



EMS

Environmental Monitoring System

Challenge

Regulated life science facilities face an ongoing maintenance dilemma in trying to balance the GMP controls of their Building Management Systems (BMS). Often, facilities have a partially qualified BMS to meet regulatory requirements for monitoring the Critical Quality Attributes (CQA) of the air within their classified spaces.

Solution

The purpose of an Environmental Monitoring System (EMS) is to provide qualified monitoring of direct impact critical data points concerning the air quality in classified areas such as laboratory suites and production areas of a regulated facility. With a properly designed and installed EMS, the BMS system can be deemed an Indirect Impact system. This relieves the facility of the requirement to have their BMS under a Quality Change Management (QCM) system; Engineering Change Management (ECM) is sufficient.

QSPEC's EMS system provides the best features of a pre-packaged option while delivering a uniquely customized system for each client. By leveraging off-the-shelf third-party commercially available software and hardware, QSPEC's solution has the advantages of both software vendor support and ultimate suitability to the client's purpose. Our solution provides proven technologies in a configurable, open-ended and expandable system.

Results

Facilities realize substantial life cycle cost savings, as costs associated with each change under QCM are many times higher than an identical change under ECM.

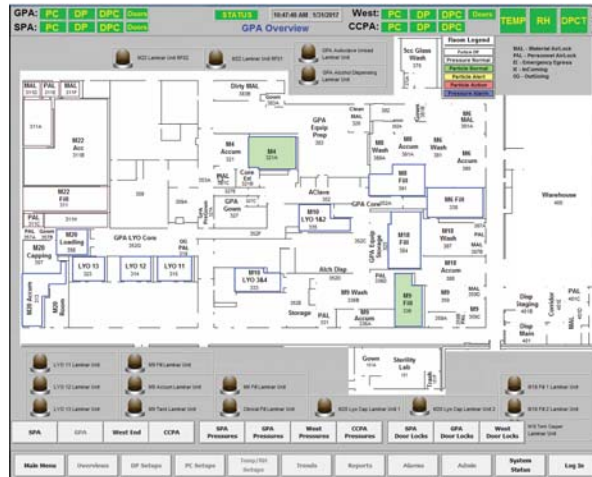
Systems are completely tailored to client needs.

The reliability and consistency of a QSPEC EMS system saves our clients considerable time in production while allowing for expansion and assisting in quality control.

EMS Architecture and Options

QSPEC's EMS System provides the best features of a pre-packaged option while delivering a uniquely customized system for each client. By leveraging off-the-shelf third-party commercially available software and hardware, QSPEC's solution has the advantages of both software vendor support and ultimate suitability to the client's purpose. Our solution provides proven technologies in a configurable, open-ended and expandable system.

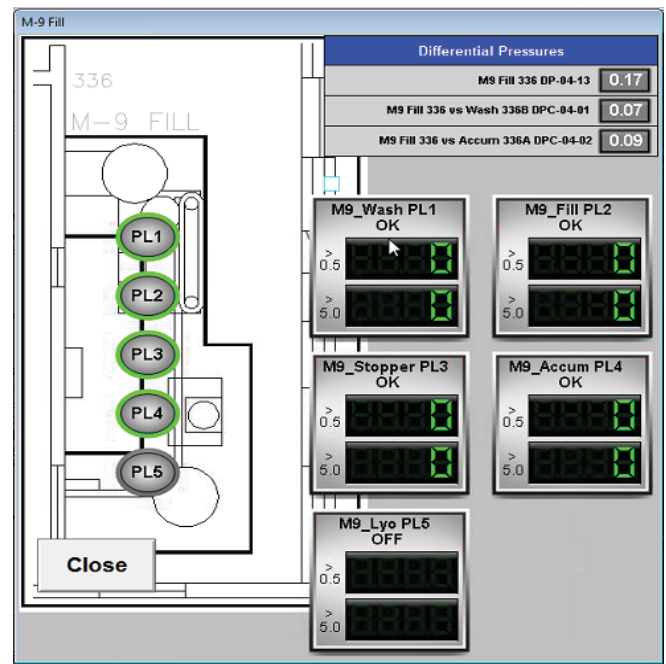
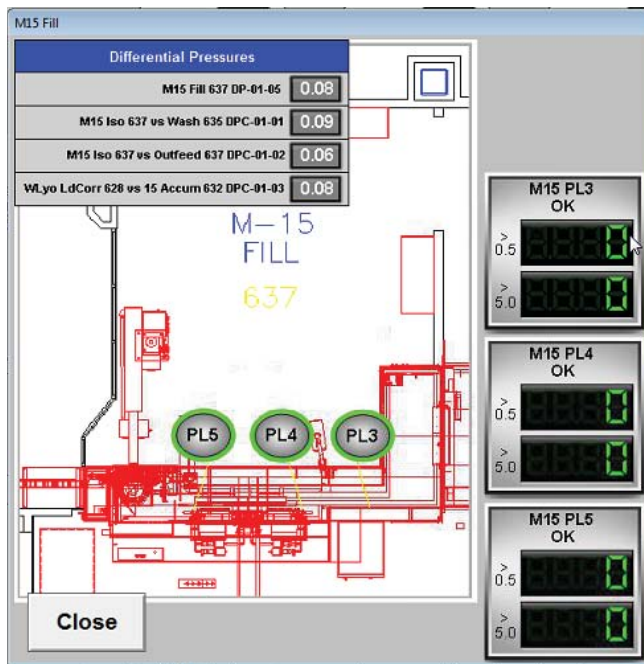
A typical example of the QSPEC EMS system configuration includes one or more control enclosures with Rockwell Logix PACs supporting both local and remote I/O, one or more standalone panel mount computers with HMI functions utilizing Wonderware's InTouch Process Visualization software, and a server running the historian and having WIN 911 Alarm Annunciation software installed and configured. This configuration is scalable and can be sized to control and/or monitor any number of instruments and/or enclosures.



The PACs monitor the various sensors and control alarm lights and horns based on alarm set points defined by the users. Live sensor data is recorded through a fault tolerant connection to the historian server. Custom-designed reports are generated to display collected data on maximum, minimum, and average values and alarms for particulate counts and room pressures, and on user interaction with the system.



An EMS SCADA system, often Wonderware's System Platform software suite, will usually be the main repository for long term data storage and the tool for real time data viewing of qualified environmental data. The EMS System is 21 CFR Part 11 compliant. The SCADA System has graphics to depict the various production suites and the associated alarms. The system is configured to allow the operator to enable batch monitoring for each suite independently by entering a batch number against which to track the suite's activity.



A reporting system is provided to allow client personnel to view and print EMS reports. QSPEC typically provides three reports of qualified EMS data. Reports provided include a Production Batch report, a Production Room report and an Audit Trail report. The Production Batch report will use the operator-entered batch number for EMS monitoring of a room to aggregate the report across multiple production suites. The Production Room report will provide EMS Data for a specific room across a specific time frame.

Environmental Monitoring Systems usually include alert and action level alarms, live and historical trending, and web-based reporting. Other options may be included for door interlocks, stack lights, and “map views” of the system.

QSPEC Solutions works with our client to develop a Functional Design Specification for the EMS system that meets their unique requirements. The FDS defines the control sequences, the InTouch display and data entry, data collection and storage functions, alarms and events and other pertinent information necessary to meet the client’s user requirements. QSPEC Solutions documents all details associated with the functions described. Software design architectures are identified and documented.

QSPEC Solutions custom programs and tailors the system based upon client needs and goals. We specify and procure instrumentation, field devices, enclosures, and all hardware and software for the EMS system. QSPEC develops all project documentation, including Functional Requirements and Detailed Design Specifications, test protocols and drawings. We program the PAC, create and configure clear and concise HMI screens, create trends and reports and assist with overall system validation. We provide training as necessary to ensure that our clients have full understanding and can utilize the capabilities of their new system completely.

Critical Quality Attributes that are commonly monitored include:

**Differential Pressures
Particulate Counts
Temperature
Relative Humidity
Air Flow Rates**