

Calculating quality management costs



MASSIMO CRUELI: AX FOR PHARMA

AX for Pharma enables pharmaceutical companies to understand and reduce the costs of total quality management procedures

Quality management is vital in the pharmaceutical industry. Raw materials and finished products must be meticulously tested for quality to ensure patients receive safe drugs in correct doses that do not inadvertently worsen their compromised immune systems.

A study by PwC has shown that the average medium or large manufacturing facility spends up to 25% of their total site operating budget (excluding raw materials) to achieve compliance with both internal quality policies and external regulations. Another PwC report found that manufacturers in the pharmaceutical industry often operate their plants at less than 15% capacity, and accept that between 5-10% of their production will need to be scrapped or reworked. They also

“AX for Pharma is built as a foundation for a quality management system”

expect that quality control processes will account for more than 20% of total production costs.

Quality control teams are struggling to keep up with the rising demands of regulators, primarily the US Food and Drug Administration (FDA). Not only is scrutiny likely to further increase over time, but as global markets outside of the US, European Union and Japan continue to become more relevant, pharmaceutical companies will need to contend with multiple quality standards and regulatory regimes.

In the past, integrated enterprises resource planning (ERP) initiatives and quality management programmes have evolved independently from one another. Over the past few years, however, integrated ERP systems have become one of the most powerful tools to support total quality management. Pharmaceutical companies can use integrated ERP solutions to implement and streamline quality control and quality assurance processes, and to track the actual cost of quality management procedures across their organisation.

Cloud solutions, such as the new Microsoft Dynamics 365, eliminate many of the barriers that prevent companies implementing or upgrading ERP systems. These can be enhanced by vertical solutions, such as the Microsoft-based AX for Pharma, which integrates standard features with industry-specific modules including advanced quality management and Corrective and Preventive Action Management (CAPA).

AX for Pharma is built as a foundation for a quality management system and provides managers with an accurate real-time overview of business activities. The solution can capture the cost of quality control for critical raw materials and manufactured products, and offers extensive reporting and real-time online capabilities. Together these functionalities allow managers to use accurate information about the actual cost of quality management to decide how to reduce it.

Solutions like AX for Pharma for Microsoft Dynamics 365 can also reduce operational costs and save users time by eliminating manual, paper-based data entry and data transfer



processes for Good Manufacturing Processes (GMP) operations.

In a traditional paper-based environment, employees must double-check vast amounts of data to ensure everything is completed correctly and avoid costly repercussions elsewhere in the production cycle. For example, if an employee makes a transcription error and a test result is recorded incorrectly in the laboratory information management system, they will need to rework it once the mistake is discovered. The further down the product development chain this happens, the more expensive the remediation cost. However, when procedures are digitised, companies can capture a complete audit trail of every action in the production cycle, whether in the laboratory or on the plant floor.

AX for Pharma offers configurable approval workflows, a complete audit trail, an electronic signature capability that complies with 21 CFR Part 11 standards, and captures all master batch record elements. This eliminates paper processes, minimising the amount of time employees spend entering, reviewing and approving data.

The ERP system also manages quality controls upon receipt of GMP raw materials and provides in-process quality controls for manufactured products, allowing manufacturers to track each product and lot within a batch. Users can set tight process control limits to identify quality issues as soon as they occur, while the CAPA Management module

creates and processes deviations inside the ERP system. Consequently, raw materials and drugs are manufactured more consistently.

In addition, the Advanced Quality Management module supports and enforces environmental control monitoring procedures, and the cGMP Plant Maintenance module allows users to create maintenance plans for cleaning, calibration and other periodic activities.

AX for Pharma also supports suppliers' quality performance by allowing manufacturers to integrate approved customer and manufacturer lists into the quality management system. The system takes configurable reduced testing policies and sampling plans into account when a quality order is created against a purchase order. Plus, AX for Pharma introduces the concept of quality lead time for better material planning and management of inventory.

To reduce the cost of quality management, pharmaceuticals must be able to capture detailed cost data, and streamline quality control and quality assurance processes. This calls for the implementation of integrated ERP systems, which combines features to support operations with strong industry-specific capabilities. AX for Pharma for Microsoft Dynamics 365 make easy to manage the pharma business more effectively. ■

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