



Case Study

Precision Pharma Services, Inc.

Biologics and Contract Manufacturing Company ensures batch control system data accuracy

Precision Pharma Services, Inc. is a new business which operates a biological products facility originally started in 1979 as part of the Greater NYC Blood Program. The FDA approved facility has been operational in the production of blood products for the past decade and has been a privately held company since 2001. With approximately 130 employees, they produce products that are made into Serum Albumin and IV products. The company's focus is Biologics and Contract Manufacturing serving multiple applications.

Problem

The plant was expanding and the company wanted to look at new technologies. Due to the FDA's data collection requirements for 21 CFR Part 11, they wanted a way to check the data that the batch control system is acquiring to verify the system's accuracy. The data was currently being collected by a PLC and captured in an SQL Server. They also wanted to calibrate the vessels from the clean room, but the multi-vessel controller for the weight system was located in an unclassified area making this impossible for one person to accomplish. Precision Pharma wanted a multi-vessel weight controller located in the PLC cabinet to replace the wall of single vessel controllers they were currently using.

Other problems arose with their current load cells. To keep the area clean, they rinse and sanitize the tanks and floors regularly, around the clock. Glenn Musano, Team Leader-Metrology and Mike Underhill, Sr. Calibration Technician, had run into problems with the shear beam output cables getting damaged during the cleaning process. The system would be down for a day until they were able to change out and wire in the replacement load cell.

Application

There are a total of twenty-two vessels on load cells that need to be monitored. Twelve tanks are monitored with existing shear beam load cells and four tanks are instrumented with Kistler-Morse (KM) LDII load cells. Precision Pharma instrumented the six new vessels with KM LD360s load cells.

Solution

Precision Pharma initially interviewed three major suppliers, with KM being one of them. They decided to purchase from KM for the following reasons:

- 1) Price Advantage.
- 2) MVS controller was able to fit into a PLC cabinet in the unclassified electrical room, eliminating the need for the 25-feet of wall space used by single weight controllers.
- 3) MVS controller was scalable for future growth to include other tanks on load cells as well as other instruments (pH, temperature) readings.
- 4) KM's ORB 2.0 Remote Monitor allowed easy remote access to the system from one area so technicians did not need to constantly go from the clean room to the mechanical area.
- 5) Load cells had Turck™ connectors for quick change out if required.
- 6) KM's excellent technical support for past systems.

KM instrumented all vessels with a KM multi-vessel system (MVS) controller located in the facility control room. The KM MVS communicates the vessel weight information via Allen Bradley RIO to the plant batch control PLC. The MVS also communicates serially to the KM ORB 2.0 Remote Transformer. The ORB 2.0 ties into the plant LAN via an Ethernet connection. The primary objective of the KM system was to acquire raw data weights for the Batch Control system and Plant Server for record collection.

KM was able to help by preprogramming the MVS with vessel names and electronic calibration data. This expedited start-up where the tank calibrations only had to be fine-tuned on start-up. Calibration consists of filling the tanks through a flow meter and spanning the vessel when full.



One major advantage of the KM system is the ability for Precision Pharma to remotely calibrate the MVS via ORB using a personal computer. This allows one person to calibrate the weighing system while suited up in the clean room although the electronics are located in the plant control room. Other supplier's systems would require two people for calibration; one person located in the clean room and another person located in the control room. Also, the MVS Controller in the control room requires less than a 2-ft. by 2-ft. area in the PLC cabinet; saving precious panel space.

Another benefit of the ORB-MVS combination is that it allows two vessels to be simultaneously calibrated saving Precision Pharma Services time and money.

Glenn Musano stated, "The KM ORB 2.0 Remote Monitor allows for an internal check of the batch control system and allows an additional avenue for data acquisition and data integrity." In the past if the PLC batch system failed, the plant was down or had to operate in manual mode with operators manually performing the required data collection activities. The ORB 2.0 system has the capability to download the data independently of the PLC to the LAN via an SQL server database.

With the ORB 2.0 Remote Monitor, the data capture occurs automatically, offering a backup to the existing PLC system. In the event they need to run with the PLC offline, the data is continually logged automatically eliminating the need for manual data recording and the associated risks with transcription errors. Operators can focus on maintaining the batch when running in manual mode without distractions.

In the near future, Precision Pharma Services will be evaluating collecting temperature data to the ORB 2.0 Remote Monitor for the data-logging purposes described above. This will allow them multiple readings from their process to be captured automatically. They are also looking at uploading the data from the Transformer to an SQL server so they can have a reliable check of the data from their batch controllers. This will give them an independent validation of the system and batch.

The LD360s load cells were attractive to Glenn Musano because the vessels that the load cells monitor are located in an aseptic environment where the systems are washed down every 12 hours of operation. The sanitary design, advantage of not having exposed cables and ability to withstand the CIP activity was considered a plus.

Also due to their problems with cables being broken during cleaning, the KM load cell with the Turck™ connector ensures quick load cell cable replacement if necessary, diminishing production downtime. As an added bonus, Precision Pharma also believes the KM sanitary load cells aesthetically look much better than the shear beams.

Glenn had positive words for KM's technical support group. He stated, "KM provides unbelievable technical support from equipment selection through start-up. Their personnel are very experienced and knowledgeable. They are very accessible and great to work with." He also stated, "the ORB unit makes calibration ten times easier and this investment will pay off two-fold because we save time and money on calibrations and the system is scalable for future growth." They have also discovered that KM's load cells stay in calibration much better than the other load cells they've used.

Precision Pharma Services, Inc., is still learning the dynamic uses of the system and what it is capable of doing for them.

Benefits

Precision Pharma Services, Inc., was able to realize immediate benefits due to several factors. For internal record keeping requirements, the vessel calibrations are checked a minimum of every 6 months. With the ORB-MVS combination allowing two vessels to be calibrated simultaneously, easily and reliably, they saved time and money. FDA reporting is secure as no one can modify the data. The space needed for their control systems have been scaled back dramatically offering them valuable space for other expansions.

The other area that benefits from implementing KM systems is in the diminished down time from possible damage to the load cells during their cleaning process.

Contact KM at 1-800-426-9010 or visit online at www.kistlermorse.com to learn more about how KM can ensure your plant receives the same World Class service as provided to Precision Pharma Services, Inc.

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