Embracing ***paperless*** production

PAS-X MES from Werum IT Solutions (Werum) could hold the answer to transforming paper-based production at South African pharmaceutical manufacturers. Abby Vorster speaks to Albert Landman, the company's manager for sales and business consulting, about the benefits of this leading IT solution.

In an industry where producing progressive and life-saving treatments is the norm, heavily paper-based operations seem almost contrary to the forward-thinking focus of South African pharmaceutical brands and manufacturers. Beyond our borders, PAS-X, Werum's out-of-the-box manufacturing execution system (MES), is used by the majority of the world's top 30 pharmaceutical and biotech companies. It is also growing in popularity among many mid-sized international manufacturers.

The solution closes the gap for validated software in the highly regulated pharma industry, and helps boost production performance while improving quality and compliance. It supports all major industry segments, such as vaccines, biopharmaceuticals, solids, liquids, and is suitable for other manufacturing operations like cosmetics and personal care.

A long list of benefits

Validating documents can be time consuming in a paper-based manufacturing environment. It takes long to identify production problems in process documentation where an IT solution like PAS-X allows for automated process validation. Landman explains: 'PAS-X serves to improve overall operational efficiencies. It has been proven to increase process efficiency, improve production quality, and boost manufacturing performance. It's also an ideal tool for meeting compliance requirements as the software is developed according to FDA 21 CFR Part 211 and Part 11, EU GMP and GAMP 5 guidelines.'

PAS-X is centred on the Japanese *Poka-yoke* principle of mistake proofing. This means it eliminates the risk of human error while remaining flexible enough to meet varying needs, making it a leading process guidance solution for manufacturers.

Landman says it has also been proven to reduce the time to market for pharmaceutical products, which in South Africa, is currently a major challenge.

Up to date with industry needs

Werum's MES offering covers the product lifecycle in pharmaceutical and biopharmaceutical manufacturing from process development and commercial production to packaging. 'More recently, PAS-X has evolved to include a track-and-trace serialisation solution to comply with changing anti-counterfeiting requirements,' he adds.

With the World Health Organization estimating that up to 15 percent of all medicinal products in the world are counterfeit, Werum's move to offer this new capability shows its strong understanding of the changing needs of the global pharmaceutical industry.

In addition, it should be noted the first major deadline in terms of the FDA's track-and-trace serialisation regulations for all pharmaceutical products shipped to the US is 27 November 2017. This means that all pharmaceuticals exported from South Africa to the US will be required to include a serial number on the product packaging.

Local adoption on the cards

While Werum is headquartered in Lüneburg, Germany, it has offices or certified location partners all over the world. This is to ensure a high level of on-the-ground support for its customers. Its presence in South Africa is still under review as PAS-X MES is not currently utilised in any local pharmaceutical manufacturing operations. However, this is likely to change in the future with the industry making progress in various areas. These include the manufacturing of biosmilars and the adoption of personalised medicines – a shift already heavily underway in international pharma markets. •

Werum IT Solutions – www.werum.com

▲ **ABOVE**
An operator at the user-friendly PAS-X electronic batch recording weighing and ▼ dispensing screen

BELOW
Albert Landman says Werum offers more than software with its PAS-X MES product, to include pre-configured content for the pharma and biotech processes, and consulting, training and support services

DID YOU KNOW?

PAS-X 318, the **latest available version** of Werum's MES solution, supports the move to **single-use equipment and technologies** in the manufacturing of bio-similars. This robust approach to manufacturing **reduces capital expenditures and the risk of cross-contamination**, while offering **greater flexibility** to meet changing market needs.