CHANGING TO THE NEW NORMAL WITH FULLY INTEGRATED ENVIRONMENTAL MONITORING SYSTEMS

Vital information for the most critical component in your cleanroom.

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INTRODUCTION

The manufacturing of pharmaceuticals must occur in a cleanroom. A critical component of a cleanroom is a building management system (BMS). A BMS controls the environment and personnel/material flow so that cleanroom conditions are properly maintained. For the cleanroom and the products made in them to be cGMP compliant, environmental monitoring is also required. An environmental monitoring system (EMS) ensures that the critical environmental conditions in the cleanroom, such as temperature, pressure and humidity are tracked during the operation of the cleanroom.

Routinely, environmental monitoring systems are designed and built by a separate contractor than the one who built the cleanroom. And that system is qualified after completion of a cleanroom. This practice adds unnecessary installation and testing time to the final qualification schedule of the cleanroom project. A separate EMS can also cause unnecessary issues because of extra hardware and components needed for integration of separate controllers.

With prefabricated cleanrooms, the EMS can be designed and installed during cleanroom construction by the cleanroom provider. Moreover, the environmental monitoring system (EMS) can be automated meaning that critical data including sensor readings, alarms, Audit Trail, and user access are logged and historized without additional user actions.

This paper will discuss the benefits of a fully integrated environmental monitoring system.

EMS REQUIREMENTS

Foundations of an EMS are based on 21 CFR PT 11, which defines requirements of a validated system for electronic record keeping in a cleanroom. Components of the EMS include:

- Critical environmental readings of the cleanroom including, but not limited to temperature, humidity, and pressure
- Integrity of all logged data
- Generation of an audit trail to log user inputs such as user access, set point changes, and change control
- Critical alarm logging
- Electronic signatures needed for additional user access security
- Long term data archive
- Generation of non-modifiable reports
- Confidentiality of electronic records

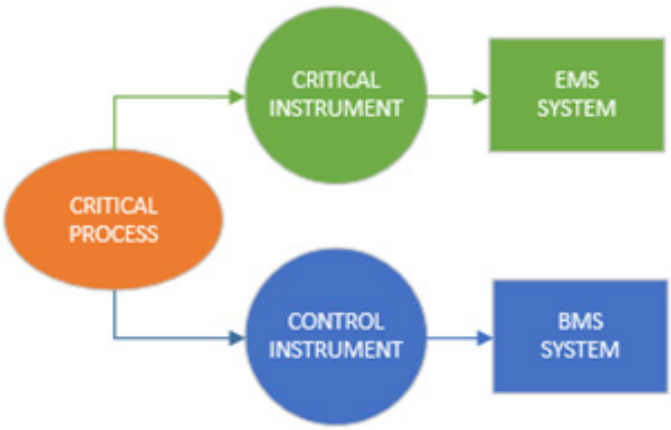
21 CFR PT 11 compliance is interpreted rigidly which can lead to issues during commissioning and qualification if an unqualified provider is retained.

CONVENTIONAL DESIGN METHODS

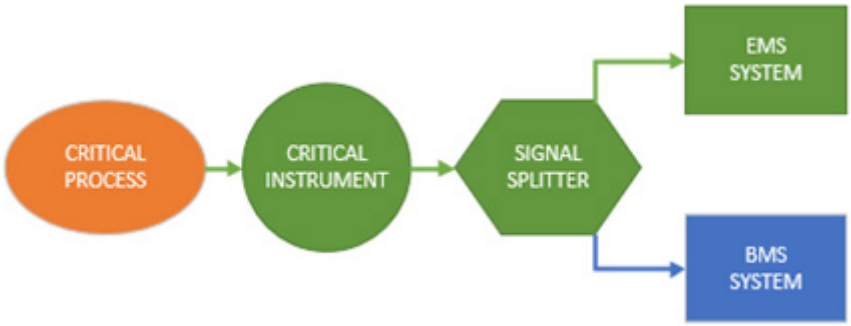
During cleanroom design, the first consideration is the process equipment needed for manufacturing. The manufacturing process defines the environmental requirements, which in turn determine BMS design requirements. Even though EMS requirements are defined by the manufacturing process, one of the last design milestones in a typical cleanroom construction is the environmental monitoring system. And at this stage, the traditional solution is to add a third-party EMS which is essentially bolted on to the cleanroom.

The third-party EMS is a separate system independent of the BMS. To integrate the third-party EMS, there are two methods. They are:

- Method 1: Install duplicate sensors so one set of instruments is connected to the BMS for control and the other reading is connected to the third-party EMS system. For example, a cleanroom would have two temperature transmitters monitoring the same temperature. One instrument would be installed for the BMS. One instrument would be installed for the EMS. Because the EMS transmitter is validated and the BMS transmitter is not validated, the EMS transmitter will be regularly calibrated. Over time, the BMS transmitter reading will differ from the EMS transmitter reading.



- Method 2: Install signal splitters to duplicate sensor readings to the BMS for control and third-party EMS. For a cleanroom, one temperature transmitter is installed, and the signal is duplicated using an electronic signal spitter.



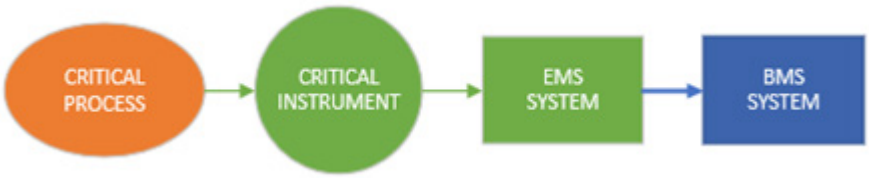
These two EMS integration methods can cause many problems in multiple phases of a project:

- Duplicate instruments cause discrepancies between the critical sensor reading that is being recorded by the EMS and the sensor reading that is being used to control the system in the BMS. These different readings will ultimately cause problems in commissioning, maintenance, and quality over the lifetime of the cleanroom.
- Additional and unnecessary construction time and material is needed to install the extra hardware. Duplicate instruments can double device material and installation costs for the project. Signal splitters can increase automation costs by 50%.
- Additional time is required for coordination of hard-wired I/O and network between the third-party EMS contractor and BMS contractor.
- Frequently, differences in control systems cause scope gaps to appear in the latter stages of a project when system integration is tested. These scope gaps can be the result of design miscommunications.
- Because the third-party EMS is not fully installed until the cleanroom is installed, the third-party EMS cannot be pre-qualified.

The time lost in third-party EMS integration is typically detrimental to the timeline of the project.

COMBINED METHOD

An integrated BMS/EMS SCADA system provided by the cleanroom manufacturer is a better method and can be provided in the condensed timeline of a prefabricated cleanroom. The design requires no third-party EMS integration because the system utilizes a controller for the BMS and a controller for the EMS. In the example discussed, one temperature transmitter is installed, and the signal is read to the EMS. All BMS integration is done via a network connection. The combined SCADA network is designed so the EMS can be validated, but the same sensor readings are used in both the EMS and BMS.



In this method, efficiencies of design, construction, and commissioning are realized in the project in the following ways:

- The EMS is part of the front-end design.
- One set of critical instrument sensor readings is used for both control and archiving.
- The BMS and EMS are commissioned together, but the EMS is validated separately.
- Factory acceptance testing for the EMS is leveraged during the cleanroom site acceptance testing because there are no additional instruments that need to be tested.
- Data archiving, audit trail, e-signatures, and PDF report generation for the EMS are pre-qualified during the cleanroom factory acceptance test.
- The EMS is flexibly designed so that it can be integrated with larger facility systems.
- On-site integration of the EMS with host facility systems is minimal.

The BMS/EMS SCADA system is not limited to cleanroom environmental conditions. Process equipment data can also be monitored and archived by the system.

These savings can rise, if the installer and contractor base requires to travel long distances to the on-site construction site or require to stay in the location for months.

PROCESS EQUIPMENT INTEGRATION

Process equipment such as incubators and freezers are typically installed after the cleanroom is commissioned at the host facility. Time is saved by integrating equipment monitoring into the EMS rather than integration with another system. By pre-wiring and testing signal connections, process equipment monitoring is plug and play. Furthermore, the signal connections are configurable from the user interface to allow for dynamic equipment integration.

Additionally, process equipment connections can be hard-wired or networked to the EMS. Many process connections can be made via hard-wired cord set connections. However, the BMS/EMS SCADA system provides the capability to monitor process equipment across multiple platforms with simple ethernet connections.

CONCLUSION

The all-in-one BMS/EMS SCADA system shortens on-site integration times because the EMS is pre-qualified before being shipped to the ultimate site. The time savings is realized by bypassing third-party environmental monitoring systems and focusing on more extensive commissioning of key EMS components during the cleanroom factory acceptance test. The addition of process equipment monitoring can be added to the EMS to further reduce on-site integration times by pre-wiring signal and data connections tested during the cleanroom factory acceptance test and designed for rapid integration. Prefabricated cleanrooms combined with an integrated BMS/EMS SCADA system provide the delivery timeline to meet the demands of todays increased speed to market in the biopharmaceutical industry.

CITATIONS

The FDA enforces cGMP compliance by requiring an Environmental monitoring system. (https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps)