Taking a COTS approach

ANDREA RUOSI: AX FOR PHARMA

Commercial-off-the-shelf software offers multiple benefits to pharmaceutical companies who want to cost-effectively manage their production processes, while remaining compliant with industry regulations

Invented as the 'language' to give instructions to computers, software has long been the backbone of every successful organisation. Initially companies invested in software to automate repetitive manual processes and thereby speed up, and improve the quality of, their operations. To differentiate themselves from the competition, some companies contracted IT vendors to develop software solutions that were customised to their specific needs. Over time, these IT vendors identified patterns in the software requirements for each industry and began to create customer-independent (or standardised) commercial-off-the-shelf (COTS) solutions.

Developed and maintained by one vendor, COTS software offers standard features that have been extensively tested for general use by any company, which means it can be quickly scaled and validated when it is implemented by a business. COTS solutions can be more easily updated and revalidated whenever a new version of the software they're built on is upgraded, which means that companies face significantly lower costs and fewer compliance issues. COTS solutions designed for a specific market have the added benefit that their standard features can be configured to meet a company's specific needs without extensive programming. For example, one organisation could configure a standard COTS solution to offer one step item approval process, while another could configure it to provide a more complex approval process by involving different departments.

"AX for Pharma Dynamics 365 is the only COTS solution that covers all the needs of pharmaceutical manufacturers"

The first COTS software was designed to address basic business needs, such as sending written communications electronically and performing calculations. These COTS solutions included operating systems, integrated development environments and individual productivity applications (such as spreadsheets and word processors). Next, IT vendors created COTS software that automated industrial business processes, such as financial management, accounting, and sales and purchasing. These solutions saved companies time, increased quality and user satisfaction, and generated business performance data. Financial management systems evolved into enterprise resource planning (ERP) systems, which can be integrated with other external systems and applications to provide all the functionality a company needs to operate successfully.

The International Society of Pharmaceutical Engineers' Good Automated Manufacturing Practices (GAMP) subcommittee adopted the COTS concept to develop and implement software solutions that complied with the pharmaceutical industry's Good Manufacturing Practice (GMP) guidelines. The guidelines provided in GAMP 5 are used to classify software into various categories, including Category 4 configurable COTS solutions that can be parametrised to meet a company's needs without coding.

Today, there are multiple GAMP 5 Category 4 configurable COTS solutions that can be implemented by pharmaceutical companies, but there's not yet an end-to-end solution that

covers all their IT needs. Consequently, pharmaceutical companies often purchase separate Category 4 COTS systems (usually from different vendors) for ERP, laboratory information management, weighing and dispensing/manufacturing execution, warehouse management/handheld devices and other processes. Some companies operate each system in insolation, while others ask vendors to partially stitch them together using manual operations and interfaces. However, there's a risk of incoherent data and human error if documents and data need to be managed in multiple systems. The complete stitched together solution is more difficult to test and maintain over time, and the interfaces between applications cannot be regarded as GAMP Category 4 configurable software. In addition, ERP platforms weren't specifically built for the pharmaceutical industry, so they don't fully comply with guidelines and regulations such as GAMP 5, GMP and US Food and Drug Administration 21 CFR Part 11.

How does a pharmaceutical company achieve compliancy and validation with such a plethora of disparate solutions, without hiring dozens of additional quality assurance and IT personnel? AX for Pharma for Microsoft Dynamics 365 is the only global solution that covers all these needs and meet the requirements to be considered as GAMP 5 Category 4 configurable software. It offers modules for various manufacturing and quality control processes, in compliance with GMP and other industry guidelines and regulations. Since inception, AX for Pharma has been built on the Microsoft Dynamics platform using Microsoft-dictated standards, so it's easy to test, validate and keep up to date when new versions of Microsoft Dynamics are released.

Following standardisation approaches like the International Conference for Harmonization, AX for Pharma Dynamics 365 tries to align with pharmaceutical requirements in North America, Europe and Japan and global requirements in general. It's the only COTS solution available worldwide that covers all the needs of pharmaceutical manufacturers with a GAMP 5 Category 4 approach, evolving with Microsoft Dynamics, while always focusing on the pharmaceutical industry's specific requirements. ■

Andrea Ruosi is CEO of AX for Pharma

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