GMP Monitoring System for Rooms and Processes

Environment Monitoring System

User-friendly GMP Monitoring System for monitoring, trend recording, alarming and logging GMP-critical values. It is possible to collect and record different physical measured variables such as temperature, pressure, humidity, airflow and number of particles.

The system is implemented in compliance with FDA 21 CFR Part 11 regulations.

The scope of supply consists of the turnkey version including qualification testing in accordance with GAMP4 comprising qualification testing stages DQ, IQ and OQ. Thanks to the modular structure and extensibility of the components used, it is also possible to integrate measuring points from existing systems made by third-party manufacturers. Deploying future-oriented Web technology yields a system that meets any requirements of operation and extensibility.

**Clear operation**
- Simple, intuitive system handling
- Little time and effort needed for support
- Clear signaling of limit value violations
- Easy analysis of historical measured value records

**Facts**
- Realtime
- Alarming
- Reports
- Trend Representation
- Audit Trail
- Remote Alarming
- Web Access
- Remote Access
- Interfaces
- Data Backup
- Link to IT network
The User Interface

Display of the Sensor Measured Values
Depending on the size of the building to be monitored and the number of sensors, operators use the main screen to get to the story or room view. This view shows a floor plan of the room with all the measuring points and possible alarms.

Detailed Information for Each of the Sensors
With just a mouse click, you get from the floor plan with the displayed measured value to the detailed information of the corresponding sensor. The relevant settings in addition to the individual trend and the entry in the alarm list are available as information for the analysis. With appropriate authorization, it is possible to customize the settings of each individual sensor on a user-defined basis.

Recording the Data
All the measured values are recorded as trends. In this connection, it is possible to group trend diagrams in accordance with a functional grouping. Authorized users can generate their own individual user-defined trend configurations from the recorded values at any time. You can print out diagrams for a time range that can be defined in any way you like.

Monitoring and Alarming
You can set any alarm limit values you like for each measured value. If an alarm limit value is exceeded for longer than a freely selectable time, the system triggers an alarm. All alarms are listed in the alarm list. Authorized users can acknowledge alarms and add comments on them. In a similar way to trends, the alarm list also includes a History function that allows you to view previous alarms.

The operation of the monitoring’s user interface is adapted to Windows standards.
Data Conditioning / Reporting System
The system offers a wide range of functionality for data conditioning and reporting in various representations. The GMP Monitoring System makes possible the following reports:
- Trend report configuration
- Alarm and audit trails
- Disturbance reporting statistics
- Delimited file export of GMP data for offline analysis

Web Access to GMP Monitoring
Using Internet Explorer, authorized client stations have Web access to the functionality of GMP Monitoring at any time.

Turnkey project supply as total contractor:
- User requirements analysis
- Planning and realization
- Installation & start-up
- Qualification and training