

SIGMA PHARMACEUTICALS



Higher Regulatory Compliance, Lower Cost of Manufacture.

The Sigma group is a leading Australian manufacturer of prescription, over-the-counter and generic pharmaceutical products, a leading full line wholesale and distribution business to pharmacy and the owner of the two largest pharmacy banner brands in Amcal and Guardian. Sigma Pharmaceuticals is also the largest contract manufacturer in Australia.

Sigma Pharmaceuticals projects strong profit growth through better scale economies. The Dandenong site, Sigma Pharmaceuticals main manufacturing plant, has undergone a major expansion and redevelopment program costing \$60 million that will significantly improve production capacity, efficiencies and provide a platform for future growth. The other existing manufacturing facilities were becoming difficult to maintain, especially given the strict requirements of regulatory bodies such as the Therapeutic Goods Administration (TGA).

The Challenge

The project at Sigma Pharmaceuticals Dandenong site, is the first application of a commercially available Manufacturing Execution System (MES) to be deployed in the Australian Pharmaceutical Manufacturing industry. The key is that Sigma Pharmaceuticals is looking to improving quality, increasing efficiency and reducing waste.

A key requirement of the project was the implementation of a 'paperless' manufacturing environment, along with a manufacturing process that required a high degree of automation. Dickinson Autocon Systems, Elan Software Systems' local certified partner, was chosen as the Systems Partner to provide the complete control system, including the Manufacturing Execution System (MES), which manages the overall process and the automation system, which controls the plant equipment (valves, motors, pumps, etc). The scope of the whole project includes HVAC, Plant Utilities, Purified Water Distribution System, Environmental Monitoring System and Automation of the Manufacturing Sites.

"XFP-MES helped achieve highest regulatory compliance and drastically improve batch release time."

Scott Siddall, Plant Manager

The Solution

Sigma Pharmaceuticals chose XFP by Elan Software Systems distributed in Australia by Dickinson Autocon Systems, due to its strengths in meeting stringent pharmaceutical needs.

The implementation of XFP includes control of the dispensing, manufacturing and clean-in process (CIP) systems using electronic batch records (eBR). The eBR are essentially an electronic copy of the standard paper-based batch records that most pharmaceutical manufacturers use to control their manufacturing process. The advantages of eBR include better traceability through the use of electronic signatures, security and bar-coding, improved repeatability due to stricter control of key process parameters, and simpler review, cross-referencing and storage of batch information.

XFP utilizes the Weighing and Dispensing module which integrates seamlessly to the eBR, sharing a common database which allows such functions as material reconciliation (via barcode scanning) and campaign weighing.

XFP interfaces with Sigma's existing BPCS Enterprise Resource Planning (ERP) system, downloading raw material and batch information, and uploading material usage data. This allows for automatic integration of the new facility into Sigma's existing processes, and helps to prevent human, data-entry errors. Dickinson Autocon Systems engineers used S88 techniques to code the PLC by creating phase logic to map into the XFP equipment module. This allowed new manufacturing instructions sent from the ERP to be deployed to XFP Weighing & Dispensing with electronic process



instructions across both automated and non automated manufacturing.

An essential for the project was to meet the requirements of data storage and security in accordance with Good Manufacturing Practice (GMP). The standard guidelines covering electronic storage of data are the U.S. Food and Drugs Administration (FDA) Code of Federal Regulations 21, Part 11. This Regulation sets forth the criteria under which electronic records are considered reliable, trustworthy and generally equivalent to paper records. This was relevant for the MES implementation. The XFP-MES suite includes pre-defined electronic signatures, comprehensive security features and complete audit trails of user actions and executed eBR. It stores data in an industry standard database. A set of clustered servers and a redundant Storage Area Network (SAN) were used to ensure security of the batch data.

The Benefits

The system demonstrates true MES by using workflow management and replacing cumbersome paper-based traceability with electronic work instructions. The innovative beauty of this application is the merging of automated components in the manufacturing process with manual tasks. This allows a common validated record of all manufacturing steps with genealogy tracking enabling Sigma to achieve the highest regulatory compliance and to drastically improve batch release times.

The deployment of Elan Software Systems' XFP-MES and Dickinson Autocon Systems expertise will enable Sigma Pharmaceuticals to gain significant advantages over its competitors by reducing regulatory compliance time and management, reducing time to manufacture new and existing products, reducing QA time and resources to release products, reducing errors by up to 75%. These all provide Sigma Pharmaceuticals with a lower cost of manufacture.