CAS DATALOGGERS

Cleanroom Monitoring Systems Keep Pharmaceutical Data Secure

Delphin Technology Offers Secure Data Acquisition

Continuous, secure data acquisition and documentation are especially important in the pharmaceutical industry with its unique production and storage requirements, as well as for proprietary research and development. According to FDA CFR21, Part 11, data acquisition and cleanroom monitoring systems must operate in compliance with GAMP/GMP guidelines.
For effective monitoring, measurement data and limit values for parameters such as Temperature, Humidity, Particle count, and Pressure all need to be logged and archived in a format safe from manipulation. Additionally, any user intervention relevant to the processes in question must also be recorded to an audit trail. Delphin Technology's Expert and Message series data loggers, combined with ProfiSignal analysis software, offer pharma companies a complete system performing all facets of cleanroom monitoring systems including data acquisition, monitoring, reporting, and user management.

Application Features:

- Secure acquisition of all measurement data acquired from cleanrooms and pharmaceutical development, manufacturing, and storage environments
- Redundant, independent data storage within the Delphin data acquisition system
- in parallel with the PC or network storage
- Flexible setup of alerting functions using email, FTP, text messaging, or digital outputs

- Flexible visualization and reporting using ProfiSignal software
- Comprehensive user management including multiple logins and access levels
- Scalable systems for both small and large facilities

Automated Measurement and Alarms:

Capturing the environmental conditions in pharmaceutical production and storage areas can be a particular challenge. To this end, many pharmaceutical facilities are equipped with Delphin cleanroom monitoring systems. Here environmental conditions affecting raw materials, work in process and finished products need to be continuously monitored, recorded, and archived. Any changes in operational parameters--such as calibration values or alarm threshold limits--also need to be recorded in a way that is both reliable and secure.

Increasingly, users are turning to integrated systems which also offer built-in alarm management. These systems need to handle alarm acknowledgment and disposition while recording the users' corrective actions to satisfy audit trail requirements. All digital documents and annotations are recorded in secure, uneditable formats.

Typical Areas of Application:

- Cleanroom environmental monitoring of temperature, humidity, air pressure, etc
- CFR21 Part 11-compliant systems to provide secure storage and an audit trail
- Continual monitoring of production facilities in accordance with the FDA guidelines for CGMP regulations

- Automated alarm systems for immediate notification of out of tolerance conditions and alarm acknowledgement with corrective action documentation.

Professional Measurement Devices

Delphin Technologies data loggers and [data acquisition systems](#) solve a variety of measurement and control problems for cleanroom monitoring in labs, manufacturing, and storage applications. Delphin systems feature a variety of analog and digital I/O modules that can accept a wide range of signal types including voltage; 4-20 mA current; thermocouple and RTD sensors. They are scalable from just a few up to hundreds of inputs and offer flexible communications allowing distributed systems to cover large or multi-build sites. They also offer powerful computation and alarming capabilities enabling them to process measurements and initiate actions on their own. Delphin systems can be used for local data acquisition and logging when connected to a PC; for remote unattended data collection connected to the internet; or as stand-alone devices.

For more information on the [cleanroom monitoring systems](#), or to find the ideal solution for your application-specific needs, contact a CAS DataLogger Application Specialist at **(800) 956-4437** or [request more information](#).