

Differences Matter: Knowing BMS and EMS Systems

By: Jason Kelly

An Environmental Monitoring System (EMS) is very different from a Building Management System (BMS). A BMS, also referred to as a Building Automation System (BAS), is a computer-based control system installed in facilities to control and monitor the facilities' mechanical and electrical equipment such as heating, cooling, ventilation, lighting, power, fire, and security systems.

In industries like aseptic manufacturing of pharmaceutical medicinal products, facilities require Control (BMS) *and* Monitoring (EMS) solutions. Questions invariably arise regarding system validation. Since critical steps are mandated for Good Manufacturing Practices (GMP) based on validation and regulatory compliance, an EMS is authenticated based on validating that the system design meets the system's functionality, which should be outlined in a User Requirement Specification (URS) document.

A URS is typically developed following a formal risk analysis study of the facility, the processes, and the product critical locations. All EMS data must be GMP compliant: data records with timestamps and alarm details are used to provide evidence that a product batch has been manufactured in ideal environmental conditions and product quality, safety, and efficacy remained intact before market release.

What Is the Difference Between a BMS and an EMS?

An EMS *monitors* the environment of a facility, collecting and recording critical environmental data to verify compliance; **a BMS *controls* the environment and other process driven automation functions**.

A BMS controls facility and process 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 and access.

An EMS monitors environmental conditions that are deemed GMP-critical, including parameters such as particle counts, humidity, temperature, and pressure and to monitor and record critical data logging of support equipment such as fridges, freezers, incubators, or product warehouse storage.

All are GMP-critical for product release based on set parameters for environmental and support equipment not exceeding certain alarm set-points during the product life-cycle from production to shipping. Some EMS systems utilize data logging sensors to monitor transportation

environments for products where set environmental conditions must remain stable in transport.

Combining a BMS and an EMS

Combining BMS and EMS requires a well-planned risk assessment from conceptual design to validation of the critical sensor devices that monitor critical environmental parameters. Unfortunately, the level of risk becomes a question of reliability when the control sensor is also used as the monitoring sensor.

Scenario:

1. Room pressure or temperature and humidity is controlled by the same sensors and are also recording the historical data.
2. That data is used for GMP compliance.
3. Since the control aspect of the system is also the GMP monitoring solution, there are some issues.
4. If the control sensor was to drift, it would go on unnoticed.
5. Since most BMS system users do not regularly calibrate the sensors, the chances of drift issues becomes greater.
6. With a separate EMS sensor, the drift would be picked up immediately and when alarm limits exceed the operating set-points, a production manager would be notified.

Another issue surrounding the use of a BMS and providing GMP data is FDA 21 CFR Part 11 compliance. Many BMS systems have not been designed to meet FDA 21 CFR 11 compliance and therefore the data could be rejected as true compliant GMP data.

EMS systems require strict security 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.

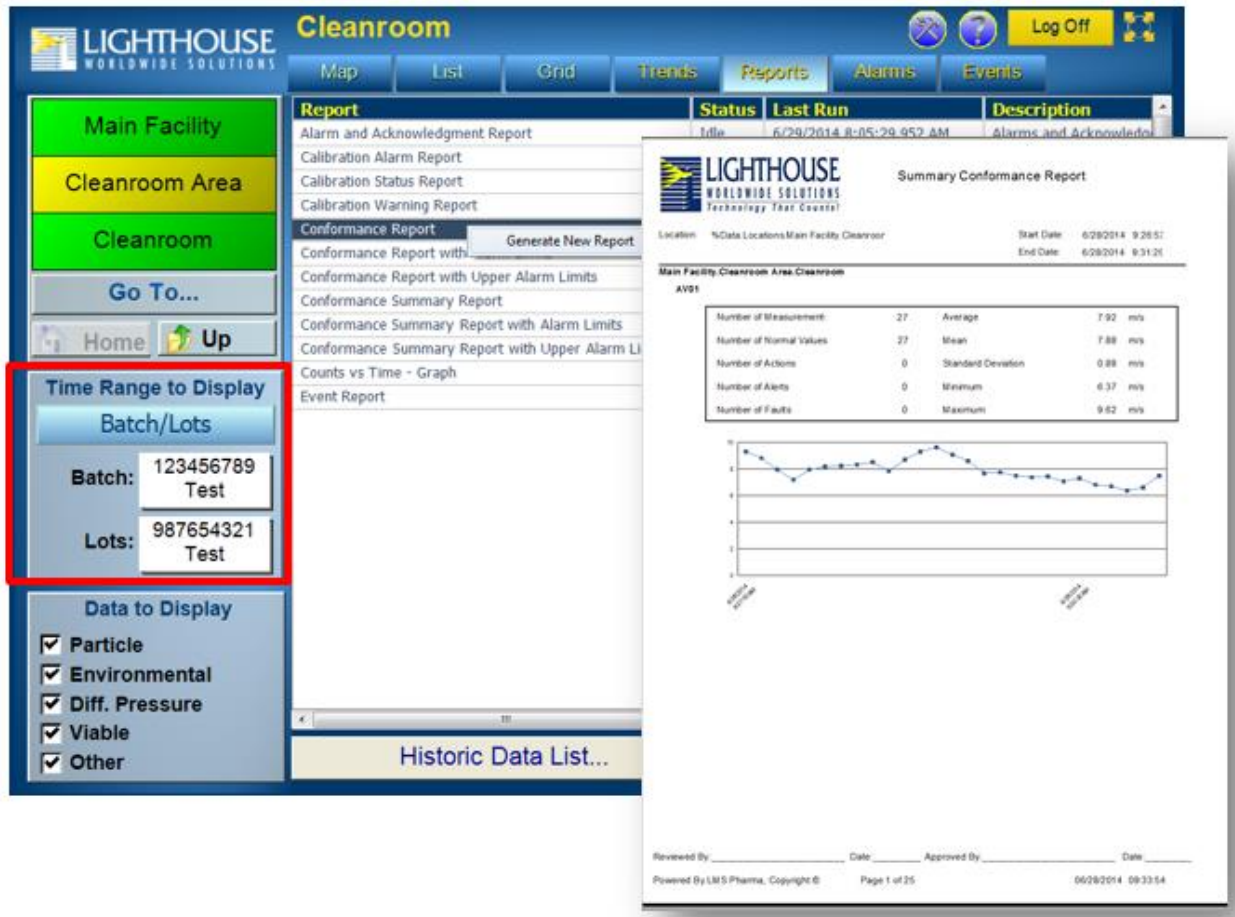


Fig.1 EMS software with GMP Conformance report indicating critical alarms

The Advantages of Separate BMS and EMS

If a BMS control system was also used to provide GMP data, data integrity risks arise that cannot be ignored, especially when FDA and other regulatory bodies are scrutinizing data integrity and validation. The advantages of segregating a BMS and an EMS should be considered and below are some of those advantages outlined:

- With the EMS, all GMP data from critical environmental locations is logged and stored on a secure database that is backed up. The BMS does not require full validation however, it will require a level of commissioning to verify control limits and functions are working correctly. Having separate systems only requires validation of the EMS system, otherwise the entire BMS system would require validation and the end-user would have to undergo a change control process to even adjust the office thermostat.

- If the BMS system experiences a software or sensor failure, the EMS would continue to keep data records from critical locations. For example, if product storage equipment like a refrigerator was compromised, the EMS would verify if the environment was compromised, allowing for informed decisions to be made regarding the release or rejection of valuable product. This is critical when there are temperature-sensitive products.
- Some BMS systems use lower rated HVAC quality sensors that are not easy or impossible to calibrate in the field. These sensors may not have the resolution required to validate GMP data. EMS system suppliers typically use field-calibrated, high-resolution sensors that are also designed for cleanroom use.
- From a regulatory perspective, segregation of control and monitoring is desirable because critical data is verifiable and integrity remains 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 a BMS are also designed to provide GMP data.
- EMS with particle counters are generally digitally connected to EMS software using IP addresses. Raw data is managed accurately and transferred to the EMS software without any necessary conversion via manufacturer-developed drivers. Where particle counters are connected to a BMS without integration of manufacturer drivers, using analog output signals from the particle counter, issues can arise in data resolution and accuracy. 4-20mA analog signals are susceptible to resolution issues especially when using low-quality analog to digital convertors (12 bit A/D). Where alarm limits for 5.0µm particle sizes are so low in ISO 5 or Grade A Cleanrooms (the expectation is 0 and current GMP guidelines accept ≤ 20 particles per cubic meter of air sampled), any deviation in data resolution or accuracy could trigger alarms and falsely notify end users where the production process is halted or if the batch was compromised. When stakes are high, accurate and reliable data is absolutely necessary.



Fig.2 Cleanroom operator connecting to EMS monitoring particle counts inside an isolator

EMS Minimum Requirements

There are many EMS vendors on the market, so choosing the right EMS is important, especially when much ground work and research is required. The following is a list of attributes an EMS should possess:

- User should design the EMS URS following a formalized risk assessment and work closely with the vendor in designing the Functional Design Specification (FDS),
- Capable of immediate alert and action alarm notifications,
- Provide a full audit trail capability,
- Possess security features in line with FDA 21 CFR Part 11,
- Possess a redundancy and back-up system automatically,
- Possess a redundant vacuum system when using remote particle counters,
- Designed to be FDA 21 CFR Part 11 and PIC/s Annex 11 compliant,
- Follow Good Automated Manufacturing Practice (GAMP) guidelines from design to start up and operation,
- Offer Vendor Service Level Agreements for technical support, and
- Designed with business continuity.

In Summary

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 should have the highest resolution and accuracy, be cleanroom-friendly, and allow for field calibration.

Sharing one sensor for control and monitoring is not the best approach in providing GMP validated data. Regulatory auditors expect control and monitoring functions to be independent of each other. System validation must be conducted on critical sensors with the validation tracing back to the user-supplied URS with proof that the system was designed, is operational, and meets GMP compliance. Data integrity is mandatory and data accuracy is required when reviewing GMP conformance reports and making critical quality decisions about product release to the market.

Author Biography

With over 20 years in management, Jason Kelly now manages the Lighthouse Systems Group, located in Oregon. A specialist on Environmental Monitoring Systems Service, design, installation, validation, and ongoing support, his experience includes working for top life-science, semi-conductor companies assisting in procurement, delivery, and compliance to ensure regulatory acceptance, along with BMS and HVAC vendors such as Siemens and Honeywell to integrate BMS and EMS independent monitoring systems in GMP processes. Jason's international work includes projects in the UK, Ireland, Europe, and Australia. Contact Jason at jasonk@golighthouse.com or LinkedIn.



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