

Rockwell Automation Accelerates Propack Data™ Strategy with Datasweep Acquisition

Summary

The announced acquisition of Datasweep at the Automation Fair™ event in November 2005 was met with great enthusiasm and anticipation among the thousands of user attendees. This was particularly true of those in the pharmaceutical industry, many of whom were looking for a clearer and accelerated path forward for Propack Data PMX MES and CTM. However, the importance of this acquisition in accelerating the path forward for their pharmaceutical clients and their pharmaceutical industry strategy was initially difficult to see because Rockwell Automation was emphasizing the importance of this technology within their technology platform plans. While industry specific functionality was emphasized as a part of this plat-

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form and their FactoryTalk® Integrated Production and Performance Suite, very little industry specific details or roadmaps were available for any but a few select clients. This left many in the pharmaceutical industry wondering whether Rockwell Automation would continue to support Propack Data PMX MES or CTM.

The acquisition of Datasweep with its significant functionality and underlying technology platform was an excellent choice. It certainly has provided Rockwell Automation with a clear path forward for Propack Data PMX MES and CTM and added additional complementary software functionality to meet the increasingly demanding and critical needs of their pharmaceutical clients as well as clients in other industries such as medical devices, automotive, food, beverage, brewing, health and beauty, and home care.

Propack Data PMX MES and CTM

Propack Data has always been recognized for their significant pharmaceutical industry domain expertise. This application knowledge and “can do” attitude has enabled them to meet customer requirements through modification and expansion of their basic software functionality. While the



software functionality and domain expertise continued to expand to meet growing customer needs, the underlying software was becoming an obstacle to continued growth. It did not provide a good migration path or allow them to meet increasing customer requirements in a timely and cost effective way. It needed more modularity, scalability, flexibility, and ease of use. Designed specifically for clinical and commercial pharmaceutical manufacturing, it also did not have the functionality to support discrete Life Sciences applications such as medical devices and the growing drug delivery segment. This was extremely important for future growth and because future quality system functionality required by the FDA would borrow from medical device requirements. Although Rockwell Automation continued to invest in Propack PMX MES and CTM, it was not clear that needed enhancements to the Propack Data software could meet the industry or many of their clients' timetables.

Industry Business Drivers Demand Radical Change and Improvement

The paradigm shift to global pull-based manufacturing is bringing with it increasingly rapid change and greater complexity. External pressures driving change include increasing competition, new socio-political price and delivery pressure, the new scientific risk-based approach to regulatory requirements, continuing advances in bio-medical science and technology, the growth of importation and parallel trade, and the increasing threat and

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growth of counterfeit drugs. At the same time the traditional growth drivers, new drug development and sales/marketing, are slowing down. This has placed a new and urgent focus on manufacturing to drive margin and growth, improve time-to-market of new technology and new drug products, and adjust to the

FDA's new scientific risk-based approach to compliance, inspection, and enforcement. It has placed a greater emphasis on increasing automation to improve productivity and record keeping in both clinical and commercial manufacturing. Emphasizing the urgency at a recent ARC Forum, Paul Greene, Director Drug Product Automation Pfizer Global Manufacturing, said that pharmaceutical manufacturing must actively seek out and rapidly deploy innovative manufacturing technologies and develop more standardized business and manufacturing processes in order to meet the daunting challenges facing the industry. He says this requires radical change and

improvement not incremental change and that suppliers must play a more proactive role.

Accelerating Rockwell Automation's Technology Strategy

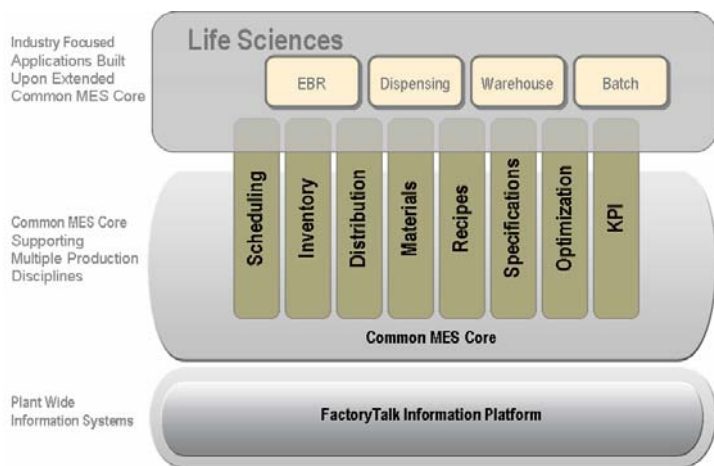
The acquisition of Datasweep with its functionality and underlying technology have provided Rockwell Automation with an accelerated clear path forward for Propack Data PMX so that they can continue to meet the increasingly demanding and critical needs of their pharmaceutical industry clients. FactoryTalk® ProductionCentre from Datasweep provides a scalable multi-plant technology platform and additional functionality that is complementary to the Propack Data and FactoryTalk® Suite functionality. In addition, the recently released FactoryTalk® Integrator provides the ease of integration with multiple types of business systems needed to complete the infrastructure that can truly enable ease of integration with the supply chain and provide a "PAT" ready infrastructure as well as the necessary tools for increased productivity and flexibility.

Rockwell Automation's Next-Generation Unified Cross-Industry MES Solution

FactoryTalk® ProductionCentre technology will be the basis for Rockwell Automation's next-generation unified cross-industry MES solution, while PMX functionality will be the basis for pharmaceutical industry-specific functionality. Rockwell Automation's Pharmaceutical MES customers will get the benefit of current technology and an accelerated path forward that

can effectively respond to rapidly changing regulatory and business requirements that is of concern to many of their current Propack Data clients.

Rockwell Automation is crafting the new solution around a modern Information Platform approach. They first identified an archetypal set of production management functionalities – called "Production Disciplines". They are *Performance & Visibility, Production Management, Quality & Compliance, Asset Management, Data Management, and Design & Configuration.*



Rockwell Automation's Next-Generation Unified Cross-Industry MES Architecture

They then set about the work of building a comprehensive solution platform that provides these basic functionalities, along with all appropriate security, maintenance, and access to a common data model. It turns out that existing FactoryTalk® ProductionCentre products map directly to four of the six Production Disciplines.

The next architectural layer in the new solution consists of core MES functionality including Scheduling, Inventory, Distribution, Materials, Recipes, Specifications, Optimization, and KPI. Again, existing FactoryTalk® ProductionCentre solutions provide the bulk of these core capabilities on a modern J2EE platform. The system is capable of exposing functionality to select communities of users as a service. Operator access using an Internet browser via a Java applet is an effective way to provide users the necessary

Propack Data PMX MES and CTM and FactoryTalk® ProductionCentre Medical Devices functionality and embedded domain expertise provide a solution applicable to the broader life sciences market.

flexibility when deploying solutions. An automatically downloaded thin-client means no executables need to be loaded onto client machines. Clients are readily deployed remotely into external manufacturing facilities and with customers, suppliers and distributors.

The next layer in the architecture is the industry solutions layer. This is where the existing PMX pharmaceutical functionality will be expressed. It will leverage the underlying layers wherever possible.

Life Sciences Industry-Specific Functionality

PMX functionality will be the basis for Rockwell Automation's next generation pharmaceutical industry-specific functionality. This will be accomplished by layering the embedded domain expertise from PMX MES and CTM on top of the core MES functionality. In addition, Rockwell Automation will blend in FactoryTalk® ProductionCentre medical devices functionality and embedded domain expertise to make the solution applicable to the broader life sciences market.

Moving Forward with Propack Data PMX MES and CTM

Rockwell Automation plans to continue to invest in product functionality and ongoing product support of PMX MES and CTM during the transition to the next generation unified MES platform. Propack Data MES 4.X and CTM 4.X will continue to see incremental point releases with additional minor features plus Migration, Archive, and other extensions to supplement core MES functionality. Over time, the migration of PMX MES and

CTM application functionality and IP will culminate in future convergence. Incremental “interim releases” along the way will include functions such as enhanced EBR and Warehouse functionality.

With this new platform, manufacturers will be able to respond in a comprehensive and effective way to FDA’s new scientific risk based approach to regulating the industry. It is a platform that supports comprehensive Knowledge Management and FDA’s concept of a modern Quality Management System modeled around medical devices. Its functionality and

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scalability, even over a multi-plant environment, make it deployable from early in the drug discovery cycle through commercial manufacturing helping to reduce the long and costly technology transfer time.

When it comes time for migration, Rockwell Automation will provide additional tools to help customers make the move. One existing tool that will help is FactoryTalk® Integrator, which can automate the export and import of data and because it is capable of supporting high volumes, can be used to keep two systems in synch during a migration. This should minimize potential instances requiring revalidation and lost plant time where it can least be afforded.

Conclusion

Rockwell Automation has an aggressive strategy, a clear vision, an execution plan, and a technology platform that should enable them to accelerate their product development and release timetable to meet the urgent needs of the pharmaceutical industry as well as the medical device and drug delivery segments of the life sciences industries.

The decision to acquire Datasweep shows that Rockwell Automation truly does understand and has responded to the urgent needs of the life sciences industries and their Propack Data clients.

This paper was written by ARC Advisory Group on behalf of Rockwell Automation. The opinions and observations stated in the paper are ARC's. For further information or to provide feedback on this paper please contact the authors, Greg Gorbach and John Blanchard.

