Data handling. Focus on electronic records and electronic signature.

Data integrity supported by 21CFR Part11 compliant software.

Memobase Plus, Raman RunTime™, Memograph and Field Data Manager are the "tools" that supports the veracity and traceability of your daily work processes in both GxP and non-GxP environments

More information:
Multichannel, multiparameter software Memobase Plus CYZ71D
www.nl.endress.com/CYZ71D

Memograph M RSG45
Advanced Data Manager
www.nl.endress.com/RSG45

Field Data Manager Software
www.nl.endress.com/MS20

Raman spectroscopic analyzers
https://eh.digital/3ykBHoe

Data integrity based on ALCOA+ principles
https://eh.digital/3OYsGXS

www.nl.endress.com

The primary goals of current good manufacturing practices (cGMP) are on one hand to minimize product quality risks and to protect patient safety on the other. cGMP have to do with design, implementation and data handling. Both United States and European Union government agencies expect accurate and reliable data.

GMP regulations have been in place for more than fifty years. In 1978, computers, electronic systems and automated equipment were added.

In 1997 the Code of Federal Regulation (CFR) Title 21 Part 11 as law came into live. In the content of this regulation is defined the concept of ER (Electronics Records) and ES (Electronic Signatures). ERs are considered equal to a paper record and ESs are considered equal to the traditional handwritten signature.

Data security in the GMP environment is not only focused on production data or batch records but also labs and distribution; properly implemented **leads to Compliance**.

Each user of the system must have a unique ID and access code that cannot be share with any other users. Users must be trained in the CFR21 Part11 system and they must know the implications of its use. The responsibility always lies with the user because the system only supports a work process, data accuracy is always guaranteed by the people.

Endress+Hauser
People for Process Automation

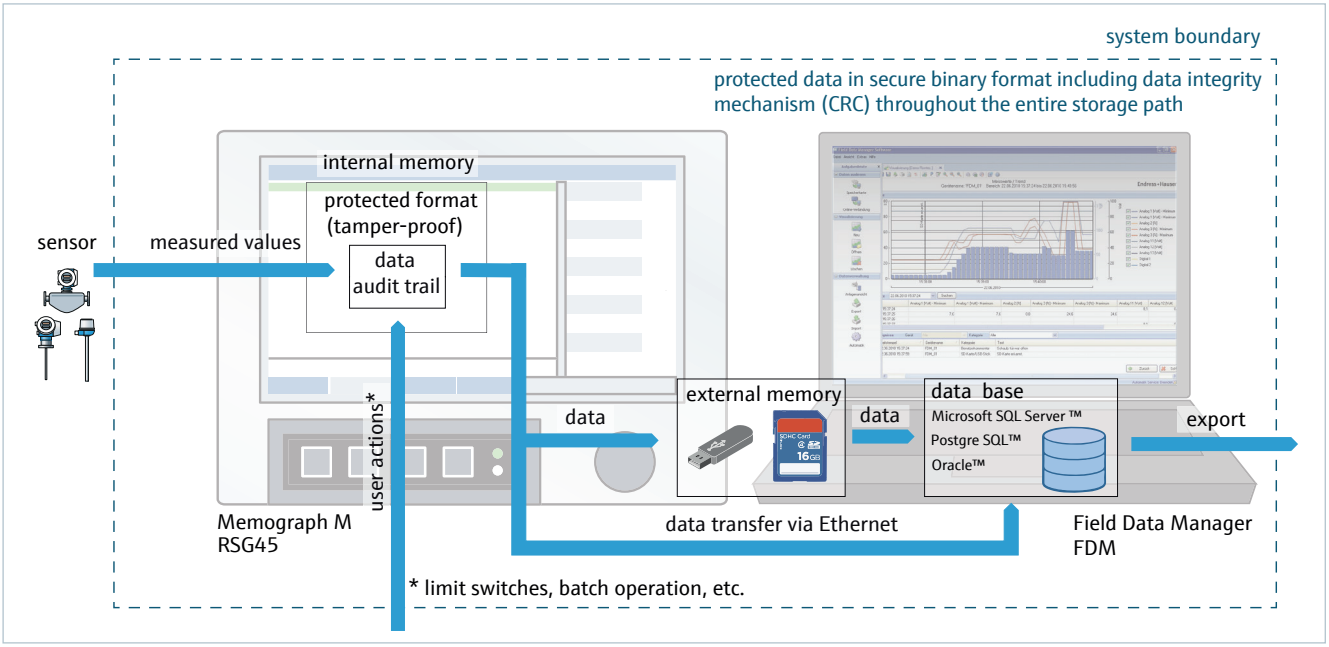

Fig. (1) System acrhitecture and data flow

The audit trail is a fundamental function that the software must meet. The audit trail has to be available and demonstrable to government agencies at any time. The document stores all actions of each user, complete with username and timestamp of each action. What, who, when and why (change justification) are always stored and made available to show traceability of the entire process. The editing or modification of settings, configuration data at the system are recorded.

Emphasis on technology in operations and calibrations

PAT: pH, conductivity and, oxygen

The pH, conductivity and oxygen Memosens sensors from Endress+Hauser can be calibrated with the use of **Memobase Plus** software. The software supports the complete life-cycle of each sensor because it is FDA CFR21 Part 11 ready. In the latest software release, to improve the laboratories calibration work process, an additional Measuring Range Indicator functionality has been added. The **Measuring Range Indicator** provides the ability to store or export the values, which remain within the measuring range of the sensor and which comply with good laboratory practice (GLP) regulations. Sensors outside of measurement range cannot be recalibrated or reused.

The **calibration timer** ensures that the sensor cannot be used longer than the predefined adjustment time. If it happens, no value can be saved or exported.

In both cases, outside GLP measuring range or above adjustment time, the sensors are deactivated immediately. The deactivation is software-based and takes place in the chip installed in the Memosens head. This means that the status of the deactivated sensor is recognized by any Memobase Plus system or Liquiline process transmitter or Mobile handheld.

PAT: Endress+Hauser Raman technology

Raman RunTime™ is the embedded control technology for Raman Rxn™ analyzer systems. It offers a user-friendly, common interface from process development to cGMP. By connecting to leading PAT platforms like synTQ, SIMATIC SIPAT, or DeltaV™ Spectral PAT, our Raman RunTime™ software supports 21 CFR Part 11 / GMP compliance. By enabling continuous in-line process measurement and understanding, Raman RunTime™ empowers companies to optimize, adapt, and control their processes. This capability makes Raman a practical tool for PAT and aligns with the principles of QbD by allowing companies to achieve greater real-time quality assurance and better risk management.

Data over data

Increasingly, there is talk of meta data that is called "data over data". This is the information needed to get a better understanding of the data. A value without meta data has no value! Measurements, time stamp, operator/scientist userID, instrument usage, sensorID, sensor calibration certificate, audit trails.... these are all examples of metadata. Metadata is important not only in the validated environment but also in the non-validated environment. In labs in the research phase and sometimes in the small-scale development phase, data is still recorded manually. This means that the scientists or operator have to walk to the production environment every time to read the data via displays and fetch the data manually. In the office, the data is then copied into electronic format, integrated with data from different sources and then analyzed. Endress+Hauser has produced a specific version for the life sciences data safety recorder **Memograph RSG45** to perform the data and meta data recording work process and to avoid the risk of mistakes during data entering. This version has a stainless steel front with touch screen, features that offer trouble-free operation in a hygienic and regulated environment.

If desired to integrate the recorder into an overhead system, the Memograph offers the broadest portfolio of communication protocols herein such as Modbus, Profibus DP, Profinet and EtherNet/IP. In addition, the Memograph comes with specific Installation Qualification (IQ), Operational Qualification (OQ) documentation and software backup capabilities with the possibility to define your own archiving concept.

To access the Memograph remotely at any time, there is the integrated web server. Every time the process flow needs to be checked, you can have direct access to the Memograph thanks to the web browser. This provides access to current and historical process data as well as loading and saving device settings and firmware updates.

The functionalities, from visualization to modification, are secured at different levels username and access code. Historical and real-time data can be visualized via **Field Data Manager software** (FDM). The measured values, the graphs and the analyses are exported in a secure database that is not manipulable.

Memograph recorder software and FDM management software comply both with the above mentioned CFR21 Part 11 regulations and with the **ALCOA/ALCOA+** principles.
The Endress+Hauser data logging system, which consists of the Memograph M RSG45 Data Manager and Field Data Manager (FDM) analysis software, was designed specifically for users in the life sciences industry based on the "Quality by Design" (QbD) concept. With Its internal system functions and product features, it can fully meet the requirements based on the ALOCA/ ALCOA+ principles. Compliance with the ALCOA/ALCOA+ principles is demonstrated by linking the ALCOA/ ALCOA+ attributes to functions and capabilities within the system and describing how data are handled internally throughout the complete data life cycle. This serves as a valuable guidance to users in the life sciences when selecting, evaluating and also validating and verifying this data logging system and its application in customer processes Users receive an innovative, automated system for recording and documenting their quality-related data, which enables them to meet the legal requirements and the requirements of regulatory bodies and associations.

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