

Pfizer Global Research & Development Groton, CT Liquid Dosage Manufacturing



Pfizer Global Research was renovating a liquid dosage manufacturing area for use with Drug Products in Clinical Trials. Facing a very fast track project schedule, Pfizer established a goal of having a robust, stand-alone control system that could be easily validated. Pfizer selected Hallam-ICS to lead this project.

Hallam-ICS made two key decisions at the onset of the project. First, the control system platform selected was to be PLC-based, as opposed to the traditional DDC controls that had been used in the past with limited established standards. Second, a GAMP 4 methodology would be followed, utilizing the V-Model.

Along with the engineering and operations staff, Pfizer's quality assurance and validation teams were brought in and actively engaged during the design and specification process, leading to a smooth validation effort.

Developing the design documents (FRS, HDS, SDS) and the functional test documents (FAT, SAT) with validation in mind, the project team was able to complete the project within the aggressive schedule and budget without impact existing manufacturing. The end result for Pfizer included a fully documented and verified control system with a trained operations staff.

