CAS DATALOGGERS

Complete Cleanroom Environmental Monitoring Solution in a Single System

Send Your Data to the Cloud for a Hassle-Free Audit

Whether you're a Quality Engineer, Pharmaceutical Microbiologist or hospital staffer, proving cleanroom sterilization and decontamination is critical for both open and closed processes. Defining your monitoring points, sampling frequency, and documenting the results must all be part of your cleanroom environmental monitoring plan. However, when performed manually, a high frequency of cleanroom measurements only lead to more contamination through human activity. To avoid this, automated monitoring is the preferred solution.

Accsense Monitoring systems are ideal to monitor filling machine cleanrooms, ISO 5 product fill cleanrooms, test sample incubation, non-sterile manufacturing, and more. Accsense is a complete cleanroom validation solution that automatically records, monitors and provides display of your environmental data.

Monitor, Alarm and Validate with Accsense! Our automated systems make it easy to show your best practices to inspectors during cleanroom audits.

Automated Environmental Monitoring

Microbiological environmental monitoring guidelines are in place to protect product from contaminants and to ensure that no out of tolerance excursions ocurr. To pass an audit and to show quality by design (QbD), all your **methodology** must be validated!

While settle plates are commonly used to get a basic idea of contamination levels, they're nowhere near accurate enough for audit purposes. Rather, they are only a supplemental tool which cannot by itself give an accurate view of microbiological contamination. Cleanroom environmental monitoring should still take place during settle plate exposure periods. For this reason Accsense Monitoring is the choice of many pharmaceutical cleanrooms and healthcare organizations.

Cleanrooms require both air and surface monitoring to achieve sterilization/decontamination. Accsense is a reliable and accurate solution for continuous monitoring of samples and environments. Accsense monitors preparation areas, corridors, surgery rooms, and more. You can configure Accsense to monitor daily or for each batch (for ISO 5 environments) or weekly (for ISO 7 areas) in gowning rooms and areas peripheral to ISO 5 areas.

Armed with a year's worth of environmental data, you can view detailed trends to ensure that your monitoring regime is effective (and if you can lower the monitoring frequency), or if it needs to be reevaluated for sterility assurance.

Gram-Negative Applications

Automated temperature monitoring is also an effective way to detect specific fungi/bacteria and to oversee operation-dependent regimes. In high-risk cases such as gram-negative bacteria applications, Accsense makes measurements with a high accuracy to address the main risk of losing sterility through microbiological contamination.

Accsense Monitoring can also accommodate different monitoring frequencies for different cleanroom types. Sampling rate should be high, for example a reading taken at each batch filling, at defined intervals, and after sanitization of isolation & sterile areas.

Accsense systems also feature wireless communication, giving you the ability to remotely monitor data in real-time. Wireless environmental monitoring is especially useful in maintaining Grade A cleanrooms.

Remote Alarms and Automated phone Alerts

Accsense serves as a reliable foundation of cleanroom risk assessment strategies, giving staff time to take corrective/preventative actions before product and/or sterility is lost. Meanwhile, these smart systems are also effective for out of specification (OOS) and out of limit (OOL) investigations—find out why alarms went off before they happen again!

Accsense also features remote alerting capability, with sequential call lists that can dial each number until the alarm is acknowledged! This is especially useful in gram-negative bacteria areas which generally have a higher risk and require immediate corrective action.

Prove Your Best Practices with Trends

Historical data is critical to validating your environmental monitoring plan. Trending the data over time is also a useful risk management tool. Accsense also helps you to view out of tolerance data (OOT) for risk management. The collected data has many uses, for example as an easily-accessible documentation and validation for audits.

Trend documentation and examination includes microflora evaluation, especially to check for resistant strains as part of good manufacturing practice (GMP) in the FDA and the EU. As an example, Accsense can significantly help to achieve this by monitoring and trending the room's temperature data over time.

For further information on our Accsense Monitoring systems, cleanroom environmental monitoring or to find the ideal solution for your application-specific needs, contact a CAS DataLogger Application Specialist at **(800) 956-4437** or www.DataLoggerInc.com.