

Automation & Validation Solutions for the Biopharmaceutical Industry

E-Technologies Group provides engineering solutions across multiple industries, adapting to meet the diverse scheduling needs of its clients. In one case, a biopharmaceutical company making a new drug to treat a common, serious disease selected E-Technologies Group to design and implement a large automation solution for a complete greenfield facility, and to provide FDA-required validation services for automation deliverables throughout the manufacturing plant.

Background

In 2006, a biopharmaceutical company began building a manufacturing facility to produce a new product. This manufacturing facility would be this client's first facility capable of producing a drug in quantities needed to support global commercial distribution. It would incorporate single-product manufacturing areas, filling/capping areas, packaging areas, a final product storage area, and process and mechanical facilities.

E-Technologies Group has proven experience in automation and integration services for regulated clients and was an obvious choice for system integration. From project inception, E-Technologies Group has served as the sole-source control systems integrator for this client. E-Technologies handles the making, batch, utilities, filling, and packaging systems integration; process control; facilities management systems; and all required support documentation.

E-Technologies also provides validation services for this client. These services range from master planning to protocol execution for third party vendor-built equipment and stick-built control systems that have been custom-engineered by E-Technologies Group.

Services Provided by E-Technologies Group

E-Technologies Group developed the automated systems and design deliverables required to support these operations: the Supervisory Control and Data Acquisition (SCADA) System, Process Control System (PCS), and Facilities Management System (FMS). These systems are described in more detail below.

SCADA System. This system controls the production process and utilities with continuous, discrete, and batch software programs. These programs include both automatic and manual modes for obtaining, processing, and managing production line data, as well as batch process control, alarm management, and historical data/event collection for the process, clean utilities, plant utilities, and HVAC equipment. Terminal sessions for end-user operators are provided over a redundant Ethernet communication network, and all operator entries are recorded for 21 CFR Part 11 compliance audit purposes. The SCADA system is designed to be S88 compliant.

PCS System. This system provides automated control, monitoring and management of the bulk manufacturing process, clean-in-place (CIP) and steam-in-place (SIP) operations, along with associated utilities, such as those used for water intended for injection, clean steam, and solvents. This PLC-based system is also designed for S88 compliance and achieves input/output communication via redundant ControlNet Networks (except for motor control center communication, provided through DeviceNet).

FMS System. The Facilities Management System provides control of major building systems, including the HVAC system. Environmental monitoring of clean rooms—including relative humidity, temperature, and differential pressure—is provided, as well as incoming power monitoring and appropriate shutdown and restart of utility power systems for specific applications. This PLC-based system is divided into validated and non-validated systems for critical and non-critical areas, and is connected to its own physically isolated field panels. Network communication is redundant over ControlNet, except for motor control center communication provided via DeviceNet.

Altogether, the current system includes 23 Human Machine Interfaces (HMIs), 20 Programmable Logic Controllers (PLCs), and approximately 8,000 input/output (I/O) points. These numbers continue to grow as additional requirements are added for new phases of construction.

Validation Services. E-Technologies Group's full-time, in-house validation staff is made up of experienced validation engineers and specialists. This team has provided validation master planning, project management, commissioning support, Factory Acceptance Testing (domestic and international), Site Acceptance Testing, SOP development, impact assessments, risk assessments, qualification protocol development and execution, and summary reporting. All validation activities are based on current FDA industry guidance, the most recent GAMP methodologies, and standard practices for the integration of commissioning and qualification activities. Additionally, all validation activities are aligned with the quality procedures and requirements established by the client.

Scope of Services

The scope of services provided by E-Technologies Group includes:

- Functional Requirement Specification (FRS)
- Detailed Design Specification (DDS)
- PLC/HMI Software Development
- Software Factory Acceptance Testing (SFAT)
- Instrument Check-Out (ICO)
- Automation Check-Out (ACO) Support
- Automation Operational Qualification (AOQ) Protocol Development
- Validation Planning and Project Management
- FAT and SAT Testing
- Validation Protocol Development and Execution
- Validation Summary Reporting
- Integration of packaged systems, such as WFI Still, Clean Steam Generator, Air Compressor, RO/DI System, Switchgear & Generators with the appropriate utility or process system.
- Contracting the fabrication of PCS & FMS control panels
- Specification, purchase, staging and deployment of the SCADA system servers, HMIs and engineering workstations
- HVAC Control

Client Benefits

The solutions provided by E-Technologies Group have allowed this biopharmaceutical client to meet stringent production and scheduling demands for the medication it is bringing to market, and in meeting federal regulatory requirements for the manufacture of drug products for human consumption. Moving forward, E-Technologies Group will continue to provide this client with robust automation systems and regulatory services to meet the client's manufacturing and quality requirements.