THE CHALLENGES OF GMP-COMPLIANT PARTICLE MONITORING

The life science industry is one of the most highly regulated and requires companies to comply with all applicable laws in order to survive. As a result, unnecessarily high costs often arise over the entire life cycle. The challenges lie in optimizing these costs over the whole life of a clean room, while at the same time complying with all regulations.

Reliable capture of all quality-relevant parameters is an essential part of the rules of Good Manufacturing Practice (GMP). An autonomous monitoring system can make life easier by minimizing costs and maximizing competitive strength. However, regardless of the size or number of data points captured, this system must be validated in compliance with all GMP

requirements and on a project-specific basis.

In clean rooms, environmental conditions have an important impact on product quality. All systems that lead to quality-relevant decisions must be validated according to EU or FDA GMP guidelines. To avoid validating the entire control functionality of ventilation systems, there is an increasing tendency to use independent monitoring systems.

Particle counter readings are an add-on to the extensive reports of environmental conditions and to supply proof of clean room compliance during production in accordance with the clean room's classification based on number and size of particles per air volume.

Challenges of particle counters

A number of different particle counters, which must meet applicable regulations, exist for a wide range of clean room environments. Permanently installed particle counters guarantee continuous monitoring, are very close to the process and are connected to an Environmental Monitoring System (EMS) in order to issue alarms when deviations from the preset parameters occur. Portable particle counters work just like permanently mounted devices, but offer greater flexibility and can be used anywhere.

The challenge of particle counters is not only to select the right device but also to place the particle counter in the right location. If different systems are installed in the clean room, all systems must be validated and trained separately. However, this process can be made easier by integrating the different systems into a single one.

Proof of compliance

To provide measured proof that a clean room meets the applicable regulations, all process-relevant parameters must be monitored and documented. Siemens offers a solution for the standardized integration of particle counters into the Environmental Monitoring System (EMS) in order to provide this proof of compliance easily and conveniently. Integrating particle counters into the EMS guarantees clean room compliance and facilitates extensive reporting on the clean room status during the production process. The instantaneous values of the particle counter are displayed online in the EMS and permit early intervention in the production process in the event of particle contamination. The Siemens solution records all values and alarms relating to critical particle counter readings; as required, this information is archived in a central database together with other process-related parameters.

Maximum safety through automatic alarms

A central function of the EMS is to provide automatic alarms in the event of a malfunction. Alarms are automatically logged and forwarded to the correct recipient, depending on time, priority and/or installation type.

The advantages are clear:

- Ability to immediately intervene in the production process by detecting particle contamination in real time and forwarding this information without delay to the management station.
- Improved diagnostics in order to identify anomalies in the environmental conditions, such as open doors or faulty filters.

One unit for all necessary functionalities

Compact Monitoring Technology (CMT) by Siemens is a tested system solution that combines all required functionalities, such as temperature, relative humidity, differential pressure and particle counts, into one compact unit. Other critical quality attributes can also be integrated into the CMT.

The series-produced solution is delivered pre-manufactured, pre-configured and pre-tested, minimizing the installation work required to precisely customize the system. It therefore substantially simplifies compliance with regulatory requirements and greatly reduces the time, money and risk involved in validating the monitoring system.

Like a "tachograph" in a commercial vehicle, CMT reliably records critical parameters, prevents tampering and makes the data available over the long term.

CMT is based on the Siemens Desigo building automation system. All components needed for the validated recording of data are located in a pre-configured cabinet, including an industrial PC on which the entire operating software is installed, as well as an audit trail for logging all modifications to the system.

The system is operated either from a built-in touch panel, a separate monitor with a keyboard and mouse, or with a remote connection over the network.

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