

Section17:Automated Systems

17-1:Enterprise Resource Planning System (ERP)

The ERP system is designed to model and automate many of the basic business systems required to properly manage an API manufacturing facility. The ERP system integrates information across the facility from finance to the shop floor, eliminating complex and time consuming links between computer systems that often stand alone, disconnected from each other.

The ERP is an extension of the Manufacturing Resource Planning (MRP) system standardized by the American Production and Inventory Control Society (APICS). The ERP system is the main transactional device used in modern manufacturing plants to automate and integrate both business and production management processes.

ScinoPharm has installed the SAP R/3 software for the ERP system. R/3 is the SAP client-server package that provides the following business modules:

- * Asset Management (AM),
- * Controlling (CO),
- * Financial Accounting (FA),
- * Human Resources (HR),
- * Plant Maintenance (PM),
- * Production Planning (PP),
- * Quality Management (QM),
- * Sales and Distribution (SD),
- * Material Management (MM).

17-2:The Process Automation System (PAS)

The PAS is a hybrid-computerized system consisting of a distributed control system (DCS), programmable logic controllers (PLCs) and a process data historian (PDHS). The hardware consists of a modular controller, PC-based operator consoles, PLC and an open system connected to PDHS and other third party software running on plant network computers. There are total of 14 PAS consoles at ScinoPharm, including two consoles for the pilot plant, two for the Small Manufacturing Unit (SMU), one for the Kilo Lab, one for the Mini-Plant, two for plant utilities and seven for the Production Bays 1,2 and 3.

ScinoPharm's requirements for process variable measurement, control, process safety interlocks, batch sequence control, operator interfaces, and batch reporting are met by applying the DeltaV distributed process control system, supplied by Fisher-Rosemount Systems, Inc. The DeltaV forms a foundation for process automation with which multiple-packaged process control systems and an enterprise resource planning (ERP) system are integrated. The result is a state-of-the-art process automation system (PAS) with vertically integrated batch-process data-management capabilities.

The ScinoPharm Taiwan Active Pharmaceutical Ingredients (API) facility is designed to manufacture drug compounds in strict compliance with current good manufacturing practices, as regulated by the US FDA. The PAS, with its configured software and custom batch control software, has been specified, built, tested and managed to result in a validated computerized system.

Batch process units are instrumented and controlled using strategies that enhance the plant's multi-product, multi-stream flexible batch manufacturing capabilities. The reactor controls include utility selection, nitrogen purge, temperature ramping, vent path selection and appropriate interlocks. The entire automation system has been designed and implemented to maximize plant-operating time, while minimizing product changeover time.

The hardware architecture is scalable in nature, permitting hardware modules to be safely and readily added while the plant is in operation. The batch control software is constructed in reusable, completely verified modules which can be implemented in many combinations enabling new process units to be rapidly, and reliably brought on-line.

The suite of PAS software supports (in addition to standard measurement and control functions) alarm management, trend data storage/display, event monitoring/chronicling, batch sequence control, batch operation reporting, hardware diagnostics, access control, on-line system documentation, and open system network connections. PAS data can readily be presented in Microsoft Office program compatible file formats for export to other plant computer systems.

17-3:Interface of the ERP with the PAS

The PAS prepares process unit reports, including utilization results, batch chemistry reports, motor run times, utility consumption totals, etc. and stores them in the PDHS environment. These reports can be retrieved through the ERP system for on-line review, for scheduling preventative maintenance, for financial accounting, etc.

17-4:Process Automation System (PAS) Technical Fact Sheet

- * Based on the Fisher-Rosemount's DeltaV Distributed Control System (DCS).
- * Validated computerized system compliant with US FDA regulations.
- * Scalable hardware architecture, fully distributed and with redundancy at critical points.
- * Advanced batch process control executive and historian features.
- * Custom batch software modules developed in compliance with ISA S88.01 standard.
- * M5 batch controllers support batch unit operations and phase logic.
- * Packaged process equipment PLC integrated with PAS using OPC standard.
- * Digital communications with instruments via HART protocol.
- * Operator interfaces run on high performance PCs under Microsoft Windows NT.
- * Open system connections to other plant computers via TCP/IP running on Ethernet.
- * Intrinsically safe circuits in classified hazardous electrical areas.
- * Tools for exporting data to standard Microsoft Office suite programs.

17-5:Process Automation System Capabilities

- * Batch process unit and utility system automation requirements are met with implementation of most current generation of distributed control system, the DeltaV.
- * The PAS is specified, built, tested and maintained in strict compliance with US FDA regulations and validation expectations.
- * Scalable hardware architecture easily expandable as processing requirements grow.
- * Open computer system design enables data from manufacturing operations plant floor control systems to be easily transferred to the enterprise resource planning (ERP) system.
- * The PAS is configured, and batch control programs developed to enable multi-product, multi-stream flexible batch manufacturing operations.
- * Batch control and reporting software is modular, compliant with international development standards (S 88.01), and reusable.