Contract Manufacturer Cedarburg Pharmaceuticals Taps DeltaV[™] System's "Built For Batch" Flexibility

RESULTS

- Reduced installation/startup cost
- Reduced engineering cost
- Increased configuration flexibility
- Reduced configuration/documentation error
- Process scalability
- Current good manufacturing practices (cGMP) compliance

APPLICATION

Batch, pharmaceutical products

CUSTOMER Cedarburg Labs, Grafton, Wisconsin

CHALLENGE

As a contract manufacturer, Cedarburg Lab's customers include some of the world's largest pharmaceutical companies. The facility is designed to accommodate several customers simultaneously in four "suites" containing glass-lined reactors varying in size from 50 to 500 gallons. Cedarburg's control equipment has to handle multi-product situations, accommodating frequent product and process changes.

The control requirements include simple to complex control strategies, with production processes always rigorously documented—all batches must adhere to current good manufacturing practices (cGMP). Further, for scheduling purposes, and to maintain customer credibility and repeat business, the facility must ensure that every customer's batch is executed correctly the first time—on time. Process repeatability and reliability is crucial.

Configurations often must maintain customer confidentiality among the suites. If different customers each use a different suite, no part of a given suite's hardware or software can be accessible to other suites. But a single customer's product might occupy the entire facility, so Cedarburg must also be able to create a single plant environment, with process control and data seamlessly integrated among all the suites.



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Dr. James Yarger President, Cedarburg Labs





SOLUTION

By implementing a PlantWeb[™] field-based architecture based on the DeltaV[™] digital automation system and smart field devices from Emerson Process Management, Cedarburg Labs is cost-effectively filling a unique niche as a contract producer of active pharmaceutical ingredients and intermediates.

Cedarburg Labs selected Emerson's DeltaV automation system and various Emerson smart field devices to automate the processes in its suites. The DeltaV system's flexibility, combined with the integration of field devices allowed easy configuration on-the-fly for one-of-a-kind products.

Because each suite has its own DeltaV workstation, the equipment in that suite can be operated and monitored independent of other suites. Yet all workstations are networked, so the entire facility can be operated as a unified plant from a single workstation if needed. "We're impressed with the flexibility and ease of use of Emerson's DeltaV and PlantWeb architecture solution," said Cedarburg Labs president, Dr. James Yarger, "We chose it as the best answer to meet our complex production needs within our multiple use manufacturing suites." He added, "The system will provide us with invaluable information for use in process development, will provide us with supporting documentation for our full cGMP facility, and will allow us to provide our customers with highly reproducible manufacturing processes."

Working with a single supplier for the control system and many of the field devices simplified set-up and ensured that all the components of the whole process control solution worked together harmoniously.

The DeltaV system's ease of use allowed adjustment and reconfiguration without an in-house process control staff. Once parameters were set in the field devices, they could all be loaded into the controller for implementation. Any modifications could be made from the operator interface. The configuration could be stored for use on subsequent or scale-up projects. The DeltaV system's graphical interface and batch recording allowed operators to quickly view documentation and determine if the process was executed as required.

The DeltaV system's Windows-like workstation makes changing from one customer batch configuration to the next easy. The process operator simply copies existing batch modules into the new configuration file and modifies the parameters using the DeltaV graphical user interface.



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The DeltaV system allowed Cedarburg operators to model new processes. This helped anticipate process problems and ensured correct process execution from the first run. Not only can customers be assured all batches will be executed properly, they can also get accurate information to perform the continued scale-up.

Cedarburg Labs customers need full process documentation of their product runs. The DeltaV system provides a continuous, real-time plant historian and batch historian, along with event data, and batch production data to keep the operation 100% cGMP. And all this information can be interlinked to provide meaningful data to customers for analysis.

The DeltaV scalable system can grow as Cedarburg adds suites and reactors into a new building. In the same way, DeltaV can accommodate additional control devices in the existing suites, as well as adding on new automation systems for future sites. When expansion becomes necessary, adding new reactors to the process control system will be as simple as copying existing reactor configurations and modifying them, using the DeltaV system's graphical interface.

Because each manufacturing suite is small and requires its own process automation system, the system must be economical and scaled for available floor space. Placing DeltaV rail-mounted controllers and I/O modules in wall-mounted cabinets next to the system's Windows workstations saved valuable control room space. Additional controllers or modules can easily be hung on the rail and plugged into the system wiring.



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