Leading Healthcare Company Improves Reliability and Compliance with Honeywell Paperless Recorder

"Honeywell's Multitrend SX paperless recorder enables us to monitor, alarm and archive FDA data seamlessly so we can concentrate on maximizing product quality and throughput."

Validation Manager

Benefits

A developer of medical diagnostic and data management equipment was in the process of moving to a new building and needed to monitor several temperature and humidity points in refrigerators, freezers and storage rooms that contain its products. All of the points needed to be FDA validated to prove that both humidity and temperature were within the current Good Manufacturing Practices tolerances.

The company was considering paper recorders for the project when it turned to Honeywell for recommendations on other options. Honeywell demonstrated how the Multitrend SX Electronic Data Recorder could be used to archive data electronically and meet 21 CFR Part 11 requirements for electronic records. This approach would also eliminate the time and cost of replacing paper charts and pens, and storing the charts for several years to meet FDA compliance. The company selected the Honeywell electronic data recorder and the Honeywell IQ/OQ validation software.

The Honeywell validation software prints out the electronic data recorder configuration including input and pen configuration, alarm setpoints and other functions that have been selected. An IQ/OQ document is then printed with testing and signature locations to be filled out during execution.

With Honeywell's validation software and the assistance of a Honeywell service tech, the company was able to complete the validation effort in less than two months, far less than similar electronic instrument validations.

Honeywell's paperless recorder help improve reliability and compliance.

Benefits of Honeywell's electronic data recording solution include:

- Reduced cost of consumable items including charts and pens

- Elimination of paper chart jams

- Wide availability of data on the company network enables key people to monitor as needs arise from their own desktop

- Electronic data from all process inputs are automatically uploaded and archived once a day

- A network outage has no effect on the archived data since the recorder has a large buffer to hold this data until network communications are restored

Challenge

The company was on a tight deadline for a move to a new building and needed to validate sensor points in a timely manner. The challenge was validating the sensors and proving that all the points and alarms were working within their operating tolerances. It normally takes four to six months to complete this process, which would not have met the move-in schedule for the new building.

Solution

The company installed the Honeywell Multitrend SX Electronic Data Recorder, Trend Server Pro software and Honeywell IQ/OQ software. The Honeywell solution is connected to the company's network via Ethernet, providing plant-wide connectivity of the recorder so those who have a need to see and review data can easily access it.

Honeywell's paperless recorder and software package helped complete the sensor point validation process in less than two months, saving a substantial amount of time and money by keeping on schedule for the building move.

The Honeywell paperless recorder system helps meet stringent FDA requirements and has reduced costs of charts and other consumables.

Instead of storing paper charts for years, a customer can simply upload the latest data from a computer that has Honeywell's Trend Server Pro software, which automatically archives the data to the computer hard drive.

Honeywell's paperless recorder provides the ability to capture continuous temperature and humidity data electronically, making the data analysis easier, faster and more reliable. The data is recorded in a secure digital format, eliminating interpolation errors, and can be easily exported to a spreadsheet format for further analysis.

The ability to have data in an electronic format saves significant time and expenses. It is much easier to analyze electronic data using the software tools and custom reports.

The company is pleased with quality of Honeywell's products and the professionalism of its employees. In addition to helping the customer install and implement the paperless recorder in a timely manner, Honeywell also instructed users on how to use some of the recorder's advanced features so they were able to take full advantage of the technology.

More Information

For more information on Honeywell's paperless recorders, visit www.honeywell.com/ps or contact your Honeywell account manager.

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