

Global Pharmaceutical company implements clinical trial management solution

From product development to finished patient kits, Rockwell Automation equipment is used throughout the entire process

Challenge

- Implementing a new Clinical Trial Supply Management system to:
- Speed time to market
- Secure GXP-compliant documentation, productivity improvements, permanent inventory control and traceability
- Structure the process flow
- Improve quality

Solutions

- Rockwell Automation RS PMX Clinical Trial Management (CTM) solution Including a central information database
- Rockwell Automations Life Science Solution Delivery team's experience and project execution
- A complete recipe/packaging management solution
- A warehouse system
- Comprehensive master data administration
- User role/access rights

Benefits

- Faster time to market
- More flexible control of systems
- Improved quality
- Better stock management



The company

With a unique combination of experience in biology and chemistry, the global Pharmaceutical company focuses on severe diseases in two therapeutic areas - CNS and Immunology.

The challenge

With a rapidly growing business, it was looking for a better solution to manage its clinical trial supply chain from product development through to deliverable patient kits.

The diversity and complexity of the company's development product portfolio was growing as it integrated recent business acquisitions. It was undertaking larger studies with more complex designs and there was a constant pressure to shorten the timeframe to deliver clinical trial material. These business pressures were also underpinned by the continuous need to meet worldwide compliance regulations.

Historically, the company had used several in-house developed systems for Pilot Plant and Clinical Packaging, which relied heavily on manual and paper processes. The pressure on the system was leading to poor stock management and reporting and the company was not in the best position to

LISTEN.
THINK.
SOLVE.®



meet emerging worldwide regulations, such as the electronic records and signature guidelines of FDA compliance 21 CFR.

As a result, it decided to evaluate a new system to manage clinical trials which could improve and speed the process whilst meeting all compliance requirements.

Solution and implementation

It chose Rockwell Automation® RS PMX Clinical Trial Supply Management TM (CTM) application and Rockwell Automation's Solution Delivery team to implement the solution. RS PMX because it was designed specifically for pharmaceutical company needs and the Solution Delivery team for their knowledge and experience in delivering CTM solutions in regulated the pharmaceutical environment.

RS PMX CTM from Rockwell Automation is one of the premiere clinical trial supply management software applications in the life sciences industry. A highly flexible package, RS PMX CTM supports the wide range of different products changes and variations of formulations and processes and manage the inventory, production and documentation of Clinical

supplies (GMP), Preclinical supplies (GLP) and Formulation Development.

This helps to reduce complexity in order preparation and execution, documentation, and traceability, to help shorten product lifecycle development from R&D to commercial manufacturing.

Working together, Rockwell Automation and the pharmaceutical company took a phased approach to the roll-out of the solution across the Pilot Plant and Clinical packaging sites in its European plant.

The first step was to establish a development environment allowing the company's staff to be familiar with the system. Rockwell Automation then deployed a complete recipe/packaging management solution in combination with a warehouse system, comprehensive master data administration, and user role/access rights.

Using a modular approach, RS PMX CTM allowed it to organise the complete material and information flow from production, through primary and secondary packaging to delivery.

The system is even used to manage and track outsourcing of some packaging elements to a third party, which allows it to trace each batch released and avoid duplication of data among systems by maintaining all data entry within the RS PMX CTM system managed within the company.

Learning from the implementation

The person in charge of the initiative said he had recognised some important lessons during the project. The first was to take a "Baby-Steps" approach by defining a manageable project scope (up to 6-months), progressing by phases if necessary,

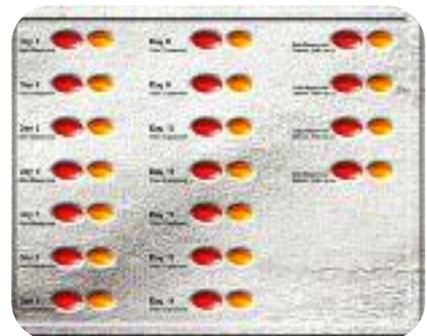
and looking for quicker wins to gain the trust and support of the business.

He also recommended dedicating appropriate resource to the project, identifying a core, dedicated team and making sure all parties were informed of the project detail. Finally, he recommended optimising business processes to match the new system, avoiding system changes wherever possible to save time and reduce complexity.

Benefits

"We have seen benefits in a number of areas," he explained. "All around quality has been improved. The system is now fully compliant with worldwide regulations and stock management is more efficient because we can see at the click of the button what we have and what we need. Lastly, we have direct traceability in the system for all in-house and outsourced activities."

Moving forward, the pharmaceutical company is looking to develop the system in phases. Plans under consideration are to extend the RS PMX CTM system to other packaging unit sites integrating all packaging outsourcing activities to include the US, UK and Germany; evaluating the integration of RS PMX CTM with a new label printing system and integrating all shipping, reconciliation and destruction data within the RS PMX CTM system.



www.rockwellautomation.com

Power, Control and Information Solutions Headquarters

Americas: Rockwell Automation, 1201 South Second Street, Milwaukee, WI 53204 USA, Tel: (1) 414.382.2000, Fax: (1) 414.382.4444

Europe/Middle East/Africa: Rockwell Automation, Vorstlaan/Boulevard du Souverain 36, 1170 Brussels, Belgium, Tel: (32) 2 663 0600, Fax: (32) 2 663 0640

Asia Pacific: Rockwell Automation, Level 14, Core F, Cyberport 3, 100 Cyberport Road, Hong Kong, Tel: (852) 2887 4788, Fax: (852) 2508 1846

Publication LIFE-AP185A-EN-P – Expiry 15 April 2012

Copyright ©2010 Rockwell Automation, Inc. All Rights Reserved