

Evaluating and Applying Data Loggers for Pharmaceutical Monitoring

The ability to monitor environmental conditions easily and reliably is important in many areas of the pharmaceutical industry. From the moment raw materials are received to final product delivery, it's crucial to ensure that factors such as temperature and humidity remain within acceptable limits. In the case of an out-of-tolerance event, it's essential to be able to quickly pinpoint the location and time of a violation in order to address the problem and get back on track. It's also necessary to be able to provide industry, federal and international regulators with the data they require in the event of an audit.

Today's battery-powered data loggers are small, low-cost, rugged devices that can take secure, unattended measurements at user-specified intervals 24 hours a day, 7 days a week. They monitor a wide range of environmental parameters (e.g., temperature, relative humidity, CO₂, light), and are proven powerful tools for use in storage, shipping, manufacturing, research and facilities management applications. They don't require wires or power sources, and eliminate the human effort and error associated with manual monitoring operations.

Whether you are an experienced data logger user or are just getting started, this guide will help you to understand how data loggers can be applied in the pharmaceutical industry, and provides advice on important factors to consider when evaluating different data loggers for your application.

The Pharmaceutical Industry – How Data Loggers Fit In

Battery-powered data loggers can be used anywhere time-stamped environmental monitoring is required, whether on an ongoing basis or occasionally for assessment purposes. For example, a quality assurance manager might deploy loggers around a refrigerated warehouse to constantly monitor temperature or humidity, or an engineer may want to determine how often ventilation fans operate in a production facility. Following is a brief discussion about data loggers and how they can fit into pharmaceutical operations.

Generally, data loggers are small devices that fit in the palm of a hand. They are unobtrusive in shipping containers, laboratories, or the process environment and have no attached wires or cables that can get in the way of workers or equipment. The most advanced loggers can be launched and configured to record data at any interval the

user chooses, and are supported by user-friendly software that makes deployment and data downloading and analysis simple. Additionally, certain loggers have accompanying software that supports the Food and Drug Administration's title 21 CFR part 11 regulations surrounding electronic data security.

Data loggers can be deployed for many applications, from the receipt and storage of raw materials to customer delivery. Here are some examples:

- Storage of product and raw materials – Loggers can be deployed around a warehouse or in refrigeration units to monitor humidity, temperature, and light levels.
- Manufacture of products – Loggers might be assigned to individual pieces of equipment to record power use, or can be deployed in work areas to monitor carbon monoxide, temperature and humidity.
- Transportation and shipping – Small and inexpensive loggers can easily hitch along within product containers. Technicians can download environmental conditions data to ensure cold chain continuity.
- Research laboratories – Loggers fit easily in incubators, refrigerators, hoods, and in general lab spaces and can constantly monitor and verify temperature, gases, humidity, etc.
- In-depth assessment of any of the above – An array of loggers can easily be deployed in a manufacturing plant or at points around an office building to troubleshoot problems or assess energy efficiency.

Choosing A Data Logger For Pharmaceutical Monitoring

There are certain things to look for when choosing any data logger, but there are concerns particular to pharmaceutical applications. Following are ten considerations to keep in mind as you're evaluating loggers, software, and manufacturers.

Measurement parameters

First you must identify what you need to measure, and where.

Battery-powered data loggers can monitor a wide range of parameters, singly or in combination. These may

include: temperature, relative humidity, light intensity, CO₂, differential pressure, gauge pressure, events, light on/off, motor on/off, AC and DC voltage and carbon monoxide, among others.

Where will you be taking readings? For instance, if you will monitor temperature in a very humid environment, make sure the logger you select can operate consistently under such conditions. If a logger will tag along with a container that moves from cold storage to warm warehouse or shipping conditions, check that the device's measurement range includes the temperature extremes of these environments.

How many loggers will you need? Will you deploy one in each refrigeration chamber on site, or will you need a dozen or so in order to do concentrated analyses of storage, laboratory, or office conditions? You don't need to buy more logging capability than necessary, though you should consider future monitoring requirements.

Measurement accuracy

Once you know what you'll be measuring, think about your accuracy requirements and take a look at the technical specifications for the loggers you're evaluating.

Accuracy specifications vary widely among different loggers, and understanding your requirements will prevent you from buying more accuracy than you need. For example, monitoring room temperature in a production facility may only require an accuracy of ± 2 degrees. In that case, a logger with an accuracy of ± 0.1 degree would be excessive and probably more costly. You may, however, need such accuracy in an incubation chamber.

When shopping around, be sure to look for charts that indicate accuracy over an entire measurement range, not just at a single value. Also look into whether NIST-traceable (National Institute of Standards and Technology) accuracy certification is necessary for your application and available for the logger you're considering.

Another important factor is data logger resolution, which refers to the number of increments of a value a data logger is capable of reporting. This is important if you plan to deploy a logger for months at a time, or want to record data in 10-second intervals. You should also ask a manufacturer about the device's response time.

If you're unsure about your application's accuracy and resolution requirements, an experienced data logger supplier should be able to help you determine which product will meet your needs.

Ease of configurability and launch

All data loggers require setup and configuration, but some manufacturers demand more from their users than others.

User-friendly loggers can be set up and launched by someone with no training in electrical wiring or programming. The user just connects the logger to a PC and the accompanying logger software automatically recognizes the device and asks a series of configuration questions. The user simply chooses a sampling interval and selects an immediate or designated future launch time. There is no wiring or programming involved.

Such ease of use is important if several people are responsible for launching loggers and retrieving data. If the procedure is simple and intuitive, there is less room for human error in gathering data.

Software considerations

Data logger software should be easy to use and must support industry, federal, and international regulatory and audit requirements.

The software should enable you to quickly and easily perform tasks such as setting configuration parameters, designating launch times, and offloading data with point-and-click simplicity. Applications are generally Windows-based, but some manufacturers also make Mac versions.

Check the software's graphing and analysis capabilities, including whether you can combine graphs to compare data between sites, or if you can view all of a site's data clearly in a single graph. Depending on the scope and type of your data, the manufacturer may also have special application-specific software available. Since data often needs to be exported to other software programs, make sure that the logger software allows you to quickly and easily export data with the click of a mouse.

The pharmaceutical industry must adhere to the U.S. Food and Drug Administration's title 21 CFR part 11 regulations regarding maintenance and security of electronic records. Ask manufacturers specifically how their software addresses electronic signatures, data alteration prevention, and data storage.

Finally, consider whether you require immediate notification when environmental conditions fall outside of set tolerances. If so, ask suppliers about alarm capabilities and options for internet-, telephone- and pager-based alerts.

Data offload options

Consider the time and effort you are willing to allot to downloading data.

In the most straightforward systems, data download is achieved by connecting the logger via a cable to a laptop or desktop computer equipped with the appropriate software. The software automatically recognizes the logger and downloads the data in less than a minute.

Alternatively, data can be downloaded to a shuttle-type device. These small hand-held units can store data from multiple loggers and relaunch them without having to bring a laptop to the logger.

Support for Ethernet connectivity

Recent advances in data logging and networking technologies have made it easier to access data throughout pharmaceutical production and office facilities.

In sites where an Ethernet network exists, you can now implement a facility-wide data logger network without any special wiring, and reduce the time and expense associated with manual data retrieval and logger management tasks. All logger management and offload tasks can occur from one centralized workstation. Additionally, data can be readily shared throughout a facility via any Internet browser.

Some data logger manufacturers offer Ethernet adapters or hubs that enable this type of connectivity. If your monitoring application could benefit from a networked data logging solution, be sure to ask suppliers if they offer solutions for linking data loggers over Ethernet networks.

Durability and battery life

Data loggers are often called upon to work under tough conditions. In an office hallway, a hard plastic enclosure is enough to protect a logger. However, in a production facility, it is wise to choose a logger with a rugged, moisture-protective enclosure. Make sure a logger's enclosure is designed to withstand temperature extremes, moisture, and physical wear and tear, when necessary.

Data loggers are generally extremely low-power devices, but because they are used in a variety of environmental conditions and sample at different rates, battery life can vary widely. As a general rule of thumb, make sure the data logger you select has a battery life of at least one year. Most logger manufacturers' software will indicate when the logger's battery power is getting low.

Cost of ownership

Today's battery-powered data logging devices are very

reasonably priced, and can be a real value if you plan to use them over and over again in multiple applications. It is important, though, to look closely at the total cost of ownership when shopping around. Will the logger need to be periodically calibrated by the manufacturer, and if so, what will it cost over time? How much does the software cost?

Ask your supplier about whether or not the data logger battery is user-replaceable, as this can eliminate the time and expense of having to ship the logger back to the manufacturer for battery replacement.

Asking these questions will help you understand the true cost of owning the data logger over the long-term.

Product support

Data loggers should be easy to use and not require a great deal of technical assistance. Still, as with any high-tech product, there will always be questions.

Seek out a supplier offering a range of product support services. These often start with the initial assessment of your application requirements, and should include telephone and internet-based support resources.

Does a potential supplier have the track record and financial stability to maintain their role as a long-term solutions provider? Be assured that the company will be there to meet your future data logging requirements. Ask the supplier for application notes and other references to gain a sense for how their loggers perform in applications similar to yours.

Flexibility and range of solutions

In most cases, simple stand-alone data loggers are suitable for most pharmaceutical monitoring applications. However, there may be situations where you need a more centralized data gathering system for monitoring multiple parameters.

For example, if you need to carry out a complete environmental analysis or verification of a facility's large incubation chambers, you may need to measure temperature, humidity and light intensity each at several points in each chamber. Ask a supplier if they offer systems-based data logging solutions, where multiple sensors plug into a central, multi-channel logger. With the simplest models you can simply plug in individual sensors to measure various parameters and the system automatically recognizes each one without the need for complicated wiring, programming or calibration. Most are also battery powered and allow you to configure the system with any combination of available sensors.

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Think about what your future monitoring needs might be, and take this evolution and expansion into consideration as you investigate manufacturers and loggers. A supplier who can work with you as your needs change can be extremely valuable.

Conclusion

Data loggers are the ideal tools for monitoring environmental conditions throughout the pharmaceutical industry, from manufacture and storage to research and development. The affordable, reliable units collect data when and where you need it, and the best loggers pair with intuitive, easy-to-use software so you don't waste valuable time and effort configuring devices or formatting data. A supplier with in-depth logging application experience can offer valuable guidance in helping you not only to understand features and benefits of a particular logger, but also how certain factors in your own application may affect logging performance. Seek out a manufacturer with a long track record who can offer solid customer service and a range of data logging solutions so that as your needs change, your supplier can work with you.

About Onset

Onset Computer Corporation has been producing small, inexpensive, battery-powered data loggers and embedded controllers since 1981, and has sold over one million loggers

that are used around the world by over 50,000 customers. The company manufactures a broad range of data logger and weather station products that are used to measure temperature, humidity, light intensity, voltage, and a broad range of other parameters. Onset products are used widely in research, commercial, industrial, and educational applications.

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