

Project Brief...

Biological Process Control

QSPEC Solutions

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QSPEC Solutions' client is an integrated pharmaceuticals manufacturer. The client's new production suites required an S-88 compliant Batch system to control and document the manufacturing process. The process included bioreactors, fermentors, centrifuge, filtration and distillation equipment.

QSPEC's solution utilized the software suite of automation tools currently in place at this site. A batch server was used to create more than 100 recipes, schedule and monitor batches and store critical process information in an MS SQL database. Over 150 HMI screens were created to interface to the batch server and display critical process information to the operators. QSPEC Solutions integrated the Batch and HMI security modules into a single security system. Batch Reports are automatically generated from the database to meet the documentation requirements of both the FDA and of the client.

Solution Overview

Requirements

Install S-88 compliant batch system to control all components of manufacturing process

Solution

Wonderware's InBatch and InTouch automation software

Results

Over 100 recipes and 150 HMI screens were created to interface batch system and display critical process information

The batch server schedules, monitors and stores critical process data to a MS SQL database

Computer Validation cost are eliminated when a process change is necessary.

Batch reports are automatically generated

QSPEC Solutions provided Functional Specifications, configured the Batch System, developed and tested recipes working closely with the chemists, created clear and concise HMI screens, HMI configuration, created report and assisted in the overall system validation. The system is operating and has received FDA approval for production.

QSPEC Solutions

Automation Consulting and Technical Services
