PRACTICAL GUIDE

Environmental Monitoring in Pharmacies and Hospitals

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Practical Guide to Environmental Monitoring in Pharmacies and Hospitals

Maintaining control of environmental conditions in highly regulated pharmacies and hospitals to comply with standards can be complex and time-consuming. Smart automated technology and real-time monitoring have enabled employees to easily collect and access data.

Ensuring the proper condition and calibration of temperature data logging equipment and environmental monitoring sensors within refrigerators, freezers, ultra-low freezers, cryogenic storage containers, incubators, or growing chambers is crucial to the daily work. Documentation is key for precise analysis, traceability, and compliance.

This practical guide pharmacy directors, heads of quality assurance and compliance, and healthcare administrators will take you through several important aspects to consider when mitigating risk and maintaining compliance in a pharmacy or hospital.

1 | Wired vs. Wireless Monitoring? It All Depends.

It sounds overly simplistic, but it is important to clarify the context of wired and wireless monitoring solutions in a GxP environment. Be sure to evaluate both LAN (local area network) connectivity throughout your facility and sensor connectivity in your monitoring solution.

Network Connectivity

Network connectivity indicates how a system connects to your organization's overall network – either via wireless local area network (WLAN) connectivity or hardwired (LAN). When it comes to monitoring in a large multi-level complex facility, a wireless system may require more maintenance and installation cost than anticipated. Consider the reach and strength of wireless signals. Also, consider the battery life of the monitoring equipment. The system may require electrical power as well as back up power. If you are operating in a regulated environment, evaluate how easy it is to validate a WLAN system and determine how secure it is.

Tip: Buffering Sensors Eliminate Data Gaps

Truth is, even the best wireless technology will lose signal "connection" from time to time. Some organizations even define an "acceptable level" of dropped signal in their SOP with regard to monitoring. However, the best solutions employ data buffering sensors that keep measuring environmental parameters during signal loss and send the measurement data to the logging device once the sensor's signal reconnects to the logger. This safeguard helps eliminate data gaps in your reports and increases confidence and assurance during audits.

Tip: Define Data Ownership In Advance

Don't take data ownership for granted. Regardless of whether you choose to store your data onsite or in the cloud, make sure your service level agreement (SLA) states that you always have full access and complete ownership of your data. Not all solutions grant data ownership rights.

Monitoring System Sensor Connectivity

An environmental monitoring solution can be both wired and wireless. Many organizations implement a combination of both types. The decision to choose one type over another often relates to data reliability, infrastructure, and even construction material of a facility. Wireless temperature data monitoring systems offer dependability with greater flexibility, especially if you have plans to relocate lab equipment such as freezers or refrigerators to different rooms, floors, or buildings. A wireless system cuts down on installation costs and provides a great deal of flexibility. In a highly regulated environment where data security, a faster data stream, and reliability are paramount, a wired sensor system is often preferred.

2 | GxP Compliant Data Storage: Cloud vs. On-Premises

Today more and more organizations are opting for cloud database solutions as they provide a secure and easy platform to deliver applications without the hassle of additional servers and infrastructure maintenance and upgrades. However, for the regulated pharmaceutical environment, the benefits of the cloud need to be clear for GxP compliance. When purchasing a solution as a service, be sure to determine data ownership, control, flexibility, and access. If you are evaluating a cloud solution, ask if it is a shared resource and how agile and scalable is it when you want to make changes. More importantly, predetermine how you will validate the cloud solution to ensure GAMP® 5 compliance.

In a cloud-hosted solution, there are also questions of network security that may be of concern for your IT department. Despite the security of the third party cloud systems, some IT managers are reluctant to provide access through their organization's internal firewall to allow hosting the data in the cloud. Be sure to ask important questions, such as what happens if the cloud service goes down? Make sure you will still receive alarms and notification of important environmental changes that could affect pharmaceutical products and samples.

Implementation of software and database solutions via on-premises servers is often the preferred choice of many pharma and life science companies. In a regulated environment where you need fast 24/7 access to your data, pharmaceutical related businesses tend to favor this option, allowing for full control of the system.

On-Premises	In the Cloud
Works with legacy IT systems	May not function well with legacy IT systems
Data may feel more secure	Data secure by third party with 24/7 security measures in place
Local IT responsible for maintenance and updates	Third party responsible for maintenance and updates
Data stored on local servers managed by local IT	Data stored through third party, easy scalability
Additional investments for physical space, energy costs, associated equipment, and personnel	Service fees
Local IT responsible for secure network backup	In most cases, backup is more secure

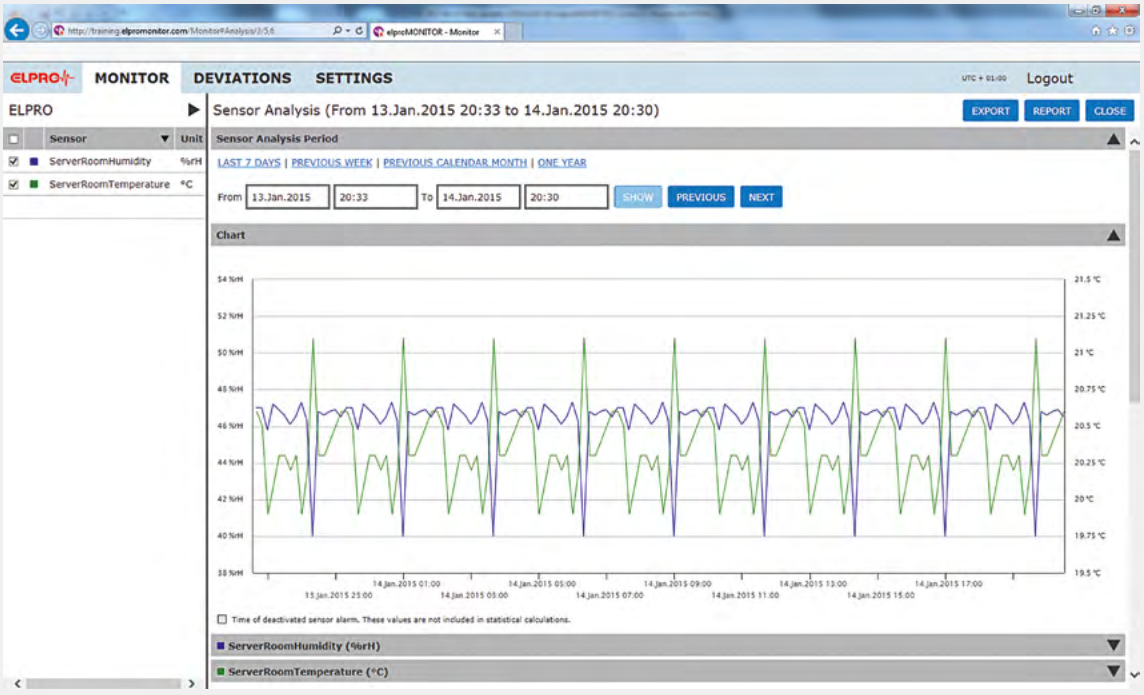
3 | Reporting: Assessment, Analysis, and Archival

Beyond regulatory compliance, the purpose of an environmental monitoring system is to simplify operations, automate processes, enable easier reporting, provide a full audit trail, and create time and cost efficiencies in your organization. Choosing the wrong system can have a drastic, negative, long-term impact on the total cost of ownership to your organization over the first five years.

A central database software solution can provide automated excursion assessments, data analysis, and one click access to reports and data archives. 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 means all of your equipment, assets, and networked locations are connected and instantly accessible online.

A sensor-based system enables you to assign bespoke access and responsibilities to certain individuals or users groups (e.g., view and analyze only, deactivate alarms).

Robust database solutions also enable customized reporting capabilities. The ability to send automated reports is extremely helpful for large organizations with diverse user groups and several system owners. You can customize reports so the metrics are provided to predefined recipients via email, phone, or SMS text. All reports can be auto archived for efficient and compliant record keeping. Modern database solutions include one click deviation report, which is automatically generated to give a snapshot overview of alarm details.



Centralized database software such as elproMONITOR (shown above) enables quick, easy, and secure analysis of temperature excursions, reporting, and data archival for rooms, refrigerators, freezers, and cryogenic and ultra-low containers.

4 | Remote Alarm Notifications

An absolute necessity, one of the biggest advantages of using a networked software platform is access to real-time data visibility on the environmental conditions of your critical assets from anywhere at any time. As all measurement point values, alarms and deviations are recorded on a central database, you can simply search the time and date of any historical point. The solution can also be custom configured so that responsible persons or teams are immediately notified of any deviations via phone, email, or SMS text.

5 | Regulatory Compliance

Auditors want to see comprehensive evidence that demonstrates and proves maintenance of the correct environmental conditions for pharmaceutical and healthcare related materials. Their job is to ensure the safe handling of processed and manufactured materials that are used to create human healthcare and consumer products – from advanced therapy medicinal products (ATMP) and tissue samples to clinical trials and everything inbetween.

In a regulated environment, authorities not only want to see data on temperature excursions and how long they lasted, but they also ensure that the IT solutions you're using are validated. In the US, this means according to FDA 21 CFR Part 11, in Europe according to EU GMP Annex 11. For some pharmacies and hospitals, validating software is a complex and daunting task. However, software solutions, such as elproMONITOR and elproCLOUD, are fully GAMP® 5 validated out-of-the-box, which saves organizations a significant amount of time and eliminates cost. These systems provide the necessary data infrastructure needed for compliance and to successfully clear audits.

Regulating authorities also want to ensure that the automated environmental monitoring system that replaces manual processes will not deter quality. This is accomplished via a built-in audit trail that records all historical data of all measuring points and is easily retrievable for inspection.

In Summary

In today's highly regulated pharmacies and hospitals, automation is the key to maintaining compliance. A robust environmental monitoring solution can ensure critical, often-irreplaceable samples, research, and assets are fully-protected and remain viable. An investment in these systems can positively affect the bottom line of your organization within the first five years of implementation by empowering your teams to work more efficiently and automate processes, saving time and cost.

This practical guide is part of the Pharmacy & Hospital website content for pharmacy directors, heads of quality assurance and compliance, and healthcare administrators. Topics include wired vs. wireless monitoring, cloud vs. on-premises data storage, reporting, remote alarm notifications, and regulatory compliance.

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About ELPRO-BUCHS AG

Founded in 1986, ELPRO is a globally acting Swiss provider of innovative monitoring solutions specifically designed for the highly regulated pharmaceutical, life science, and healthcare industries. As a leader in these fields, ELPRO is a “full service” organization offering state-of-the-art data loggers, cloud SaaS software platforms, including data analytics and a team of validation engineers to support the system integration into their customers’ business processes. ELPRO is part of the Bosch Group.
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