



FMS delivers a critical focus that BMS cannot match

Synopsis

It's a common misconception that a Building Management System (BMS) can serve as an acceptable substitute for a Facility Monitoring System (FMS) that monitors specific critical environments within a building or facility. In our long experience, this is rarely the case.

Building Management Systems invariably deploy single sensors for the purpose of control and monitoring. While this kind of function sharing sounds efficient, it is far from the optimum approach when looking to deliver validated data compliant with Good Manufacturing Practice (GMP). In fact, GMP (and GAMP – Good Automated Manufacturing Practice) regulations require control and monitoring to be entirely independent functions.

Monitoring sensors need to deliver high resolution and accuracy, be designed for cleanroom deployment and permit calibration on-site. Reasons for this become clear

with greater understanding of the practical limitations of most BMS sensors and when visualising situations that may arise where a BMS could fail to alert or issue false positives. In aseptic manufacturing, for example, both scenarios are potentially disastrous.

The M Difference

The main difference is in the M. In BMS it stands for Management. In FMS, it signifies Monitoring. There's a significant distinction between management and monitoring.

As a computer-based control system, a BMS is installed in premises to manage and control the various facilities within. Functions typically include mechanical and electrical equipment, power supplies, emergency generators, lighting, heating and air conditioning systems, ventilation, fire and smoke detectors, and building access and perimeter management security systems. In contrast, FMS is a dedicated and focused

system, concerned only with monitoring a specific critical area or sensitive environment. It records and stores environmental data to verify compliance, monitoring GMP-critical attributes such as inert particle counts, viable particle counts, humidity and temperature levels, and sometimes pressure. The recorded data provides current and historic validation of compliance within the sensitive environment, including refrigerators, freezers, incubators, or storage areas. BMS controls the broader environment across the building in terms of attributes like temperature, humidity, and pressure.

Meeting Stringent User Requirements

An FMS is created and validated against a system design, itself created to meet the exacting needs and functionality of the desired operation – manufacturing, bio-testing, research, etc. That operation will be detailed in the User Requirement Specification (URS). Validair can assist with the creation of the URS based on 30+ years of experience in critical environments. System validation requires the use of critical sensors with that validation linked to the URS, proving that the system design is functional and GMP compliant. In aseptic pharmaceutical manufacturing, for instance, the business is likely to need BMS and FMS solutions. These can be designed to work together (see below). To meet the stringent validation requirements – not just of GMP but also those that dictate the rigorous needs of specific products being manufactured – the FMS data must be fully compliant and adhere to regulatory standards.

The monitored, recorded and stored data includes time stamping for chronology, information on drift or deviation from optimum (even where still within the acceptable range), and any alarm incidents with details of those alarms. This data is used as certified proof

that the operational environment adhered to all standards during the process, thereby validating the integrity of the manufactured product and giving confidence to market release. Or it provides hard evidence of out-of-tolerance alarm incidents that may impact that integrity and lead to products or product batches being rejected on quality grounds.



FMS Working with BMS

The functions of FMS and BMS do overlap in concept. With the right equipment and expertise, they can operate successfully together. However, it's wise to understand where the typical limitations of BMS affect the integrity of monitoring a critical area or environment. The sensors deployed are pivotal.

One key potential weakness is the dependability of a sensor used to monitor and control, especially when used to comply with GMP. With the same sensor controlling and monitoring the environment, there's an opportunity for drift to go undetected. This is troublesome in the context of GMP.

In contrast, an independent monitoring sensor as part of the critical FMS infrastructure has no relation to the control system. It would therefore detect a departure from the norm immediately and issue an alarm. Unlike particle counters and cleanrooms, Building Management Systems tend not to be calibrated regularly, thereby exacerbating the chance of undetected sensor drift.



HVAC quality sensors often used in BMS are typically lower rated devices. On site calibration is invariably difficult and sometimes simply not possible. In addition, these sensors may not have the resolution required to validate GMP data. FMS uses field-calibrated (and easily recalibrated), high-resolution sensors suitable for the most demanding applications like cleanrooms in an aseptic core. Particle counters are best interfaced directly with FMS. This interface is digital, with seamless data transfer between parts of the infrastructure needing no conversion or transmutation. Interfacing sensitive instruments like airborne

particle counters directly to a BMS typically involves proprietary software drivers. Validating the efficacy of those drivers is a challenge, especially if they need to deliver GMP compliance. Connecting a BMS to particle counters without proprietary drivers usually means using the counter's analog output signals. But here we see concerns around data resolution and accuracy, given that 4-20mA analog signals tend to exhibit resolution problems, particularly with the low-quality A/D converters typically deployed as standard. Few BMS systems are designed to meet FDA 21CFR Part 11 compliance.

That means the data could be rejected as not being truly compliant with GMP standards. Conversely, FMS demands strict access controls, with secure electronic record assets, an audit trail and e-authentication to comply with FDA 21 CFR Part 11 and PIC/S Annex 11 on computer systems.

FMS Independent of BMS

There are undeniable benefits in keeping BMS and FMS functions separate. With FMS, data from critical environments (including GMP data) is securely logged and stored on an independent database and often directly to the cloud. Standard IT protocols and procedures apply, like failover redundancy and auto-backups. While the BMS doesn't need full validation, it does require commissioning to validate its control limits and correct functionality.

Separate systems mean that only the FMS requires validation. In turn, this eliminates the onerous need to validate an entire BMS system, which presents impractical usability constraints and procedural issues for simple everyday actions like adjusting the temperature in parts of the building.



alarms, particularly in applications where the expected particle count is very low (or zero, in the case of Grade A cleanrooms). Here, even a small particle count deviation due to a data resolution error can raise an alarm and conceivably cause the manufacturing process to be stopped. The quality and commercial impact of that on batches or product is clear.

It's best to visualise the two separate systems working in a 'cause & effect' manner, which is also useful when investigating a failure or an out-of-limit situation. The FMS reveals the effect of the failure; the BMS allows the cause to be identified and investigated. Both systems work hand in hand, with neither fully able to perform the function of the other.

FMS 5 from Validair

Validair's FMS 5 monitoring system from world leader TSI Inc. uses software specifically designed and developed according to GAMP guidelines. FMS software is assigned as ISPE GAMP 5 – Category 4 – Configurable. Our provision and implementation of a monitoring system supports ISPE GAMP 5 compliance.

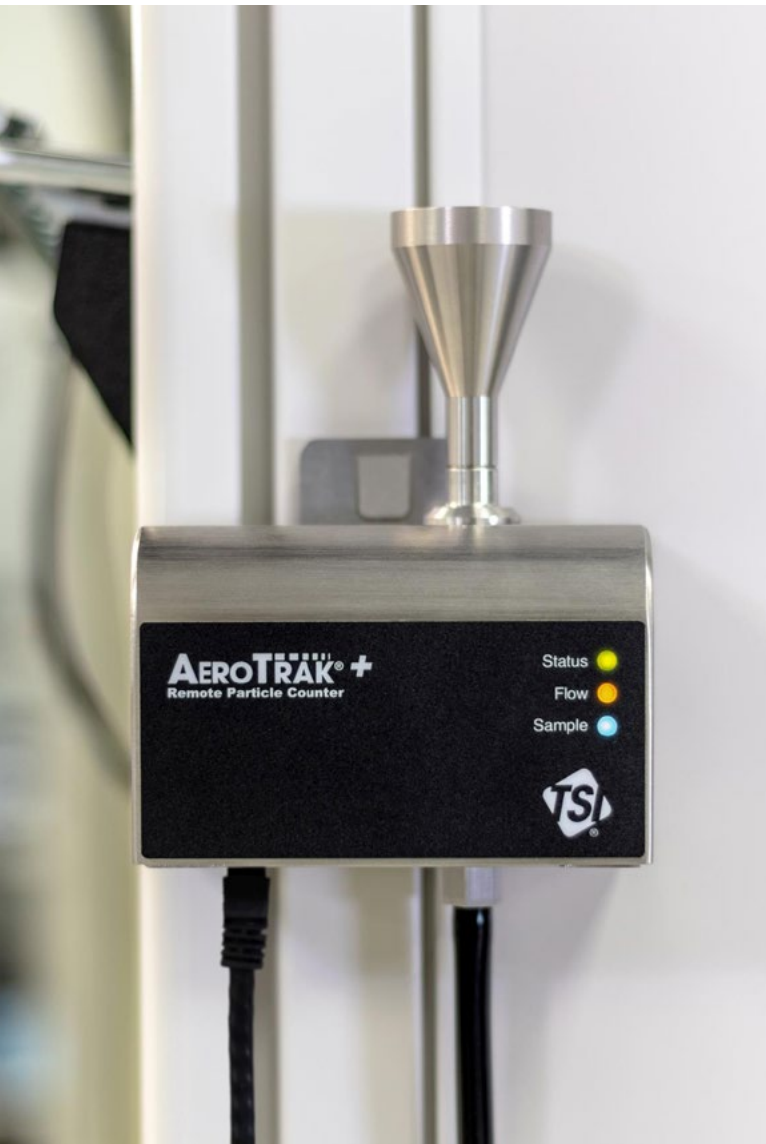


FMS continues to maintain data and keep records in the event of a failure at BMS level, for instance a damaged sensor or software fault.

That assures the availability of GMP compliant data across equipment interfaced to the FMS that may be compromised by higher-level failures, thereby permitting decisions to be taken about integrity – for instance with products held in a storage area where a BMS fault has allowed environment changes to go unchecked.

The regulatory bodies like separation. Independent control and monitoring functions mean the integrity of critical data remains intact and verifiable. Justifying the use of a BMS to regulators is a challenge as it cannot operate like an FMS. The industry witnesses many reports of regulatory auditors writing up deviations where a BMS is cited as the origin of GMP data.

In cleanroom applications, false positive particle counts can be as vexatious as undetected viable particles. Deploying lower resolution sensors exacerbates the likelihood of false positive



FMS 5 system is an advanced, reliable and user-friendly monitoring software suite that features a truly distributed architecture and is compatible with OPC UA client/server solutions. High availability databases and hot standby system failover functionality assures compliance and peace of mind. Standard inputs include airborne particle counters, active air samplers, temperature/humidity, differential pressures, air velocity and digital inputs.

FMS provides direct connectivity to TSI monitoring instruments, including AeroTrak+ Remote Particle Counters, AeroTrak Portable Particle Counters, the AeroTrak Cleanroom Condensation Particle Counter and the BioTrak Real-Time Viable Particle Counter. It provides immediate alarms and alert notifications independently of the BMS and generates a full and secure audit trail.

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