Companies don't need to worry about their IT system becoming a burned platform."

AX for Pharma leverages Microsoft SQL Server, SharePoint and Office to support modules for manufacturing, weighing and dispensing, quality management, plant maintenance, regulatory compliance and activity-based product costing and more.

"Companies using AX for Pharma have an overview of critical business processes for procurement, manufacturing, sales, inventory and quality management," says Ruosi. "Plus, the solution integrates with Microsoft technology, allowing staff to use Word, Excel and SharePoint to complete tasks."

Most importantly, adds Ruosi, AX for Pharma ensures pharmaceuticals comply with industry regulations, including Good Automated Manufacturing Practice 5, Good Manufacturing Practice, and electronic documentation requirements.

"Pharmaceutical and life sciences companies want to manufacture products in the most cost-effective and compliant way possible and our AX for Pharma solution certainly allows that to do that, and more," he says. ◎