



VERITEQ

Superior Temperature & Humidity Monitoring

Client: DaVita Clinical Research Inc.

Category: Data Logger Technology Assures Accuracy and Reliability of Clinical Freezer Monitoring

Lab manager sees valuable reduction in human error

When scientists at DaVita Clinical Research (DCR) - which conducts human-subject based clinical trials for the pharmaceutical industry - decided to move to an automated temperature monitoring system for their laboratory freezers and refrigerators, they turned to data logging technology.

Based in Minneapolis, DCR has worked with more than 65 drug and device sponsors in more than 320 clinical trials, guiding pharmaceutical advancements from initial human trials through US Food and Drug Administration approval. The company performs Phase I-IV clinical trials of drugs and devices using subjects with diabetes, heart failure and chronic kidney failure. They measure and maintain samples of blood, urine, dialysis and pharmacokinetic samples used in the trials, which are stored in lab freezers maintained at -70 degrees C and -80 degrees C in order to remain stable and to satisfy validation requirements set by the pharmaceutical companies that support the trials, and by the FDA.

Many of these samples are kept for weeks and even months, making temperature stability even more important. At stake is the integrity of the samples, the validity of the trials, and the reputation of DCR as a leading research center.

DCR wanted to move from a manual measurement system - in which freezers were routinely opened to monitor temperatures - to a fully-automated approach that removes the risk of changing temperatures as freezer doors are unlatched. The answer is data logging technology, which provide validatable 21 CFR Part 11-compliant records that DCR can present to pharma companies or the FDA at any point in a clinical trial process.

Data logging systems employ electronic records as well as signed paper records; once the electronic records are created, they cannot be modified, meaning they can be printed and signed by DCR statisticians with full assurance to the companies and agencies that they are an accurate representation of the recorded data.

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By using portable, compact data loggers that rely on battery power, DCR was able to implement a highly-accurate, time-based system of temperature and humidity recording that rapidly updated their lab processes. Thus, they removed the potential for recording errors or variations in temperature that might be caused by opening the freezers and refrigerators for manual temperature taking.

DCR selected state-of-the-art data loggers developed by Veriteq Instruments. Veriteq uses very low temperature loggers in the VLT 1000 series, which operate to -86 degrees C, and low temp loggers from Veriteq's VL 1000 series - operational to -20 degrees C - According to DCR laboratory managers, the switch to data loggers enabled DCR to upgrade the quality and availability of documentation, with a higher level of detail now available to the FDA and pharmaceutical companies.

Data loggers such as those developed by Veriteq use on-board thermistors, which eliminate the need for time-consuming cumbersome pre-calibration and post-calibration steps. The Veriteq data loggers also use internal batteries developed to last for 10 years, so the loggers can operate independent of each other modularly, with no wires, or the potential for wiring errors. Data from each logger can be consolidated quickly into a single on-screen display or into a graph report.

DCR is currently using a total of 13 Veriteq validatable data loggers to monitor temperatures in a pair of -70 degrees C freezers, one -80 degree freezer, a pair of -20 degree C freezers, and four refrigerators.

"The Veriteq data loggers are far better than the way we used to do it," said DaVita Clinical. "Just the act of opening the freezers changed the temperatures a few degrees, but the data loggers are much more accurate and they virtually eliminate the possibility of human errors."

For more information about DaVita Clinical, visit <http://www.davita.com/dcr/>

To learn more about Veriteq precision data loggers, see www.veriteq.com or call (800)683-8374.