



Greenfield Pharma

High Value Solutions in Packaging Automation

Success Story



Challenge

- A major pharmaceutical company embarks on multi-year greenfield project to manufacture their new line of injectable extended-release drugs and assemble their proprietary drug delivery system. Their goal is to receive FDA approval of the facility and get their product to market.
- They needed a new process control system, building management system, and SCADA designed, installed, and validated.
- They needed the integration of over 39 vendor delivered systems (from 9+ separate OEMs) into the SCADA system and historian.
- The five year work schedule was needed to be completed in one and half years.

Solution

E-Technologies was chosen to be the sole-source system integrator for the process control and building management systems, providing all automation and integration services for the new facility. A brief overview:

1. **Implement Process Control System (PCS)** - PCS consists of automated control, monitoring, and management of the bulk manufacturing processes operations and their associated utilities, such as water for injection, clean steam, and solvents. All direct impact processes have Clean-In-Place (CIP) and Sterilization-In-Place (SIP) operations. The PCS application software was designed using ANSI-ISA S88 methodology to be modular and is configurable to allow for flexibility in operations, and uses a standard physical model consisting of control modules, equipment modules, units, process cells, and areas.
2. **Applied Industry Standards for Recipe Management** - designed all aspects of the batch-related controls using ANSI-ISA S88 methodologies. The standard procedural model was built, consisting of phases, operations, unit procedures, and procedures.
3. **Link all Automation into Networks** - E-Tech linked all PLCs and OITs to their related servers using a plant-wide redundant Ethernet network. Communication to distributed I/O is via either redundant ControlNet networks or DeviceNet networks.
4. **Implement Client-Server Supervisory Control & Data Acquisition (SCADA) System** - the SCADA system supports operation of the plant utilities, manufacturing processes, and building management systems by operators using Operator Interface Terminals (OITs) that are connected to servers via terminal services sessions over a redundant Ethernet communication network. It also includes alarm management and historical collection of data and events.
5. **Data Historian**- captures all operator entries and interventions and complies with 21-CFR Part 11.
6. **Implement Building Management System (BMS)** - The BMS controls major building systems such as HVAC skids and monitors the relative humidity, temperature and differential pressure of clean rooms. The BMS also shuts down non-essential equipment when it detects the failure of utility power and sequentially restarts critical systems automatically upon restoration of power.

E-Tech designed and implemented the SCADA system, PCS, and BMS complete with all necessary hardware, software, configurations, and documentation.

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Technologies Involved

- Rockwell Automation ControlLogix
- Rockwell Automation FTBatch
- Rockwell Automation FTView-SE
- Rockwell Automation VFDs
- DeviceNet
- EthernetIP
- ControlNet
- Redundant Ethernet
- Terminal Services
- Redundant VMware virtualization with backup/restore
- ANSI-ISA S88 .01 batch methodology

Technical Services Provided

- Project Management – System Integration
- Integration of over 39 pre-fabricated systems supplied by 9+ OEMs
- System Design Documentation:
 - Develop Functional Specifications
 - Develop Detailed Design Specifications (DDS)
- PLC / OIT Software Development
- Specify, purchase, stage, and deploy the SCADA system servers, OITs, and engineering workstations
- Fabrication of the PCS & BMS control panels
- Batch and recipe design and implementation
- Software Factory Acceptance Testing (SFAT)
- Commissioning:
 - Instrument Check-Out (ICO)
 - Automation Checkout (ACO)
- Control System Validation (CSV) expertise:
 - Project Management
 - Authoring protocols (IQ/OQ/PQ)
 - Document Management
 - Executing protocols, resolving discrepancies and closing out protocols

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