

Solution

- **New control platform**
 - Improved reliability
 - Enhanced on-site diagnostics and maintenance functions
 - Seamless integration with manufacturing global control network
- **New batching system**
 - Master recipe controller
 - Simplified recipe configuration
- **New supervisory system**
 - Improved plant visibility
 - Improved alarming
- **New electronic validation & batch recording system**
 - Meets FDA regulations

Results

- **Plant risk alleviated**
- **Reduced maintenance time**
 - 60% faults don't require engineering

Pharmaceutical manufacturer takes control of its plant via S88 automation solution based on RSBizWare Batch

A complete automation upgrade provides ease of trouble-shooting and maintenance, saving time and technical resources on an estimated 60% of reported faults, now identified and repaired by plant operators.

Background

The manufacturing division of an Australian pharmaceutical company operates a series of discrete production modules for different drugs. One of these manufactures a variety of drugs for the massive USA market, and must therefore comply with the regulations of the USA's Food & Drugs Administration (FDA), the world's strictest pharmaceutical authority. All the manufacturing modules must also comply with good manufacturing practices (GMP) — a system defined by global food and drug authorities for ensuring pharmaceutical products are consistently produced and controlled according to quality standards.

In common with many pharmaceutical companies around the world, the Australian pharmaceutical manufacturer sought to incorporate S88 methodology for its batch control systems. The S88 standard of the Instrumentation, Systems, and Automation Society (ISA) defines a common set of models and terminology that can be used to describe and define batch manufacturing systems in accordance with GMP. Its 'modular batch automation' methodology breaks down each manufacturing module into a pyramid of smaller and smaller process



steps, known (in descending order) as 'procedures', 'unit procedures', 'operations' and 'phases'.

The basic process of pharmaceutical manufacturing commences with the transferal of raw products into dispensing silos, from which they are conveyed into a weigh bin. The combined powders plus any solutions that might be added are mixed together, then dried using heated air flow. All weight is reconciled, followed by milling and final blending of the batch; then the resulting product is ready to be pressed into tablets.

Challenge

The decision to introduce S88 batch control methodology arose out of a recognized need for the latest batch control technologies. Although each manufacturing module was (and is) compliant with GMP, the control technology in the plant was not sophisticated. One of the modules incorporated manual recipe entry and operation, with 15-year old relay logic and an unsupported microprocessor for batch-weighing. The manufacturer also wanted to increase the visibility of operation throughout the plant.

So, in a move that was to set the standard for the entire plant, the company embarked on a complete automation and control system upgrade of one of the modules in the first quarter of 2001. The broad requirements of the new system were the integration of a dedicated S88-based module control system with a plant-wide manufacturing control communications network and the company's enterprise network. The new automation system was also required to demonstrate ongoing compliance with GMP.

Solution

Based on its experience with S88 and its ISO9000 quality management system, Rockwell Automation system integrator Dickinson Autocon Systems was selected to design and implement the batching, automation and control solution for the first module. The work was carried out in collaboration with the pharmaceutical manufacturer's project team.

At the manufacturing module level, the new control system is centered around an Allen-Bradley ControlLogix system for control of both analogue and digital I/O. The open device-level communications network DeviceNet was used to link the various weigh-scales and Allen-Bradley Flex I/O modules to the controller, allowing easy incorporation of the original wiring into the new control system.

Supervisory control of the module is in the hands of Rockwell Automation's supervisory monitoring and control software, RSView32. The main RSView server is located in a central server room, and connected to the dedicated controller by a high-speed fiber optic Ethernet link. Three RSView clients located on the plant floor are linked to an Ethernet control network local to the module, as is a wireless barcode scanner.

In the server room also sits the new master recipe controller and the 'brains' of the S88 batch system — the manufacturing batch server, running RSBizWare Batch software. Both the batch and supervisory servers are part of the 'manufacturing global control' Ethernet network, which is connected to the manufacturing module by the high-speed fiber optic Ethernet link.

Dickinson Autocon systems manager Philip Reid explains Batch is the engine that controls the batch from a management and 'recipe-build' point of view, and provides the main window into the system. To achieve each step in a recipe, the Batch server calls for the

module control system to act on specific phases of action. "When the operation calls for a certain phase, Batch sends a command to the controller to run that phase," Reid says. "ControlLogix then sends commands to each pump or valve, for example, as required."

Operating independently of Batch, the RSView supervisory system monitors plant operation and is also responsible for alarms and plant diagnostics.

The manufacturing batch server and RSView supervisory system are joined on the manufacturing global control Ethernet network by a manufacturing database server and a manufacturing logging server; all four are in turn linked to the pharmaceutical company's regional enterprise communications network, which features the company's materials resource planning (MRP) system and 'primary domain controller'.

Together, these six servers share information in various ways to ensure electronic validations and batch events are recorded in accordance with the regulations of the FDA. Compliance with the FDA's 21 CFR Part 11 standard, which specifies how companies in FDA-governed industries must handle electronic records and electronic signatures, is also mandatory for all companies exporting pharmaceutical products to the USA market.

To meet these requirements, and to replace a manual system where all

logs were hand-written, Dickinson Autocon developed a sophisticated means of electronic validation and batch recording via Batch and RSView32.

"Whenever an operator does something, the system has to record who carried out the action and from which terminal," says Reid. "The addition of ingredients also has to be verified by one or two people; the system is capable of using multiple electronic signatures and barcode identification. We built interfaces into Batch and RSView, so that at various stages of the process it will prompt for an electronic signature before anything can proceed." Furthermore, as ingredients are added, they are scanned and verified using a wireless barcode scanner.

All batch events are logged by the manufacturing database server, which receives recipe information, alarms, and other events from both Batch and RSView. This data is required by the FDA to be stored for 11 years. A separate manufacturing logging server logs analog variables for trending and insertion into RSView and the database server for batch reporting.

Results

Once the new control system was up and running, it became clear the same solution should be extended to other manufacturing modules. "We've taken control of the plant through RSBatch and RSView," says the pharmaceutical company's project engineer. "We

alleviated the risk to the plant, and the project was validated on that alone. But there are also massive benefits in control and monitoring, and the validated electronic control means that we can know when, how and why something has happened."

"A great advantage of the electronic system," adds Reid, "is that it doesn't allow actions to be performed out of sequence. It reduces the chance for human error." The use of barcodes also eliminates the need for a second human signature in many stages of the process.

The manufacturing operations manager is also enthusiastic in her endorsement of the new system. "Not only is it a straightforward system for operators to use, but plant diagnostics are markedly improved," she says. "It's very easy for operators to identify any issues we have in the plant, and address them promptly. Under the old system, we might have had ten technicians trying to work out a fault. Now we've got a system that straight away points at the problem and provides a reason for it. We can go straight to the problem without having all the technicians in."

The project engineer adds that through the logging aspects, engineers can diagnose the system from their desks in engineering if necessary, but estimates around 60% of reported faults would not require engineers to solve.

Based on the success of the S88-based control solution, the pharmaceutical manufacturer has been upgrading the

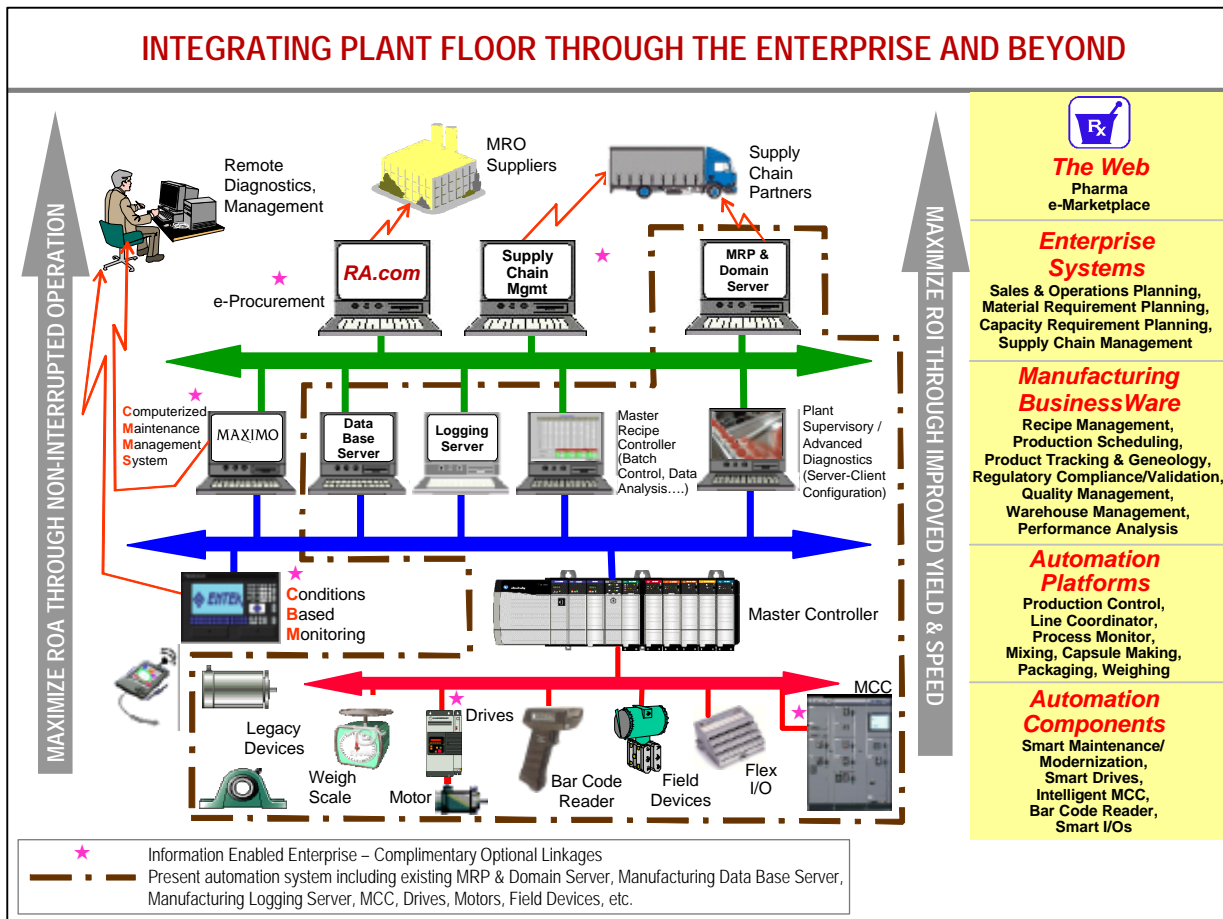
balance of its modules in stages. The company attributes much of this success to the use of RSBizWare Batch. "Batch is very powerful," says the project engineer. "It offers a three-pronged approach: configured by engineers, driven by operators, and controlled by management."

The architecture on the following page depicts Rockwell Automation's concept of an Information Enabled Enterprise. The area outlined with a brown dash line represents the present automation level under discussion in this document. The remaining portion illustrates a host of solutions that Rockwell Automation can provide today to integrate the plant floor to the enterprise and beyond.

Due to reasons of confidentiality, this customer prefers to remain anonymous.



INTEGRATING PLANT FLOOR THROUGH THE ENTERPRISE AND BEYOND



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