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Pharmaceutical processing

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Cool Technology

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pumps need to be both sanitary and highly reliable.

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Biopharmaceutical Equipment



Once solely focused on discovery, biopharmaceutical manufacturers now must contend with the problem of

getting their products out of the lab and into the manufacturing process. Products featured on this page are designed to help with the scale-up and manufacturing of biopharmaceuticals.

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Digital Plant Architecture Speeds Validation And Time To Market

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Digital Plant Architecture Speeds Key Biopharm Drugs To Market

Genzyme Corporation of Cambridge, Mass. has seen a major reduction in the time needed for validation due to its recent installation of digital plant architecture supplied by Emerson Process Management.

Genzyme Corporation is a global biotechnology company dedicated to making a positive impact on the lives of people with serious diseases. The company's product portfolio is focused on rare genetic disorders, renal disease, osteoarthritis, and immune-mediated diseases, and includes an array of diagnostic products and services. Genzyme's commitment to innovation continues today with research into novel approaches to cancer, heart disease, and other areas of unmet medical need. Genzyme currently employs over 5300 people in offices around the world.

The joint Emerson-Genzyme effort has grown from an initial project that delivered re-control of a microfiltration skid in 2000, to a strategic approach for the automation of all aspects of new Genzyme manufacturing plants. The software development and validation techniques employed, as well as the technology that made it possible, will help shave 6-12 months off new plant startup dates compared to using conventional validation methods.

"Three enormous benefits result," reports Phillip Maderia, Genzyme's Associate Director of Automation Engineering. "First, Genzyme's ROI will begin earlier, mitigating some of the risk in building new plants. Second, the cost of validating the automation software will be

substantially reduced. Third, and most exciting, for new rProtein drugs in the FDA approvals process, Genzyme will get them to market earlier, and patients will have them sooner."

"Key to achieving the time savings," according to Maderia, "is the ability that Genzyme now has to validate the software before automation equipment is installed, as opposed to after its installation. Pre-installation validation requires a combination of technology and method to assure that the application software's development, testing, and documentation is complete and unassailable. Neither technol-

ogy nor method alone can bring success. And, it's a strategic combination that can't be created overnight."

It has taken Genzyme three years to create the new procedures and validate modules for 95% of all control elements typically used in a biotech plant. The effort began by validating standalone equipment such as skids. It then graduated to partial production lines and finally to entire lines and plants. Each project required that additional modules be developed. Obviously, the upfront effort was high. But today, Genzyme is reaping solid returns by leveraging the validated modules, using



them over-and-over to quickly and efficiently automate equipment and production lines before installation.

“Our ability to apply these validated modules over and over enables cost efficiencies and earlier startup dates,” Maderia concluded. “Unlike the past, validation is no longer the antithesis of automation. This new strategic software approach will help us keep automation off the critical path of the project.”

A Closer Look At The Technology

Emerson's PlantWeb® digital plant architecture, centered around the DeltaV digital automation system, provides the advanced process control for Genzyme. When introduced in 1996, the DeltaV system was dramatically different than the distributed control systems of the day. It was designed to work with the new, standard digital control protocols to extract the maximum amount of information from what was emerging as the intelligent field. It was also built using many off-the-shelf components like standard PC keyboards, mice and monitors. It used the Ethernet

communications protocol, which was, at that time, primarily used in offices for e-mail. Unlike other automation systems, it was scalable - able to be extended by adding small modules, forming larger, efficiently working networks.

In just a few years, the DeltaV digital automation system increased its functionality to over 30,000 I/O handling capacity. Redundant controller configurations were added, permitting the system to address mission critical operations. Robust batch capabilities were also developed. New campaign management capabilities permit allocation and execution of many batches, including parameter changes with a single command.

It has become increasingly apparent that regulations in the pharmaceutical industry would require rigorous management of electronic records, like those used to run automation systems. The recent FDA regulation 21 CFR Part 11 currently defines those requirements. In order to assist customers to meet these increasingly stringent regulatory requirements, an electronic configuration audit trail and version management capability were built

into the DeltaV configuration management software. The software also keeps track of the older revisions and permits customers to “roll back” to previous generations of the configuration - a requirement of the 21CFR part 11 specification.

Batch operation logs are also automatically kept by the system. The batch history capability available with the system permits rapid and easy analysis of batch operations. Once activated, it automatically logs batch historical data. Process alarms, events and trends can be accessed on a batch-by-batch basis. Batches can be readily and easily compared. Ideal batch records can be kept as a standard for comparison and as a way to track deviations from desired performance. The data from these batch records can be transported to 3rd party storage and analysis tools for security. Even if the historian application is off-line for some reason, the records are stored and buffered in the system preventing the loss of valuable product due to temporary interruption of the record keeping chore.