- Environmental Monitoring Solutions

ELPRC

Central Monitoring Systems 101: Easier Management and Better Control of Critical Assets

we prove it.

Central Monitoring Systems 101: Easier Management and Better Control of your Critical Assets

Professionals working in any regulated environment know all too well that the technologies and devices used to perform everyday tasks vary by department, lab, floor, building and even by office. This is especially true when it comes to environmental and temperature monitoring. Some departments may use chart recorders, others manually record temperatures twice per day, while the laboratory down the hall uses thermometers, and then another area has stand-alone data loggers. While all these methods may meet very basic regulatory guidelines, as a facility, is your data easily accessible and are the appropriate alarm methods in place? If the answer is no, consider a central monitoring system to streamline data storage.

Busy organizations have a real need to implement a standardized, company-wide and centralized monitoring method. This will only become more apparent as you add equipment, new personnel and expand operations to new facilities. Just because you have something in place for monitoring now doesn't mean that there isn't room for improvement, and standardization is key. The objective shouldn't be to find a solution that matches your current processes. Look for a system that can make your processes better and more efficient.

Ideally, this setup would enable your facility to have fast, standardized responses to alarms and efficient, electronic reporting capabilities, adding a superior level of protection for your irreplaceable products. It will meet regulatory compliance for continuous environmental monitoring. Additionally, standardization would make purchasing and servicing of the environmental monitoring devices much more efficient. Does this sound too good to be true or perhaps it sounds too complicated to obtain?

The reality is that there are systems designed to meet FDA, GMP, JCAHO and other regulatory requirements seamlessly, and that the right provider will assist you through every stage of the transition, making the switch well worth the investment by improving processes, leading to cost and time savings. So, what is the solution and how does it work?

The solution is called a Central Monitoring System (CMS). The term "central" may seem intimidating, but it really is not. All it means is that all data is reported to a central location, and just because you have one or two pieces of equipment doesn't mean that a central monitoring system isn't right for you. There are "plug 'n play" systems that are ideal for smaller operations, and there are database systems that are sensor driven for monitoring many pieces of equipment.

How a CMS Works and Questions to Consider

There are several types of systems, and the terms Central Monitoring, Remote Monitoring and Continuous Monitoring are interchangeable within the marketplace. Regardless of the name or even provider, the systems share common goals: automated data collection of critical environmental parameters, data archiving, alarming and reporting. How these systems accomplish these goals, the way the systems are designed and the level of support / technical expertise from the provider are differentiating factors to consider.

A CMS will have the capability to monitor all of your critical points and environmental parameters such as: temperature, relative humidity, CO_2, O_2, differential pressure, etc. All systems include sensors, associated hardware and software for data collection and alarm. Ask the provider to describe what their system consists of.

System Design

In the industry, there are two common types of systems: wired and wireless. It is important to understand what each of these terms mean to the provider and how the system's hardware affects the infrastructure you need. For example, if your goal is to shop for a wireless system because you often move your equipment, then ask the provider what "wireless" means in terms of their equipment. One system may refer to "wireless" as wifi, or wireless network, while wireless to another provider may mean wireless sensors.

Flexibility

You should also consider troubleshooting and maintenance of

CMS hardware. For example, some systems require dedicated power outlets at all monitoring points. Ask the manufacturer what components require power outlets. How easy is it to scale the system as your grow and add equipment? Also, find out what type of network is used. Does the system communicate to the server via wifi or is it hardwired directly to a LAN connection?

Sensors

Another critical component in a CMS is the sensors because they measure your environmental parameters. Sensors may vary by system manufacturer, so you will want to confirm that sensors are of the highest quality (i.e. high-end RTD temperature sensors versus economy T/C thermocouples) for reliable, accurate measurements.

Redundancy

Some systems have sensors that report to both data loggers and software while other systems have sensors that report directly to the software. The difference between these setups is that a system with data loggers provides redundancy because the sensors report the measurements to the data logger, and the data logger also stores the data. Redundancy is the duplication critical components; if you take out one component, then it will have no effect on the rest of the system. For example, if a piece of hardware breaks, how does this affect the system overall? Redundancy will increase its reliability. Without a redundant data storage capability, you risk losing data in the event of a server failure or power outage.

Software

Now that you're more familiar with hardware, let's review CMS software. CMS software stores the measured data and gives you the capability to view trends, customize alarms and create reports with graphs and statistical calculations. Alarm customization is a key advantage over traditional equipment NO / NC dry alarm contacts and chart recorder alarms. You can avoid nuisance alarms and ensure that you receive critical information by programming in meaningful alarm settings, and ultimately protecting your valuable products. For example, you share the CO_2 incubator in your lab with several researchers who are opening and closing its door several times a day. Setup custom alarm parameters so that you receive a text message when the environment is out of spec. Something as simple as not closing the door all the way on an incubator can disrupt the environment and potentially threaten the life of the cultures inside. The same scenario is true for hospital refrigerators, pharmaceutical stability chambers, pharmaceutical storage in warehouses and the list goes on. Being notified in the event of an excursion can potentially circumvent major product loss. Otherwise, how do you know your product is safe on nights and on weekends when you're not around?

System software will vary by manufacturer, so it is a benefit to you to have a basic understanding of the different software formats. In general there are two methods. Some CMS providers use a "cloud" software approach, which is hosted on an outside network somewhere. The cloud is known for its ease-of-access; however, it is important to consider who owns your data when it is stored on the cloud.

Data ownership is critical for your operation if you are FDA audited or operating under cGMPs. Furthermore, accessibility to the cloud presents serious questions that you might want to ask the provider. When your CMS is hosted on someone else's cloud, accessibility is out of your control, putting you at the mercy of someone else's IT and security department. If you are not hosting the data, especially if you are GMP, what happens if you don't have Internet access? Can you access the data locally? Who owns the data if you switch providers?

"For example, GMP facilities require software packages with validation developed per GAMP5 and the V-Model. Some larger operations with hundreds of measuring points will require a SQL database that is sensor driven. The type of software will depend on your needs."

If the data ownership and accessibility risks are too high, then consider an alternative to the cloud, which is software on your server. Most importantly, this setup allows you to maintain ownership of your data. Technical advances to this type of setup will provide the same ease-of-access that is associated with the cloud, without the security pitfalls. For example, some manufacturers offer software packages with a secure, online system-access module that provides a real-time view of your facilities from any web browser without

compromising data ownership or security. Having access to your facility via the web 24/7 offers many advantages, including real-time view of trends and alarms, enabling fast and efficient corrective action.

Because regulatory requirements differ by market, CMS manufacturers should offer multiple software setups, which allow you to customize the software for your needs. For example, GMP facilities require software packages with validation, developed per GAMP5 and the V-Model. Some operations have hundreds or thousands of points and will want a SQL database setup that is sensor driven. The best way to determine what you need is to first consider how many points you have to monitor and what regulatory guidelines you need to meet. Have this information collected when you speak to CMS manufacturers and ask them for a software recommendation.

Support

As mentioned earlier, having full CMS product support is crucial, too. Converting from your current monitoring method to a CMS system is a considerable undertaking and the ideal CMS manufacturer will specialize in environmental monitoring with extensive knowledge of your applications, while offering project management support throughout every phase of your transition. Ask the provider if they are the manufacturer of the system and if you can speak with a technical expert about your application. You will also want to make certain that a service representative from their factory will provide a turnkey installation, training for all your staff and that technical support is offered. If your facility requires annual calibrations, ask the manufacturer if they are ISO 17025 certified for lab and field calibrations.

Conclusion

A Central Monitoring System will standardize monitoring practices for all of your critical environmental parameters. It will provide you with 24/7 peace of mind that your critical environments are being actively monitored, protecting your samples and products. CMS are fully automated and will completely replace outdated or cumbersome environmental monitoring methods (such as chart recorders) to ensure product integrity while meeting regulatory requirements.

Table 1.1 provides a checklist to use as you begin your search for a CMS. If you are considering a switch to a CMS, please contact ELPRO. Our staff of technical experts is available to answer any questions, assess your application and provide a recommendation.

Table 1.1: CMS Checklist

First, collect information about your facility:
1. How many points (i.e. pieces of equipment) do you have? _____
2. What type of equipment / storage areas do you have (i.e. Freezers)?_____
3. What parameters (i.e. temperature, humidity, CO_2) do you want to monitor? _____
4. What regulatory guidelines do follow?_____
5. Do you have plans to add equipment? _____

Ask the provider about their system hardware:
- ☑ High-end sensors (such as RTD temperature)
- ☑ Flexible / Scalable (monitors multiple points & easy to add points as you grow)
- ☑ Redundant (stores data in more than one place)
- ☑ 4..20mA signal (monitors many parameter types)

Is / Does the CMS software:
- ☑ FDA 21 CFR Part 11 Compliant (GMP)?
- ☑ Provide data ownership?
- ☑ Offer safe, web access to your facilities 24/7?
- ☑ Multi-tier software options?
- ☑ Database capabilities?
- ☑ Offer IQ / OQ validation (GMP)?
- ☑ Developed per computerized system compliance (GAMP5 and the V-Model)?

Is / Does the CMS provider:
- ☑ ISO 17025 certified for calibration?
- ☑ Make / manufacture the CMS?
- ☑ Specialize in environmental monitoring?
- ☑ Provide installation and training on-site?
- ☑ Have project management support?
- ☑ Offer technical support throughout the life-cycle of the products?

Monitoring Tasks and Regulations (Table 1.2 & 1.3)

Table 1.2

CMS Monitoring Tasks:

- ☑ Refrigerators
- ☑ Freezers
- ☑ CO_2 Incubators
- ☑ Stability (Temp/RH) Chambers
- ☑ LN2 Tanks
- ☑ Ovens
- ☑ Cleanrooms
- ☑ Warehouses
- ☑ Storage Rooms
- ☑ Cold Rooms
- ☑ Patient Refrigerators
- ☑ Blood and Tissue Refrigerators & Transport Coolers / Equipment
- ☑ Procedure Rooms
- ☑ Pharmacy Areas
- ☑ Diurnal/Growth Chambers
- ☑ General Purpose Incubators
- ☑ Production Conditions (i.e. assembly lines)
- ☑ Food Service Areas (i.e. deli cases)

Tip: Think about your facility and all of your critical assets: cell cultures, vaccines, food & beverages, ICH test areas, production lines, research, and so on. Could you lose valuable product in the event of an excursion with your current monitoring method? Consider a CMS!

Table 1.3

CMS Meets Common Regulatory Requirements, Such As:

- ☑ cGMP, GxP (Manufacturers, Continuous Monitoring)
- ☑ GLP (Laboratories)
- ☑ DSHEA (Nutraceuticals)
- ☑ FD&C (Cosmetics)
- ☑ AABB (Blood Banks)
- ☑ JCAHO (Hospitals)
- ☑ AATB (Tissue Banks)
- ☑ CBER (Biologics)
- ☑ FSMA (Food & Beverage)
- ☑ CVM (Veterinary Products)
- ☑ FDA 21 CFR Part 11 (electronic documents and signatures)
- ☑ Cap Requirements (Pathology, Hospitals)
- ☑ CDC VFC (Vaccine Monitoring)
- ☑ MHRA (Medicine / Healthcare Products)