

**Category:** Redundant Data Collection in Stability Chambers**Precision Data Loggers Prevent Data Gaps in Stability Testing****The Client**

A leading, multi-national supplier of development, manufacturing, and packaging services to the pharmaceutical industry, the client performs stability testing for a wide range of commercial and pre-market drug products.

The Challenge

In the pharmaceutical industry, stability studies are vital to drug manufacturing, packaging, labeling and sales, and temperature and humidity monitoring are essential aspects of stability testing. If for some reason there are gaps in measurement data, the entire stability testing process may be jeopardized.

Data gaps occur when, for various reasons, a data collection system (E.g. chart recorder, or centralized, hard-wired system) stops taking readings, and no temperature or humidity data is recorded. Data gaps can expose a company to potential risk on several levels. There can be regulatory risk, and companies may be cited by the FDA if data gaps occur repeatedly or for extended periods. Frequent or extended data gaps could affect product quality and erode client confidence in a company's systems.

In many cases, data gaps result from a data collection system failure. Chart recorders can create data gaps if the paper chart isn't changed on time or a chart pen runs out of ink. Centralized data recording systems can experience network failures, equipment relocation, system viruses or computer crashes. And both systems are vulnerable to power outages and human error.

To protect themselves from the risks associated with data gaps, companies within the pharmaceutical industry are installing secondary data recording systems to fill in gaps resulting from failures within their primary data collection systems. However, given the risks inherent in chart recorders and centralized systems, how can a company ensure that its secondary recording system won't be vulnerable to the same problems?

The Veriteq Solution

To offer its customers fail-safe protection against data gaps and overcome the challenges presented by other secondary recording systems, the client company utilizes Veriteq's precision data loggers as its redundant data collection system.

Precision data loggers are pager-sized, wireless temperature and humidity recorders that include a sensor, memory, 10-year power supply, clock and microprocessor in one device. Tamper-proof and fully compliant with 21 CFR Part 11, data loggers use proven thermistor technology to provide precise, accurate and reliable records.

SUCCESS STORY

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Since the client maintains a zero tolerance for data gaps, every stability chamber has a data logger inside, constantly recording data.

While the client company previously used chart recorders for secondary data recording, they recognized that data loggers offer a number of advantages. Unlike chart recorders, data loggers contain no moving parts. Their resolution is precise to a hundredth of a degree, where a chart recorder just shows increments of one degree. Data loggers are less cumbersome and easy to use, and they store data electronically, instead of on paper charts.

Veriteq precision data loggers offer a number of benefits that make them particularly well-suited as secondary data recorders. Loggers are small and completely self-contained, meaning they can be placed unobtrusively into stability chambers without wires. Because they're self-powered with a 10-year battery, they're unaffected by power outages or disruptions. They're highly stable and accurate, offering performance to 2% relative humidity and 0.15° C. Their large internal memories enable data loggers to monitor for extended periods without attention or maintenance, and they produce secure and unalterable data that's 21 CFR Part 11 compliant.

"Since information is stored on the data logger for up to three months, we know we can go to that if our primary system fails," says the client's Director of Stability Services. "This reliability is important to our clients, and it helps protect the stability testing process by all but eliminating the possibility of data gaps."

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

