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BUILDING AND ENVIRONMENTAL MANAGEMENT SYSTEMS AND HOW THEY MEET GMP REQUIREMENTS

Lighthouse Worldwide Solutions

Overview

There are major differences between a BMS and an EMS. Today's GMP Aseptic product manufacturing requires an independent validated monitoring system following GAMP guidelines. Environmental sensors used should have the highest resolution and accuracy, be cleanroom friendly and be field calibratable. Sharing one sensor for control and monitoring is not the best approach in providing GMP data. Regulatory auditors will expect control and monitoring functions to be independent of each other.

Control (BMS) Compared To Monitoring (EMS)

An Environmental Monitoring System (EMS) is often confused with a Building Management System (BMS), but they are quite different. A BMS, also known as a Building Automation System (BAS), is a computer-based control system installed in buildings. It controls and monitors the building's mechanical and electrical equipment such as ventilation, lighting, power systems, fire systems, and security systems

An EMS monitors the environment of a facility while collecting and recording critical environmental data to verify compliance, whereas a BMS controls the environment and other automation functions such as process automation, facility lighting, heating, cooling, security and facility access.

In industries such as aseptic manufacturing of pharmaceutical products, these facilities require both a control (BMS) and monitoring (EMS) system. Often people wonder about validation. Since there are critical steps for GMP based on validation and regulatory compliance to adhere to, an EMS is typically validated based on the design of the system meeting the functionality of the system. This would have been outlined in a User Requirement Specification (URS) document. A URS is typically developed following a formal risk analysis study of the facility, the process, and the product. All EMS data needs to be GMP compliant. The data should be recorded with timestamps and alarm details to provide evidence that a product batch has been manufactured in an ideal environment and the product quality, safety, and efficacy has remained intact.

A Deeper Look At The Differences Between An EMS And BMS

A BMS is used to control temperature, humidity, and pressure throughout a facility. Other controls may include automation process equipment. The main function of a BMS is to control environmental conditions and offer other levels of facility control.

An EMS is used to monitor environmental conditions which are deemed GMP critical. These include particle counts, humidity, temperature, and pressure. An EMS also monitors and records critical data of support equipment such as fridges, freezers, incubators, and even product warehouse storage. All of these are GMP critical for product release based on all environmental and support equipment, including set parameters not exceeding certain set-points during the product cycle from production to shipping. Some EMS systems also utilize data logging sensors to monitor transportation environments for products where set environmental conditions must remain even in transportation.

Can You Combine A BMS And An EMS?

This would require a well-planned risk assessment from conceptual design to validation of the critical sensor devices that monitor environmental parameters. Unfortunately, the level of risk becomes a question of reliability when the control sensor is also used as the monitoring sensor. For example, in a scenario where room pressure or room temperature and humidity is controlled by the same sensors and they are also recording the historical data which is used for GMP compliance. Because the control aspect of the system is also the GMP monitoring solution, issues arise. If the control sensor was to drift, then this drift would go on unnoticed. Since most BMS systems do not regularly calibrate the sensors then the chances of finding the drift issues becomes greater. With a separate EMS sensor, the drift would be immediately noticed and a production manager would be notified when alarm limits exceed the operating set-points.

Another issue surrounding the use of a BMS and providing GMP data is FDA 21 21CFR11 compliance. Many BMS systems have not been designed to meet FDA 21 21CFR11 compliance and, therefore, the data could be rejected as true validated GMP data.
EMS systems also require strict access control, including audit trail, electronic records, and electronic signatures in line with FDA 21 CFR Part 11 and PIC/S Annex 11 on Computerized Systems.

What Are The Advantages Of Separate BMS And EMS Systems?

The risks are too high to combine a BMS and an EMS, especially with recent FDA and other regularly bodies closely examining data integrity. There are, however, numerous advantages to separating the BMS and EMS systems, some of which are outlined here:

1. An EMS logs and stores all GMP data from critical environmental locations in a secure database. A BMS does not require full validation; however, will require a level commissioning to verify the control limits and functions are correct. Thus, having separate systems on requires validation of the EMS.
2. If the BMS failed, whether from system or sensor failure, the EMS would continue to keep data records from critical locations. For example, if product storage equipment, like a refrigerator, failed, the EMS would then verify whether or not the environment was compromised thus allowing for informed decisions to be made regarding the release or rejection of product. Especially where such products were temperature sensitive.
3. Some BMS systems use lower rated HVAC quality sensors which are not easy to field calibrate. These sensors may also not have the resolution required to validate GMP data. An EMS typically uses field calibratable high resolution sensors that are also designed for cleanroom use.

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5. From a regulatory perspective, segregation of control and monitoring is desirable, critical data is verifiable, and has its integrity intact. Unless the end user can justify using a BMS to the regulator, a BMS cannot be made to act as an EMS. Regulatory auditors have been known to write up deviations where BMS systems are also designed to provide GMP data.

User of EMS system monitoring particle counts in a Cleanroom

What Should An EMS Have As A Minimum?

There are many EMS vendors and choosing the right EMS for you can become a major task, especially when there is much groundwork to do. As a minimum, an EMS should have the following attributes:

- **User should design the EMS URS following a formalized risk assessment.**
- **Should be capable of alert and action alarm notifications.**
- **Should have a full audit trail capability.**
- **Should have security features in line with FDA 21CFR11.**
- **Should have redundancy and back-up built in.**
- **Redundant vacuum system where remote particle counters are used.**
- **Must be designed to be FDA 21 CFR Part 11 and Annex 11 compliant.**
- **Should follow GAMP guidelines from design and all the way to start up.**
- **The vendor should offer Service Level Agreements for technical support.**
- **Must be designed with business continuity in mind.**

Why Is A Risk Assessment Required For EMS Implementation?

This risk assessment is to primarily identify scenarios that may present a critical risk to the safety of the product from environmental contamination. It has also been extended to include other environmental monitoring parameters, such as EMS sensor locations, software alarm settings, and computerized systems reliability. It takes into consideration alarm generation, redundancy, and remote access.

The end user normally assesses the EMS on offer to confirm if it is capable of meeting their functional requirements and process attributes. The system must demonstrate that it is fit for purpose and has a proven track record in regulatory applications, such as aseptic product manufacturing. Critical attributes of the EMS must be tested for functionality and operation. These tests are conducted in IQ/OQ testing and validate the systems functionality and operation.

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