9 Things you need to know about Continuous Monitoring Systems in FDA-Regulated Environments

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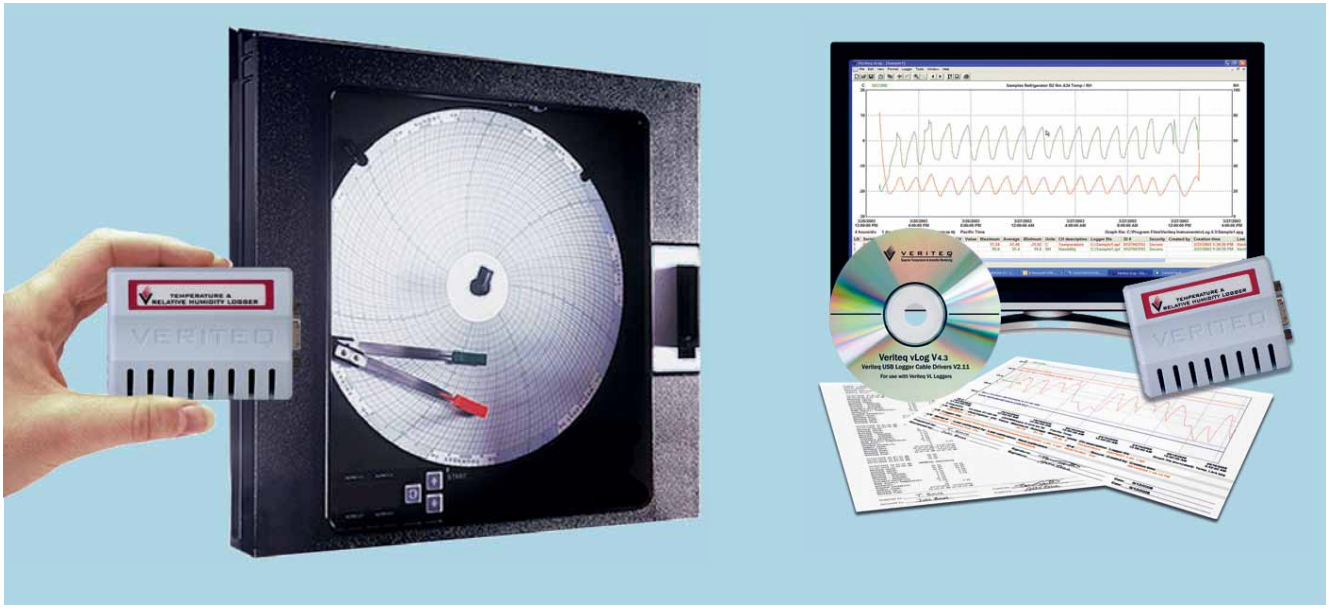
If you work in a life science company or any company that is regulated by the FDA, you know that you will have to monitor important environmental parameters (e.g. temperature, relative humidity) at locations in your facility. While the concept of monitoring is simple, a deeper understanding of how your monitoring system works can have a big impact on the success of your business, especially if regulators find your monitoring systems to be unsatisfactory. The following application note looks at several different approaches to monitoring and outlines nine crucial evaluation points that will allow you to select the monitoring system(s) best suited to your monitored applications, controlled environments, and GxP facilities.

Why Monitor?

If you are regulated by the FDA (or the similar regulatory agency in your country), the need for monitoring begins with the principles of quality that are contained in GxP guidelines and regulations. These practices minimize the risks to patient safety and ensure product quality and data integrity. Imagine a scenario where your finished product is inadvertently exposed to temperatures that render the product less safe for human consumption. If this problem is detected, you may have to scrap a significant amount of your product. Worse: if the problem is not detected during manufacture, storage or distribution, your product may harm someone. A temperature monitoring system that is designed for GxP environments and managed according to GxP guidelines will mitigate this type of risk. This is why we monitor environmental parameters like temperature and humidity and why regulators enforce cGMPs in monitored environments.

Short History of Monitoring Devices



Early monitoring systems were as simple as a thermometer in a freezer with pen and paper records. Unfortunately, if the freezer fails, the problem isn't discovered until the next time someone checks the thermometer. In the interim, there is no way to know what has happened to what is being stored in the freezer and for safety's sake, you have to assume the worst. In 1888 William Henry Bristol invented the chart recorder and J.C. Stevens patented the first environmental chart recorder in 1915[1]. The use of chart recorders improved the management of controlled environments by creating a record of temperature against time. The great innovation of the chart recorder for temperature tracking was that after a freezer had failed, one look at the chart could show how long the environment had been out of specification. At least then you had a clue as to how bad the damage was. Although chart recorders were a great improvement on the thermometer with pen and paper method, they also necessitated a great deal of maintenance, such as repairing old or damaged parts, changing the paper, pens and ink, and filing and storing the charts for future reference.

Electronic data loggers came along and improved upon the chart recorder. Like chart recorders, they create a record of temperature, but they do not provide instant notification of freezer failure. On the upside, they require less maintenance and make a record of temperature that can be saved in an electronic format, making it easier to store, review, and sort data.

Continuous Monitoring

Modern continuous monitoring systems (CMS) have changed the way sensitive products are protected. With a CMS you can collect temperature data continuously, create a permanent record of that data in a format that complies with regulations, and receive instant notification when your freezer moves out of a temperature range appropriate for the product it is storing.
A CMS can be used to monitor other parameters, such as relative humidity and differential pressure. Almost any device with an electrical output can be connected to the CMS. Additionally, a CMS requires no daily ritual of reading, no charts to be changed, no loggers to be uploaded. Like most innovations, a CMS saves time, reduces the risk of human error, and allows people to focus on more important matters.

Attributes of a CMS

The following nine attributes are common options for configuring a CMS. With each attribute, we offer methods and criteria for evaluating the fit between the system and your application. It's beyond the scope of this paper to address network connectivity, but we have addressed that topic elsewhere[2].

1. User interface

Request a demonstration of the CMS software that you are considering and make sure its UI meets your needs. A complex interface will frustrate users, negatively affect productivity, and may even become a source of errors. Some features of a well-designed UI include: extensive help section, intuitive functions like drag and drop, tab selection, and the ability to customize with naming conventions and visual elements (i.e. images or schematics of your controlled areas). Some newer CMS systems have an interface that is optimized for mobile access by users.

2. Web Application vs. Client Software

Some monitoring systems require each user to have software client installed directly to a PC that communicates to a server. Other systems are browser-based and can be accessed from any computer when the user has authorization and a connection to the Internet. Browser-based systems are more flexible and do not require software installs for each computer used to access the CMS.

3. Scalability & Flexibility

Some users will start with modest monitoring needs that may need to be expanded over time. Consider the ease or difficulty of relocating or adding measurement points to your CMS, or moving beyond one facility to an enterprise solution. Ideally, a CMS should scale up or down easily. If you can easily disassemble and move a CMS to another facility or a different application, it's a safe long-term investment that won't necessitate new or several SOPs.

4. Alarming

Look for alarm functions that provide flexibility in the alert and notification methods. Seek systems that are flexible to the needs of the application and personnel. For instance, some systems have alert options for e-mail, text, phone, flashing lights, and audible alerts. The system should have customizable options for who receives alarm, scheduling, acknowledgements, documentation and other configuration details.

5. Reporting

Define in advance what you need for reporting requirements and make sure your CMS can provide this. Start by analyzing your controlled environments and identifying the GxP requirements that apply to them. Because the guidances and regulations are written so broadly, reports that demonstrate a scientific and risk-based approach are preferable. The ability to create reports that are customized to your controlled environments and the products they contain is going to help ensure your documentation is complete and compliant with cGMP. In addition, the automated and consistent reports that are delivered on a schedule reduce workload.

6. Regulatory compliance

The CMS must enable you to meet regulatory requirements and the system must be validatable. If you have validation expertise, you can validate the CMS yourself provided the system supplier has comprehensive validation protocols available. Unforeseen validation challenges, such as changes to the CMS, can be very expensive, increasing the cost of a system far beyond the purchase price. Ensure that compliance with regulations such as CFR 21 Part 11 is designed into your CMS. The system needs to have Audit trail capabilities, data redundancy for infrastructure failure or record loss, and methods for electronic records and signatures along with hybrid and procedural solutions.

7. Robust data recording

This is less common in monitoring systems because it can be difficult to achieve, but it is especially useful in facilities that have unreliable power or IT infrastructure issues beyond the control of the CMS administrator. Failsafe data recording means that each measurement point continues to record data autonomously at the device level during any power outage and/or network interruption. With a redundant recording at the point of measurement, data will become available when services are restored, eliminating all data gaps that may otherwise have occurred.

8. Proprietary vs. Interoperable systems

A CMS that is highly proprietary or supplied as a "black box" may create support issues, limiting your ability to change system configurations and locking you into service agreements. If you need to export CMS data to other systems, check for interoperability.

9. Separate or redundant monitoring

Facilities with building automation systems (BAS) in place may choose to monitor through the BAS. Historically this has been preferable to using discrete devices for monitoring. However, today monitoring through a separate CMS will significantly reduce risks by providing features and attributes that are designed for the specific challenge of monitoring, recording, reporting and alarming GxP environments.

Selecting a CMS Provider

As we reviewed attributes of continuous monitoring systems, it's also important to consider attributes of the CMS provider. The points below are intuitive in vendor selection and we include them here only as reminders.

- **People**

The best companies hire people who are professional, polite, honest, easy to work with, and willing to go the extra mile. The CMS provider's people should know how to unite all of your stakeholders to ensure a successful CMS implementation. When assessing a provider, find out the hours of support coverage and ask for customer references. Contact at least one of the references directly and find out how they feel about the service and support personnel of the CMS provider.

- **Products**

It's often assumed that products are simply commodities and maybe some of them are. Nonetheless, the products that comprise a CMS are uniquely tied to the vendor's quality systems, industry certifications, and track record of success. Innovative firms are often driven by product excellence, providing high quality, reliable products. Solid products will reduce project risk and overall risk for your firm.

- **Knowledge**

The ideal CMS provider will have wide background knowledge of different applications and system use. They should understand your regulatory environment and industry standards. They should have this kind of knowledge not only at the level of sales, but also at the levels of technical support and software development.

- **Service**

Your CMS will have to be installed and validated. You may require on-site support to expand your CMS or to calibrate the measuring devices in your system. These services can be provided internally or by third party service providers. Look for a system provider that can provide high quality and experiential training to your staff as well as service.

- **Global presence**

If your firm has facilities in more than one country or partnerships with firms in other countries, you may want a CMS provider that is able to support your global needs.

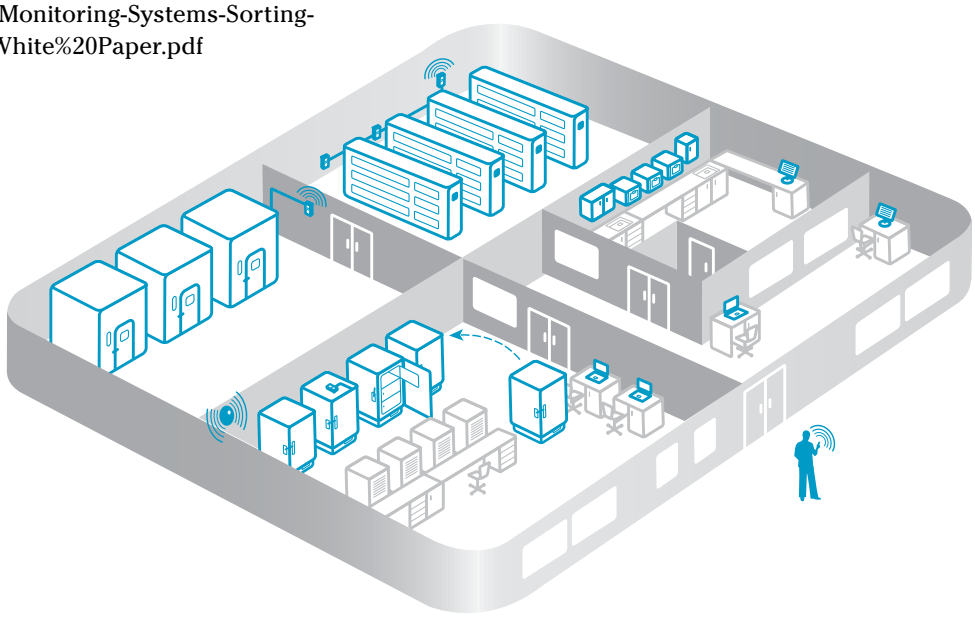
Conclusion

A continuous monitoring system from the right provider can offer value far beyond the cost of the system and services. It will mitigate risks, improve quality, meet regulatory requirements, reduce workloads and control costs. When a single catastrophic failure and product loss or adulteration is averted by a dependable system, it's clear that the total value of a CMS is more than the sum of its parts. However, system selection has to start somewhere; evaluating systems on the components most vital to its efficient and reliable function will provide crucial intelligence that will allow you to find the right system for your controlled GxP environments.

Footnotes

[1]Bristol, William H. *"Pressure Indicator and Recorder, U.S. Patent 389,635 issued Sep 18, 1888"*. Retrieved 2012-01-30. Stevens, John Cyprian. *"Water Stage Recorder, U.S. Patent 1,163,279 issued Dec 7, 1915"*. Retrieved 2012-01-30.
Bristol, William H. *"Pressure Indicator and Recorder, U.S. Patent 389,635 issued Sep 18, 1888"*. Retrieved 2012-01-30. Stevens, John Cyprian. *"Water Stage Recorder, U.S. Patent 1,163,279 issued Dec 7, 1915"*. Retrieved 2012-01-30.

[2]Monitoring Systems: Sorting Out Wireless" http://www.vaisala.com/Vaisala%20Documents/White%20Papers/Monitoring-Systems-Sorting-Out-Wireless%20White%20Paper.pdf



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