# **Cleanrooms & Regulated Manufacturing**

Pharmaceutical Manufacturing & Storage Medical Devices · High Tech Manufacturing

### **Increase Uptime, Quality, and Efficiency**

Your process demands precise environmental monitoring. From temperature and humidity to air pressure, flow, and containment, our system delivers unprecedented precision and access to data in laboratories and manufacturing environments.

#### Compliance is part of the job

When it comes to life science and medical device manufacturing and laboratory environments, our team is comprised of experts in cGMP, ISO, USP and laboratory requirements and regulations. We work with your team to implement and maintain the optimum monitoring solution for your facility.







Temperature



Velocity



Door Sensor



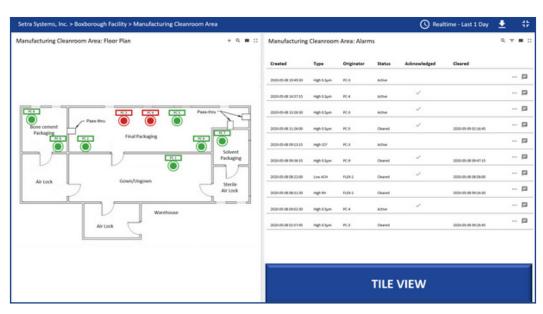
Particle Sensing



Humidity

Easily monitor the environment in cleanrooms with one system that is connected to your existing network, accessible remotely, and easily scalable up to thousands of monitored locations.

CEMS software provides alarming, real-time trend data, and reports for compliance with ISO Certifications and GxP regulations. Integration and installation of a monitoring system is fast and easy with Setra's industry leading sensors that monitor temperature, relative humidity, particle count,  $CO_2$ , differential pressure, air velocity, door contact, and more.





#### **CEMS Cleanroom Application Features**

**Continuous Monitoring** of Temp, RH, ACH, Diff. Pressure, Particulate Count, Door Status, CO<sub>2</sub>, and many more parameters.

Meet regulatory requirements contained in FDA 21 CFR Part 11, EU Annex 11, and ISO 14644.

**Enterprise wide** facility monitoring all within the same system for distributed access which is easily restricted to individuals on a 'need to know' basis".

**Alarm notifications** issued in real-time via SMS / Email with the ability to customize escalation levels. **Maps and floor plans** provide a quick overall snapshot of facility status.

Data integrity ensured through secure hosting in the SetraCLOUD or an on-premises installation.

**Easy to deploy and use** by connecting CEMS software and associated measurement sensing hardware to an existing network via Ethernet, WiFi or Cellular.

Web-based user interface allows for access to secure CEMS software from anywhere, at anytime.



## Have a question?



Talk to a Setra representative today about your project needs.

**\$ 800.257.3872** 

