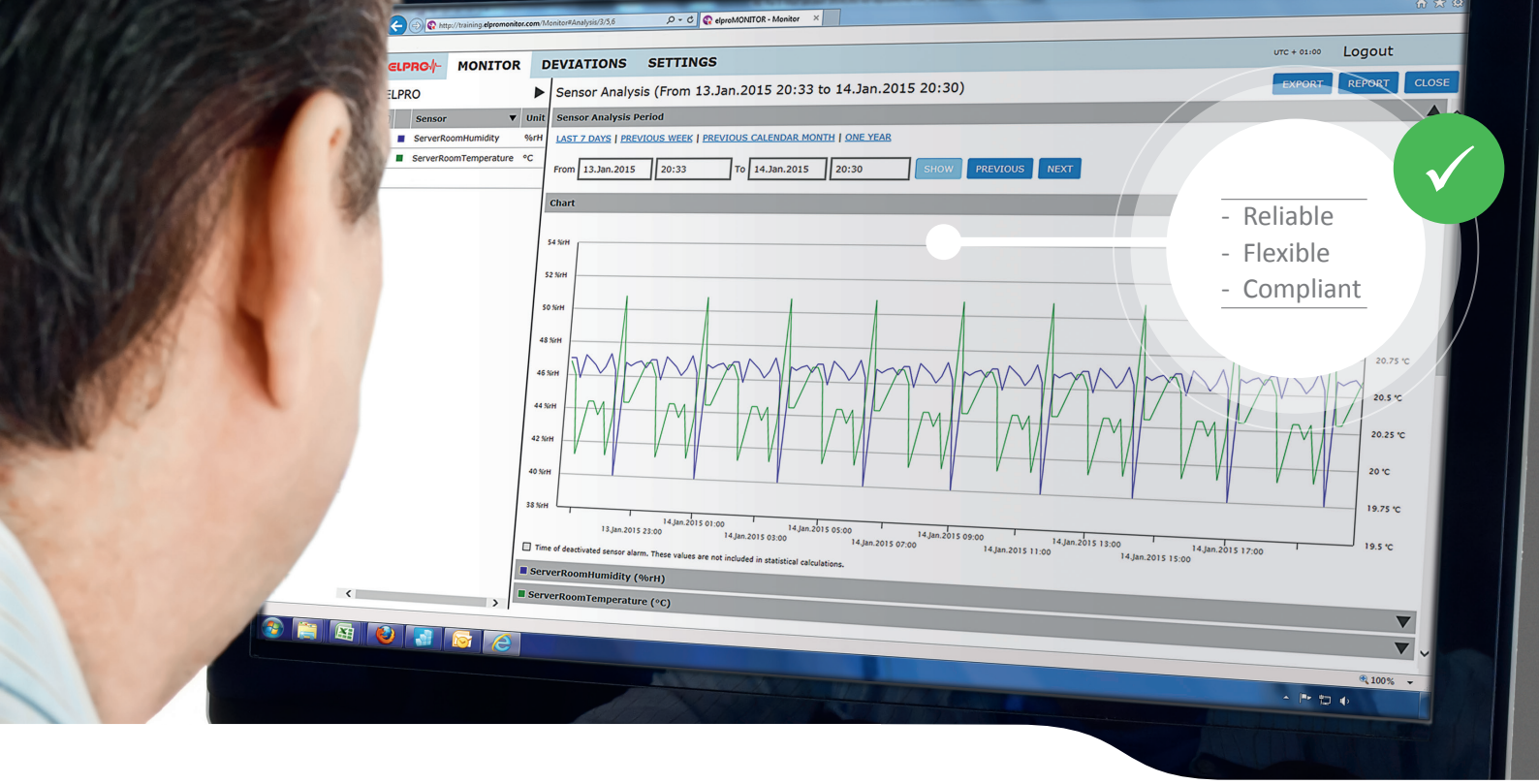

ELPRO

WHITE PAPER

Transitioning to an Enterprise-CMS (Environmental Monitoring System) in a Regulated Environment

we prove it.

Transitioning to an Enterprise-CMS (Environmental Monitoring System) in a Regulated Environment

Does this sound familiar to you? Every day your facility staff manually checks the temperature of each refrigerator, freezer and temperature controlled chamber to maintain proper storage conditions in your GxP facility. It takes a lot of time each day, especially as you have in excess of 50 measuring points.
Or is this your story … Your current environmental monitoring system is a «mish mash» of equipment that alarms individually or locally, which requires you to physically go to the facility to investigate an alarm. You often wonder, how can I get a detailed picture if there is a problem with this equipment, monitor my facility as a whole, without wading through spreadsheets of data from various sources?

As you know, temperature, humidity and differential pressure can adversely affect the quality of research materials, manufacturing processes used in cleanrooms and efficacy of finished product being stored in warehouses. For large facilities, it becomes a job in itself just to collect the required data to prove GxP compliance. But it doesn't have to be.
You don't have to stay with an existing system that may be outdated or doesn't fit your needs. Today, it's possible to automate the collection, storage and analysis of this data, in a Central Monitoring System, connecting all measuring points in a software platform that you can access from any computer or smartphone remotely. If your healthcare related facility is expanding, possibly adding another building or chamber, or constantly adding new equipment, totaling more than 50-100+ measuring points, a CMS system makes sense for you. If the system does what it should – it will do the work for you! It will notify you of alarms, create any report you wish and send a «one click» deviation report. Giving you back a huge amount of time to run your day to day operations.

Why is data important in a regulated environment?

Data is the key to compliance for a GxP facility, or for other healthcare organizations like hospitals that fall under JCAHO, outlined in Table 1.1. Regulators want to see evidence that demonstrates maintenance of correct environmental conditions for healthcare related materials and products being stored in a facility. The regulatory agencies' job is to ensure safe handling of processed and manufactured materials that are used to create human healthcare and consumer products – from drug discovery cell lines, to tissues for clinical trials and everything in between.
In a regulated environment, authorities not only want to see data on temperature excursions and how long they lasted; but in addition that the IT systems you're using are GxP validated. In the US, this means according to FDA 21 CFR Part 11. For some research and healthcare organizations, this in itself is a daunting idea – how to validate new software. However, there are some systems, such as elproMONITOR, that is fully GAMP®5 validated «out of the box», which saves organization's significant money and time; and provides the system structure that is needed to successful pass an audit.
The authorities also want to see the IT system that replaces manual processes will not deter quality. In CMS systems this is done with a built in audit trail that records all historical data of all measuring points, easily retrievable in case of a regulatory inspection.

Why can't I just use our current system or HVAC system?

Besides the manual work to record temperatures being extremely time consuming and unreliable; old technology like chart recorders are outdated because they don't take a point-by-point reading which makes it difficult to prove traceability to regulators. Also chart recorders have to be manually replaced with paper, requiring human intervention susceptible to error.

Exactly what regulations are you required to comply with? (Table 1.1)

Regulation	Industry	What is says	Type
FDA 21 CFR Part 11	Pharma (labs, biobanks)	You must have an electronic signature on all changes made to any healthcare IT system.	Regulation/ Legislative Directive
EU GMP Annex 11	Pharma	The computerized system should ensure process and quality control, making historical data available on request.	Regulation/ Legislative Directive
cGMP 21 CFR Parts 210 & 211	Pharma	Requires all facilities or controls used in the manufacture, processing, packing, or holding of drug products to ensure that they meet regulatory requirements as to safety and strength, quality, and purity; including specifically section (iv) a system for monitoring environmental conditions.	Regulation/ Legislative Directive
JCAHO	Hospitals, Pharmacies, Universities	You must 1) make sure temperature devices are accurate by conducting regular calibrations 2) have compliant record keeping for critical storage area temperatures, in some cases for up to 10 years. JCAHO will also want to ensure data integrity and have before asked for evidence that demonstrates the data is authentic and that processes were in place that did not allow for tampering with records.	Regulation/ Legislative Directive
USP 1079 & 797	Pharma, Pharmacies	You must maintain proper environmental conditions in your healthcare facilities to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations.	Industry Guidance and Standards
CDC Vaccines for Children	Hospitals, Pharma	CDC recommends digital data loggers for continuous temperature monitoring that will record throughout the day, capable of storing thousands of temperature readings which can be downloaded into a computer or retrieved from a website for review and archiving. CDC recommends having a back-up monitoring device in the event that something happens to the primary device, ensuring continuous monitoring capabilities.	Industry Guidance
Health Canada 0069	Pharma	All pharmaceutical products must be monitored and documented to be kept within their stability defined parameters during storage.	Regulation/ Legislative Directive
ISPE Controlled Temperature Chambers	Pharma	Guidance documents how to conduct GxP Qualification and Mapping of your healthcare storage facilities.	Industry Standards

A lot of people ask, «why can't I just use the existing HVAC system or Building Management System?» First, if you've ever «looked under the hood» of a BMS, you've seen it's a complex integrated system with extensive workflows and different applications. The biggest question is – can it be qualified by cGMP? If you're a hospital, this may not apply, but any other pharmaceutical related facility must validate their environmental monitoring system software. Furthermore, typical BMS systems collect output of equipment, vs. independent sensors – leaving some equipment not part of the central system. Also, BMS systems tend not to be redundant, so for example if one part of the BMS system failed, it may affect the continual logging of temperature data in your temperature controlled chambers or equipment.

You've decided you need a new CMS system. What should you look for?

When it's all said and done, CMS systems all accomplish the same goals – automated data collection and alarm notification. The difference between each system is how this is accomplished. When choosing a system, consider the system architecture, hardware components, and software functionality vs. your requirements.

Basic system components defined:

Cloud hosted vs. database on your server

This boils down to – who owns the data and where is it stored? A cloud solution seems like a quick, easy fix for many organizations. It fits the budget and quickly gives a platform to deliver applications and infrastructure to house the data. But like for many other industries, the promise of the cloud needs to be made clear for GxP. When you buy something «as a service» how much control or flexibility do you have? If you're evaluating a cloud CMS solution, ask the vendor if it's a shared resource and how elastic or agile is it when you want to make changes?

More importantly, in a GxP environment, how will you validate the cloud solution according to FDA regulations? The scary question you may not have asked your IT department yet – Will they want to punch a hole in the internal firewall to allow a third party to host the data in their cloud? For hospitals, what happens if the cloud service goes down? Will you still receive alarms and notification of important environmental changes that could affect patient samples and research materials?

The other option is to implement the software and database on your server. To some this may seem like a lot of work, with many hoops to jump through involving IT. However in a regulated environment where you need 24/7 access to your data, pharmaceutical related businesses tend to favor this option, allowing for full control of the system and availability of data.

Wired vs. wireless

It's important to know the different in a GxP environment. Often times a wireless system is preferred because it is perceived as more convenient, but in the CMS marketplace, it's important to determine what «wired» or «wireless» actually means to the system manufacturer. Evaluate both LAN connectivity and sensor connectivity – which of these components are actually wireless or wired? Oftentimes, when we think of wireless, we think of free moving equipment, but that's not always the case.

Network Connectivity. Sometimes when a system is named «wired» or «wireless» it indicates nothing more than how the system connects to the network – either via Wi-Fi connectivity or hardwired LAN. With a Wi-Fi system, if you have an extensive facility, over multiple floors, consider the need for extenders, extra batteries and the equipment (and its reliability!). The components that comprise this type of wireless system may still require electrical power, adding to the installation costs and overall need for emergency power. If you're operating in a regulated environment, how easy is it to validate a Wi-Fi system? Is your Wi-Fi secure?

Sensor Connectivity. In order to achieve true movement of equipment, a wireless sensor system is necessary. This means that there is no connection between the monitoring base station and the sensor located on the piece of equipment. In a heavily regulated environment where data security and reliability are paramount, make sure that a «wired» system provides a hardwire connection between the sensor and the base station.

Sensor type

Thermocouple (T/C) vs. Resistance Temperature Detectors (RTD). Although T/C sensors react quickly to temperature change, their readings are not always consistent or reliable because their measurements are highly sensitive to other environmental conditions. Because of their tendency to drift, metrology departments require thermocouple calibration every 6 months. Yes thermocouples are inexpensive and widely available for many applications, but what about the cost of materials you have to store? Can you put a price tag on reliability? For some sensitive products, the accuracy of ±0.2 °C vs. ±0.5 °C in the critical range can make a big difference in product usability decisions. If you find that a thermocouple has drifted and is out of tolerance during calibration, it causes a whole host of problems regarding product usability. How can you prove that the product was in range in between calibration times?

Unlike T/C sensors, RTD sensors are comprised of high-quality material, typically a fine-coiled wire made of platinum, nickel or copper. RTD's have a predictable change in resistance as the temperature changes and it is this predictable change that is used to determine temperature. RTD type sensors (Pt100) are stable, accurate, and highly resistant to drift. Although physically larger than a T/C sensor, the average RTD is 3.1 to 6.35 mm in diameter, and response time is usually measured in seconds (vs. fractions of a second that a thermocouple can respond). Due to its inherent long-term reliability and stability, RTD's are the preferred measuring device for accurate temperature measurement in healthcare and pharmaceutical applications.

Redundancy

The definition of redundancy in a CMS system is that the system will continue working even if one component is removed. How is the system affected by loss of power, hardware failure, or network failure? How will you be notified of this failure? How will data be affected? It is important to access both local and/or historical data, even in network or hardware failure. This is an important consideration and discussion to have with the vendor.

Redundancy also means multiple levels of alarms and locations for data storage. Additional layers of protection are created by having the alarm record centrally on the software, while also notifying the system user by telephone, email or computer.

Beyond the basics, what can a modern CMS system do for you?

Beyond regulatory compliance, the purpose of a CMS system is to simplify operations, giving the facility manager time back. The right CMS system will do the work for you!

Here's what to look for in a Central Monitoring System:

Central database, archiving, auditable

This is one of the key advantages of moving to a Central or Continuous Monitoring System. By having all the data in a central location, you will have faster and easier access to data, alarms and reporting functionalities. A central location also means all your equipment, assets and networked locations are connected, online available 24/7.

A sensor based system

Having your CMS system set up based on sensor groups allows you to customize your system to allow access of certain sensors to specific user groups. This is particularly helpful if you want to allow only certain access to some groups. With a sensor based system you can configure different access levels (view and analyze only; deactivate alarms) to certain people/groups.

Reporting capabilities

Having a CMS system that you can set up to send you automated reports is extremely helpful for large organizations with diverse user groups and several system owners. You can customize reports so the metrics are sent to pre-defined recipients by email. All reports can be auto archived for efficient and compliant record keeping.

A newer feature of modern CMS systems include a «one click» deviation report. It is automatically generated to give a snapshot overview of alarm details.

Remote real-time view

One of the biggest advantages of using an online software platform is to be able to access your facility data from anywhere, anytime – without having to go to the facility. As some platforms are web based, there is no need for installations at numerous workstations, making it easier to maintain. As all measurement point values, alarms and de-

viations are recorded on a central database, you can simply search time and date of any historical point. You and your teams can use any workstation or PC worldwide to have visibility on the environmental conditions of your critical assets.

New software validation

How easy is it to validate? As mentioned previously, healthcare IT systems must follow certain regulations. The industry standard is GAMP®5, using the V model. There are only a few solutions that come GAMP®5 validated right «out of the box». These options will save you a significant amount of time and cost. You'll also want to work with a vendor who has the capabilities to help with the IQ/OQ after installation.

Start investigating systems available

With a good understanding of the basic components of a CMS system, you can start evaluating vendors. Make sure you qualify how each component of their system works. To help, Table 1.2 is a «shopping list» that will help you lay out the differences in the systems you're evaluating.

Internal stakeholder buy-in

As the facility manager or end user of a CMS system, your life will be drastically simplified with more efficient day-to-day operations, and guaranteed quality control for your important assets. You want change and can see the benefits. But … you're having trouble convincing everyone that investing in a CMS system is the right move for the organization?

This is a common story for large universities, biobanks, research facilities, biopharmaceuticals, and hospitals. The two most common reasons for stalled CMS implementations are getting all stakeholders on board, and there is no funding.

These obstacles go hand in hand, and may be more perception than reality. Once you have the business case to convince stakeholders, you will have the evidence to procure the funding. We would like this article to help you achieve both.

Ask CMS vendors the right questions (Table 1.2)

Cost of ownership

- Is there a monthly fee?
- Is there an annual contract required?
- What is the up-front cost vs. the recurring cost?

System structure … and security

- What is the layout of the hardware
  - Wireless LAN (wifi) vs. wireless sensors
  - What are the components of the hardware (are there repeaters, what pieces require power and battery changes)
- What type of sensors do you use?
- Does the system require a separate server (who's server)?
- How easy is it to expand the system for future growth? Are there are minimum number of points to purchase? Does this mean a higher monthly fee?
- Where is the equipment manufactured?

Redundancy

- Where does the data reside?
- If it is hosted by someone else, what happens if they lose internet access or their server goes down?
  - Can you see the status of your system without internet access (in other words, can you access the data locally at the data logger – does it have a local alarm if the internet is out). Does it have a display?

Service

- What does the initial installation include? How about training?
- What do you recommend for annual maintenance? Can we do the maintenance ourselves?
- Can I contact you directly for technical questions and service? If you are a dealer, are you trained by the manufacturer and how often do you receive training?
- What is the warranty?

First – define your numbers. How much time monthly / yearly does it take staff to manually check temperatures / change chart recorder paper? How valuable are your assets being monitored in dollars? If asset's quality is compromised, how would they be replaced / delays to clinical trials / delays to downstream processing or manufacturing / lost finished product?

Next – define your core project team early on. Each person or department will have different interests in the system, different concerns. Consider these, decide how to address them and begin your recruitment campaign with each key stakeholder. For example, IT will need to set up and maintain the CMS system. Choosing a system that is GAMP®5 certified will be reassurance it's a quality engineered system. Can the system connect to company's active directory for easier user- management company-wide? Will they be more comfortable hosting the database on the company's own server, vs. the cloud?

Rolling out a pilot project

After rallying internal support and you've decided to trial a CMS system, there are several best practices to follow when running a pilot project. These include:

1. Define roles and responsibilities: Who will manage the new system on-going and be the future system owner?
2. Define the overall data collection goals beyond regulatory compliance. What metrics of your facility do you want to collect for facility optimal operations or provide to senior management?
3. Work with IT to locally set up the software on your server
4. Start with monitoring 5–10 points with one end user / department
5. Run the pilot for ideally 2–4 weeks to collect sufficient data to create some meaningful analysis
6. Schedule training for key users
7. Send updated SOPs including data logger and database instructions to appropriate users.

Once the pilot is completed, you should evaluate the pilot based on several key factors:

A. Reliability of the system. Was there any «down time»? Did you receive all alarms immediately? Were the alarms routed as you set up in the system, ie to a smartphone, via text etc.
B. Response of the CMS vendor. Did they ease the implementation?
C. Usability of software. Ask your end users, was the software intuitive?
D. Use of data – do you have the data to calculate what you need?

If you see the results you're looking for as the project leader based on reliability, ease of use and data metrics, then it's time to consider again how to present these finding internally. Take the pilot results and use them to create brand awareness internally with all end users and upper management. There's still a lot of work to do and you'll need the support from the organization.

Conclusion

Rolling out an enterprise Environmental Monitoring System may not seem like a quick fix or the easiest solution. But for large organizations with critical, irreplaceable assets, in a regulated environment – it's the only solution.

Once the right CMS system is implemented, your facility will be compliant and almost running itself sending you notifications of alarms, performance of certain equipment and periodic reports on how the facilities' environmental controls are running.

Please contact ELPRO if we can help you progress through this transition. Our team of trained experts, with years of experience, is happy to offer help.

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