

## **FDA - 21 CFR Part 11**

**(For reference only)**

### ◆ **What is 21 CFR Part 11?**

Sectoin 21 of the Code of Federal Regulations (CFR) is a part of the laws and regulations passed by the government of the United States of America in connection with the Food and Drug Administration (FDA).

In particular, Part 11 deals with "Electronic Records" and the use of "Electronic Signatures", i.e. With the handing of electronically stored data and the required security measures.

### ◆ **What is affected by these regulations?**

All data that are included in GxP inspections and are permanently held on electronic data storage media. Thus all files and data that may be included in an FDA inspection are affected.

Also affected are all electronic signatures that, as computer generated authorisations, represent the legally binding equivalent of handwritten signatures.

### ◆ **Why are these regulations so important?**

In the pharmaceutical industry, paper-based systems are increasingly being replaced by electronic systems and procedures. In order for these data records to be recognised by the FDA as authentic and legally binding in the same way as the former paper-based organisations and processes, the requirements of 21 CFR Part 11 must be fulfilled.

These regulation provide that data records in the pharmaceutical industry may also be handled electronically and regulate the use of electronic signatures in the place of traditional, handwritten signatures.

All pharmaceutical companies who wish to sell their products on the US market and who manage electronic data records and electronic signatures in their production processes together with the associated accountability must meet the requirements of 21 CFR Part 11.

During an inspection by the FDA, the fulfilment of these requirements is actively verified and failure to fulfil them leads to corresponding blocking notes.

### ◆ **Who must fulfil these regulations?**

All companies or manufacturers that market or intend to market their pharmaceutical products in the USA must fulfil these requirements.

### ◆ **What are the possibilities, especially in the area of measuring Techniques and data logging?**

#### **Compliance with 21 CFR Part 11**

- Such compliance means fulfilling requirements that are, above all, organisational but are also partly technical.
- fulfilling organisation requirements means that pharmaceutical companies will set up organisation structures and define, describe and document all processes in order to demonstrate what protective measures are used by the company in order to comply with the regulations and how they are enforced.
- The core of such documentation consists of SOPs (standard operating procedures), which describe and regulate all processes. These describe in detail how the responsible persons are to carry out processes and use systems in order to achieve the required results.
- Fulfilling technical requirements: the fulfilment of technical requirements is based on the use of products that have been adapted by Manufacturers for use in this area.
- This includes the ComSoft according to 21 CFR Part 11 as described here, together with the appropriately approved Testo data loggers.

**Only when suitable technical systems are combined with the appropriate SOPs for the process in question is proper fulfilment of the FDA requirements guaranteed** for the manufacturers of pharmaceutical products for the US market.

### ◆ **SUMMARY :-**

Part 11 - electronic records and electronic signatures, deals with the criteria for regarding electronic data records and signatures as equivalent to paper documents with handwritten signatures. This covers data records that are created, altered, maintained, archived and transmitted.

Such data record can be securely handled in so-called closed systems, i.e. In an environment to which only a controlled group of persons has access. In the software, this access control is implemented by the allocation of usernames and passwords and of special user rights giving or restricting access to various Software functions.

The system used must be validated within its environment in order to ensure that precision, reliability and fitness for purpose are as required. Invalid or altered data record should be identified in good time, either automatically or by suitable validation techniques, and isolated.

Further measures, described to serve to protect established electronic data records against unauthorised access and modifications.

In addition to the actual data record, so-called audit trails are stored, which contain all peripheral information since the start of the system or the creation of a data record.

Every action affecting an electronic data recorded, together with a unique user-ID and date/time.

**It draws special attention to the obligation to keep all persons concerned in the creation, processing and archiving of electronic data records up-to-date with regular training in order to ensure that these persons have the necessary knowledge to use the required systems and procedures correctly.**