

PHARMACEUTICAL CLEAN ROOM QUALIFICATION VERIFIES SECURE OPERATION

DELPHIN SYSTEMS MEASURE EVERY ENVIRONMENTAL PARAMETER



In the pharmaceutical industry, continuous and secure data acquisition and documentation is crucial for production and storage requirements, and also for research and development. Pharmaceutical clean room qualification verifies secure operation of environmental conditions in labs storing temperature-sensitive substances. According to [FDA CFR21 Part 11](#), data acquisition and monitoring systems within cleanrooms must operate in compliance with GAMP/GMP guidelines.

Additionally, measurement data and limit values for parameters such as Temperature, Humidity, Particle count and Pressure need to be acquired, monitored, and archived in a secure format. Furthermore, any user intervention relevant to pharmaceutical processing must also be recorded to an audit trail.

[Delphin's Expert series data loggers](#)—combined with ProfiSignal software—offers pharma companies a complete system covering data acquisition through to real-time monitoring, reporting, and user management.

UNIQUE ADWIN FEATURES:

- Secure acquisition of all measurement data from cleanrooms and pharmaceutical environments
- Independent data storage within the Delphin device, parallel to PC storage
- Flexible setup of monitoring functions using email, fax, text messaging or switch outputs
- Customizable process visualization and reporting using ProfiSignal
- Scalable systems for large and small systems

CUSTOMER EXAMPLE



One particular challenge for data acquisition systems is testing the long-term stability of pharmaceutical substances. These substances are stored in climate chambers and deep freezers whose environmental conditions all need to be recorded, archived and documented. Likewise, all changes in operational parameters – such as preset temperatures and threshold values – also need to be recorded in a reliable and secure way.

As a good example of this, many hospital chemist facilities are equipped with Delphin [cleanroom monitoring systems](#). These integrated systems of user and alarm management are popular for their flexibility and ease of use. Automated generation of data and alarm reporting takes place weekly. Users have also set monthly changes in measurement values including optional comment input. Meanwhile, all digital documents are redundantly-recorded.

TYPICAL AREAS OF APPLICATION:

- CFR21 Part 11-compliant pharmacist monitoring
- Cleanroom monitoring
- Dispersed system for pharmaceutical monitoring tasks
- Monitoring of production facilities in accordance with FDA
- Integrated, complete monitoring solutions for use in pharmaceutical production
- Integrated alarm systems

PROFESSIONAL MEASUREMENT DEVICES

Delphin data acquisition systems are ideal for use in cleanroom applications, both in industrial and laboratory settings. Their analog and digital I/O modules can accommodate a wide range of sensors and signals including Voltage; 4-20 mA Current; Thermocouple; RTD; and Resistance. They can also record measurements and initiate actions on their own.

CAS DataLoggers is a distributor of data loggers, paperless chart recorders and data acquisition equipment. We sell directly to end-users and also work through a network of distributors and resellers throughout the U.S., Canada, Central, and South America.

We have been in business for over 20 years and actively involved in selling data loggers and real-time systems since 2001. Our staff has over 100 years of total experience with different types of data acquisition and test and measurement equipment.

Along with recommending sensor and transducers to go with the data logger, we can also provide value-added services including on-site installation, wiring and packaging, engineering services, and turn-key systems.

For more information on [Delphin Data Acquisition Systems](#), pharmaceutical clean room qualification or to find the ideal solution for your application-specific needs, contact a CAS DataLogger Application Specialist at **(800) 956-4437** or www.DataLoggerInc.com.