

# Case Study: 21 CFR Part 11 Freezer Monitoring, Alarming & Documentation

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Company: DaVita Clinical Research Inc.

Case: How a Temperature Monitoring System Provides Accuracy & Reliability in Critical Freezer Monitoring

*“We not only improved the quality and availability of our documentation, but we can now provide a higher level of detail to the FDA and our [client] pharmaceutical companies.”*

-DaVita Clinical Lab Manager

## **Reduce the Risks of Error/Infrastructure Failure**

When scientists at DaVita Clinical Research (DCR), which conducts clinical trials for the pharmaceutical industry, decided to automate and standardize the temperature monitoring system in laboratory freezers and refrigerators, they needed a system that was reliable enough to provide gap-free data — even in the event of a power outage or network interruption.

Based in Minneapolis, DCR works with major drug and device sponsors, performing hundreds of clinical trials. Their work guides pharmaceutical advancements from initial human trials through US Food and Drug Administration approval.

Applications include maintaining samples of blood, urine, dialysis and pharmacokinetic samples used in the trials, which are stored in lab freezers at -70°C and -90° C. The temperatures for storing samples must be continuously recorded and thoroughly documented to satisfy the requirements of both the pharmaceutical companies that support the trials and the FDA.

## **Stability: The Key to Long-term Accuracy**

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DCR wanted to move from an outdated Chart Recorder system to a fully automated approach. It was critical to reduce the risks associated with fluctuating temperatures because many of the freezer doors were unlatched several times a day. The monitoring system would not only have to record the temperatures and compile those data, it would also need alarming capabilities.

There were multiple options, but the most accurate and economical one turned out to be viewLinc, Veriteq's Temperature Monitoring system. The viewLinc system not only monitors and alarms temps in critical applications, it provides

validatable 21 CFR Part 11-compliant records, which DCR requires for its clients in pharmaceutical development and production, and the FDA, which regulates clinical trials.

### **Reporting & Documentation: Compliance with Part 11**

Under the guidelines of 21 CFR Part 11, regulated applications require hybridized record keeping: electronic records as well as signed paper ones. Once the electronic records are created, they cannot be modified; they are printed and signed by DCR statisticians with full assurance that they are an accurate representation of the recorded data.

The viewLinc system employs compact low temperature data loggers equipped with long-life batteries and on-board memory. This means the temperature data of any monitored point is immune to loss due to power or network interruption. DCR was able to implement a highly-accurate, time-based system of temperature monitoring — as well as ambient humidity monitoring — that completely updated their lab processes. The system also removed the potential for recording errors or variations in temperature that might be caused by opening the freezers and refrigerators for manual temperature recording.

### **State-of-the-Art Hardware + Validatable Software**

Veriteq uses very low temperature loggers in the VLT 1000 series, which operate to -90° C and low temp loggers from Veriteq's VL 1000 series, operational to -20°C. Commenting on the system, DCR laboratory manager says, "We not only improved the quality and availability of our documentation, but we can now provide a higher level of detail to the FDA and our [client] pharmaceutical companies."

For thermal validation, Veriteq data loggers use on-board thermistors, which eliminate the need for time-consuming cumbersome pre-calibration and post-calibration steps. The loggers operate independent of each other, without 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. Alarms can be sent to PC, audible alerts, email, text and pagers.

"The Veriteq data loggers are far better than the way we used to do it," said DaVita Clinical's senior lab manager. "The system is so much more accurate and virtually eliminates the possibility of human errors."

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For more information about DaVita Clinical, visit [the DVC website](#).

To learn more about Veriteq's Monitoring & Alarming systems, call **(800)683-8374** or [Email a Veriteq Representative](#).