

Outsourcing operations



MASSIMO CRUELI: AX FOR PHARMA

External contractors are increasingly providing R&D and manufacturing services for pharmaceutical and biotechnology companies and solutions like AX for Pharma are playing a central role

The outlook for outsourcing is brighter than ever as pharmaceutical and biotechnology companies continue to rely more heavily on external service providers for R&D and manufacturing services. In fact, a 2016 *Nice Insight CRO and CDMO Outsourcing* survey of 1,173 industry representatives from pharmaceutical and biotechnology companies found that spending for outsourced services is to take a big leap over the next five years. Already, the percentage of pharmaceutical and biotechnology companies that spend over US\$50 million annually on outsourcing more than tripled from 23% in 2012-2014, to 71% for contract manufacturing organisations (CMOs) and development and manufacturing organisations (CDMOs) in 2016.

“Integrated ERP systems are the most effective way to manage increasingly complex regulatory compliance”

Currently, more than 77% of the respondents outsource their services or operations to CDMOs, CMOs or contract research organisations (CROs). The remaining 23% do not currently outsource these services, but are in the process of evaluating CDMOs and CMOs to do so within the next 24 months.

Although more than half of the companies that outsource to CDMOs, CMOs and CROs are large or emerging pharmaceuticals, it is the smaller

pharmaceuticals and biotechnology organisations that are most likely to need outsourcing services in the near future. Pharmaceutical companies will continue to fuel much of this growth as they outsource an increasing number of products and services. Biotechnology companies, which have almost doubled in number over the past five years, will also contribute to this trend as they seek new ways to bring their products to market without investing heavily in building or upgrading their own manufacturing facilities.

Certainly, there are numerous benefits to outsourcing operations to CDMOs, CROs and CMOs. Not only does it minimise investments in capital-intensive facilities, but it also reduces drug development and overall costs, thereby improving net earnings and cash flow. Outsourcing also makes it cheaper and faster to conduct research, increases the efficiency of manufacturing processes and allows pharmaceutical and biotechnology companies to divert resources to focus on other areas, such as marketing.

In addition, outsourcing makes it much easier to comply with different regulations around the world. With that said, various regulatory bodies, such as the US Food and Drug Administration (FDA), have embarked on an aggressive inspection schedule over the past few years, and external contractors are now under the spotlight. Environmental monitoring procedures, personal protective equipment and cleaning, disinfection and equipment control measures are among the most common challenges noted during the FDA inspections.



Integrated ERP systems are the most effective way to help CDMOs, CROs and CMOs manage increasingly complex regulatory compliance when providing research and manufacturing services for pharmaceutical companies. Built on the Microsoft Dynamics AX platform, the AX for Pharma solution makes it easier and cheaper for pharmaceutical CMOs, CDMOs and CROs to meet regulations and guidelines for producing drugs that are safe for human consumption.

AX for Pharma provides seamlessly integrated modules that support all of the functionalities a company needs to comply with current Good Manufacturing Process (cGMP) guidelines. The solution supports all of the processes involving inventory management, manufacturing, quality management, weighing and dispensing, and plant maintenance.

For example, it enables companies to track single product units; keep a full lot genealogy; streamline the batch release process; electronically and accurately measure ingredients during weighing and dispensing processes; simplify inventory operations with barcodes; print identity labels with product information; and manage storage and

shipping conditions. The solution also supports enterprise-wide quality control, allows companies to enforce environmental monitoring procedures, configure cleaning rules, and properly maintain production machinery and laboratory equipment. Companies can also use AX for Pharma to manage stability studies, enforce electronic signature and second-person verification for critical GMP processes, maintain approved lists for vendors and manufacturers, and to support their corrective and preventive actions procedures.

Over the next year, contract organisations that differentiate their offerings and capabilities will be able to retain customers and grow their business within the highly competitive pharmaceutical and biotechnology marketplace. Those that are able to adapt quickly, by taking advantage of the transformative nature of the industry, will position themselves as market leaders. Integrated ERP solutions like AX for Pharma are vital to streamline processes and establish consistency and efficiency. ■

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