FDA Compliant Measurement Data Acquisition Using Message Systems

- **Delphin hardware and software products comply with the requirements of FDA 21CFR11**
- **Delphin products fulfill the strictest requirements concerning data security and reliability**
- **Delphin's Audit trail function tracks process intervention**

Requirements for FDA compliant measurement data acquisition

Modern paperless measurement data acquisition systems such as Delphin Message devices have now virtually replaced all traditional line-writers in the chemical and pharmaceutical industries. Such systems are being used in applications ranging from production monitoring systems through to laboratory data acquisition for research and development purposes.

The FDA (Food & Drug Administration) formulated regulations for the US market. Companies involved in electronic data acquisition are bound by these regulations. Although the regulations only have jurisdiction over US companies and their suppliers, their international significance should not be underestimated.

FDA 21 CFR Part 11 provides the regulations under which the FDA will accept electronic data recording as a replacement for printed documentation. The major focus here is on documented verification, an essential feature in validation.

Delphin's Message systems and Mhouse-Software conform to FDA 21 CFR Part 11. Mhouse-Software is supplied with an operation protocol (Audit trail) which securely records all relevant user intervention. Each action is recorded and saved with date, time, user name and event text.

Integrated data storage capability means Message systems fulfill the strictest requirements regarding data security and reliability.

Delphin's Message systems are equipped to validate the entire plant. Installation Qualification (IQ) and Operational Qualification (OQ) documents can also be provided by Delphin. Installation Qualification is documented proof that the system has been supplied and installed according to both user and statutory requirements. Operation Qualification documents the requirements for the entire operation within pre-determined limits.

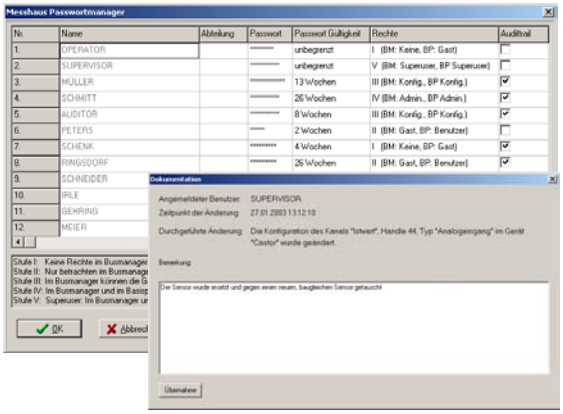
Delphin provides support to its customers from the planning of the installation through to its start-up. This includes any training requirements.

FDA relevant features in Delphin Message systems

- Hardware and software security via user management
- Audit trail function can be switched off for system set up
- Action protocols stored in various files
- Audit trail stored as an encrypted, non-manipulable file
- Audit trail testable for integrity and manipulation

Security features and functions

- User set up and management
- Allocation of user rights for specific functions
- Compulsory, periodic password change



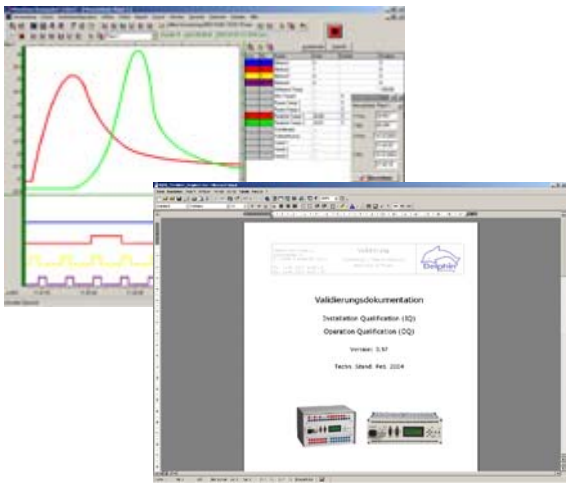
Further features in TopMessage and TopLab devices

TopMessage and TopLab devices are equipped with an Ethernet interface and are therefore easy to integrate in any existing company network. Up to 30 analog inputs are available in each device. Additional devices can be attached to a master device. I/O modules are available for virtually any processing signal including the acquisition of vibration data.

Each analog input can be individually configured for current, voltage, thermocouple or RTD measurement.

Delphin Service

As well as the requirements on hardware and software in validation applications, individual customer support is also very important.
A professional approach does not just include audit capability but also qualification documentation. This documentation deals extensively with the start up and subsequent operation of the installation.



Delphin measurement data acquisition systems have already been validated by many well known chemical and pharmaceutical companies.

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