

Commercial Scale-up Facility

MAAK supplied a fully integrated control system for a 16-stage biological process, as well as related Clean-In-Place (CIP) systems for a large integrated facility. The system included a data archiving and reporting system, compliant with FDA regulation 21 CFR Part 11 (Electronic Data Storage).

The scope of work included the software development, testing, and commissioning. System design adhered to the GAMP (Good Automated Manufacturing Practice) life-cycle approach to the validation of automated systems. ISA S88 Batch Standards were employed for all process driven operations. MAAK supplied detailed and comprehensive documentation compliant with GAMP.



Automation

The process automation hardware was comprised of over 30 PLCs, 21 HMI/SCADA units, a development node, primary and backup domain controllers, and a relational database server.

An ISA S88 compliant control system was designed and developed for the entire process. A recipe development system was also provided for developing, editing and storing recipes. PLC logic included all recipe and phase control, automatic control of devices (valves, VFD's) inter-processor communication and complex pulsing sequences.

Additionally, the process PLCs interfaced with and controlled the CIP processes with batch cleaning sequences. The CIP component was also S88 compliant.

The HMI provided a fully secure interface to the process, controlling and displaying process parameters and phase states intuitively. A Visual Basic application was developed to store and retrieve recipes from the server, and to initiate and control recipes.

The data storage was in compliance with FDA 21 CFR Part 11. The system utilized Windows integrated security, along with a secure relational database server to ensure data integrity.

System Architecture

The system was comprised of seven zones, each with a SCADA node for data acquisition and recording, as well as a varied number of PLC and VIEW nodes.