

Industry Sector Building Technologies Division

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Siemens launches a monitoring solution for the life science industry

The Siemens Building Technologies Division presents an innovative monitoring system for the life science industry with the Compact Monitoring Technology (CMT). The solution monitors and records all relevant measurement values and thus provides observation and constant documentation of environmental conditions in clean rooms, laboratories and research facilities in compliance with GMP standards (Good Manufacturing Practice). The key: CMT is completely pre-configured and can be adapted to the specific requirements with little effort, which vastly simplifies compliance with regulations. Reliable operation and data security is given highest priority. During the development phase, special emphasis was also put on scalability and flexibility when in use.

Siemens has developed an innovative monitoring system with the Compact Monitoring Technology that is particularly advantageous for small systems. The solution is completely pre-configured, which minimizes the effort necessary to adapt it to the specific requirements of the operator and its production environment. Thus not only compliance with regulations is vastly simplified, but also the commissioning is completed almost instantly. With the CMT, all critical environmental condition variables are permanently and reliably recorded in a compact system. CMT prevent possible manipulations and all recorded data are available long-term. The system in its compact box (100x80x30 cm; LxHxW) enables temperature, moisture and differential pressure measurements and allows recording of particle counter data.

The special feature of the solution is in its assembly. Based on the Desigo building automation system, the CMT is a compact series product that contains all elements that are required for validated data recording. It comprises an industry PC on which the entire operational software is installed, as well as an audit trail to record all modifications to the system. An MS-SQL database provides reliable storage of sensitive data in compliance with 21 CFR Part 11.

Flexibly adjustable to customer requirements

The new monitoring system remains flexible and scalable at the same time, meaning that it can be expanded according to special customer requirements at any time. Thus, according to requirement, various additional measurement values can be monitored. CMT grows with the customers' demands. The standard equipped solution has 32 I/O-channels, but this can be expanded to the technical limits of the Desigo system with several thousands of channels if required. The creation of graphics appropriate to the situation, such as floor plans, is just as possible as individually adjusting the alarm forwarding. The user can also easily adjust the integrated report templates and report creation routines to their needs.

Control of the CMT is either carried out using the Touch Panel, a separate monitor with a keyboard and mouse, or online using a web browser. The user can intuitively access all channels and view or print out thorough reports about all parameters.

In order to guarantee the system's validated status throughout the whole life cycle, the solution is completed by an extensive service programme. This means that the CMT is a homogeneous, complete solution that combines the most modern building management technology with the know how for qualification, validation and flexible monitoring systems.

Operation and data security are given highest priority

The entire data security, backup function and access control settings fully comply with the requirements of 21 CFR Part 11 and Annex 11 of the "Good Manufacturing Practice" guideline (GMP) of the European Union. Amongst the security features are proven industrial electronics, designed for continuous operation, and professional security solutions specially developed for GMP applications, that have been analyzed in various audits. All critical components are continuously monitored and are fitted with comprehensive alarm functions. And last but not least, locally saved data is automatically backed up on an external hard drive.

CMT's access control system that prevents unauthorized changes shows that the security of applications and data is given highest priority. Furthermore, the uninterruptable electricity supply that equalizes interference in the power supply contributes to making the 7x24 operation reliable. CMT is being intensively tested as a type-tested device combination and has a CE identification label. The system is also based on the Desigo building automation platform, the applications of which are documented as validated with regular pharmaceutical audits. CMT automatically monitors the calibration intervals of the individual control points and proactively creates maintenance and re-calibration alarms.

As a GMP monitoring system, CMT has to be validated according to cGMP guidelines specific to each project. The entire validation documentation based on GAMP 5 is already available.

The life science industry's requirements were the focus for the development of the CMT. Thus, the system is pre-destined for use in the development, production and storage of medication for

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example. The solution can be just as easily used in hospitals, laboratories and clean rooms as in blood banks, in the development and manufacture of food stuffs or in university research facilities. CMT, with its compact dimensions and high flexibility, is also suitable for all areas of use in which simple and safe monitoring, saving, archiving and presentation of environmental conditions and other variables are required.

Background information: Measures for uniform environmental conditions

Environmental conditions in production processes, clean rooms, laboratories and research facilities that are influenced by ventilation technology systems have a considerable effect on product quality. European and American authorities therefore define measures that can be implemented to protect public health and security in these facilities. These measures require documented proof that temperature, humidity, air pressure and particle measurements are recorded and saved so that they cannot be manipulated. In order to fulfill these requirements, the entire control and regulation of the ventilation technology systems has been validated so far.

With the GAMP 5's risk based approach, special emphasis is now being placed on a more economical validation. There is an increasing trend towards an independent monitoring system that records these environmental parameters. In accordance with the valid guidelines of the life science industry, only those parameters of a system that are rated as actually GxP relevant by an influence analysis must be validated. This creates a considerable reduction in costs for the monitoring system and its validation.

Further information about Compact Monitoring Technology (CMT) can be found at www.siemens.com/cmt; information about Siemens' involvement in the life science industry is available at www.siemens.com/lifescience.

Picture caption:

The preconfigured Compact Monitoring Technology (CMT) from the Siemens Building Technologies Division is particularly suitable for small systems in the life science industry.

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The **Siemens Building Technologies Division** (Zug, Switzerland) is the world's leading provider of energy efficient, safe and secure solutions for buildings („Green Buildings“) and building infrastructure. As a service provider, system integrator and product supplier Building Technologies offers building automation, HVAC, fire protection, electronic safety, electrical installation engineering and low voltage power distribution. With around 36,000 employees worldwide (September 30), Building Technologies achieved a turnover of €5.9 billion in fiscal year 2009.

www.siemens.com/buildingtechnologies