avid solutions
Industrial Automation & Process Control

LIFE SCIENCES

PARENTERAL AUTOMATION

Developing an integrated tracking and control system for a new drug manufacturing plant.

A major pharmaceutical company built a facility in Research Triangle Park, NC to manufacture and package a new cancer drug. The drug is produced from a highly potent compound on an aseptic filling line using isolator technology. Avid Solutions was given the job of implementing a control system to track and coordinate all the equipment for component preparation, formulation, filling and packaging plus the building's HVAC and utility systems. From user specifications to the coding, configuration and documentation, we were responsible for developing a control system that was functional, operator-friendly and FDA-compliant.

To meet all these objectives, we chose a control platform based on programmable logic controllers (PLCs) from Allen-Bradley and supervisory control software from Invensys Wonderware. The system was equipped with a redundant PLC and HMI network as well as redundant communications.

Using the ISPE's Good Automated Manufacturing Practices, we interfaced the control system to all the utilities, including water for injection, purified water and steam plus the plant's seven air handling units using over 1,500 inputs and outputs (I/O). For the filling lines, the I/O count topped 2,400. These data points are used to coordinate the operations of more than 40 independent machines, including filtration units, part washers, autoclaves and fillers built by several different OEMs. Automatic clean-in-place and steam-in-place functions maintain the sterility required for pharmaceutical applications.

Our I/O network provides a variety of supervisory functions from the correct sequence of operations and end-of-run reporting to equipment status, raw material tracking and electronic cleaning logs. We also implemented a manufacturing execution system (MES) to translate process orders into specific material tracking and batch data required by the control system and operators. The MES was designed per the S88 model that governs the procedures, operations, phases, and equipment allocation in the PLCs.

The MES manages process recipes needed by the OEM equipment and records all details of each recipe transaction. It also collects status information from the compounding, filling, and packaging operations such as "ready for compounding", "compounding" and "compounding complete". Barcode scanners and portable computer terminals are used to manually track the assets required for the batch process - vials, caps, stoppers, trays, etc.. The MES uses the inputs to generate an audit trail for documenting cleanliness, sterility, material tracking and lot genealogy for every step of the production process. All operator functions are regulated with ID's and passwords that can be entered at any operator terminal anywhere in the control system.

The solution we developed coordinates every step of the production process and allows operators to interact with every machine through a single, unified interface. Batch data is automatically archived to document how much of which products were produced when. The facility meets the FDA's 21 CFR part 11 electronic records requirements for the current product line-up and offers flexibility to accommodate different products in the future.

Applications

- CIP/SIP
- Building Automation
- Test Documents
- Production Operations Control
- Formulation Filling
- Packaging
- Material Tracking

Technologies

- WonderWare
- Batch Reporting
- Wireless Network
- SAP Integration
- Mobile HMI's
- ControlLogix 5000
- Panelview Plus
- EtherNet
- DeviceNet
- PROFIBUS
- Bar Code Scanners
- FactoryTalk View

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