Monitoring System
For clean rooms, pharmacies, refrigerators and stock areas as well as other applications
A flexible approach ...

Recording, monitoring, storage and analysis of quality relevant measuring data:
- FDA Rule 21 CFR Part 11 compliance
- GAMP project expertise
- Data synchronization for maximum data security
- Monitoring and trending with full traceability of alarms, events and user actions
- Service package for regular maintenance of software and equipment
- Modular, scalable and expandable

Application: Clean room monitoring
Clean rooms are a pre-condition in the pharmaceutical industry for the production and storage of high-purity active substances as well as modern sterile pharmaceutical forms. A contamination of the substances to be processed must be avoided by all means so as not to jeopardise human health on their intake or utilization. For this reason, clean rooms are subject to very high constructive and operational safety requirements.

On one hand, contamination must be avoided. On the other hand, purity and quality parameters, such as particle number, temperature, humidity, air flow and compliance of compression phases must be measured, registered and verified. For this purpose, monitoring systems are used that must be validated according to European Union GMP guidelines.

Available Modules

- **Level 1: Memograph M with Field Data Manager (FDM) Software**
  A paperless chart recorder with analog and digital I/Os and Field Data Manager software, Memograph M collects information from the connected sensing elements. 21 CFR part 11 compliant, it may be used as stand-alone or integrated into a larger system.

- **Level 2: Qualification**
  Creation of necessary documents: user requirement specification, project management plan, qualification plan, functional specification, risk analysis, traceability matrix, design specifications as well as testing of software, FAT, IQ and OQ. Support for PQ and training with creation of test certificates.

- **Level 3: SCADA Software**
  SCADA package with visualization of the rooms, measured value recording and archiving, data comparison between Memograph and SCADA system, reporting, alarming and trends, User Management and Audit Trail.

- **Level 4: Web-based Solution**
  Connection of web-based client to SCADA software. Allows user-managed access to the visualization from anywhere in the company network by means of a Web browser.

- **Level 5: Customized Solution**
  Adaptation of the standard package to a specific customer requirements, e.g. server virtualization, customized reporting formats, customized alarm concept, customized Category 5 software modules.
to your monitoring tasks

Our offering:
Endress+Hauser can provide the whole monitoring system, incorporate sensors from your favored suppliers or simply add a monitoring system to existing equipment. In each case it offers a fully documented process according to GAMP 5.

Start Page
The start page comprises an overview of monitored rooms and measuring points. Red areas indicate alarms, green areas show normal operation.

Room Layout Views
Here, measured values and status of all measuring points within the location are shown. Normally the following parameters are monitored: particle concentration, vacuum monitoring, pressure, temperature, humidity, air flow and whether the doors are open or closed.

Process Point Detail
A click on a process point shows a detailed view in which the set limits and other parameters can be seen. Up to four limits can be set for each process point in the clean room, each with configurable delay and priority level. With appropriate user access rights, the view can also be used to change parameters.

Alarming
The alarm log is integrated into the room layout or is available as a separate page. With the appropriate user access rights, the alarms can be acknowledged after entry of a comment. The alarms, time stamps and comments are then available as separate reports or in the audit trail. Additionally, alarms can be forwarded via SMS and e-mail.

Trending
A historical database allows trending of the measured values at each process point. The trend view is configurable and can be viewed according to several time filters. With the appropriate user access rights, the comments can be made at any point in the trend, the entries being available as separate reports or in the audit trail.

Reporting
Various reporting functions including trends and value lists are available. The reports are generated, checked and approved with electronic signature verification.

Data Synchronization
A special algorithm allows at least two weeks data to be automatically uploaded from the Memograph M to the system, ensuring that there are no data gaps due to e.g. the server not being available during maintenance.

Audit Trail
All alarms, events and user interactions with the system are visible in the audit trail, so that any circumstance that might affect product quality is traceable to an event, date and time.

User Management
The user management system assigns rights according to role and department. Password management is controlled by Windows Security / Domain Controller.
Additional applications

Storage Area Monitoring
The clean room monitoring system is easily adaptable to storage area and refrigeration monitoring. The same qualification requirements apply, but in general temperature, particularly mean kinetic annual temperature (MKT) and humidity are monitored.

Monitoring for pharmacies and hospitals
Module Level 1 is engineered to fit the requirements of pharmacies and hospitals.

Supplementary Documentation

- Life Science Industries
  Industry Brochure - SO00201B/29/ae

- From Concept to Commissioning
  Competence Brochure - CP00002S/04/en

- Clean Room Monitoring
  Case Study - CS00002S/04/en

- Recorders and data acquisition technology
  Field of Activities - FA00014R/09/en