

# Electronic Records and Signatures FDA Requirements 21 CFR Part 11

## Electronic Records are

Any combination of text, graphics, audio data or other digital representations of information that can be produced, changed, maintained, archived, or distributed through a computer system (11.3.b.6).

## FDA Requirements

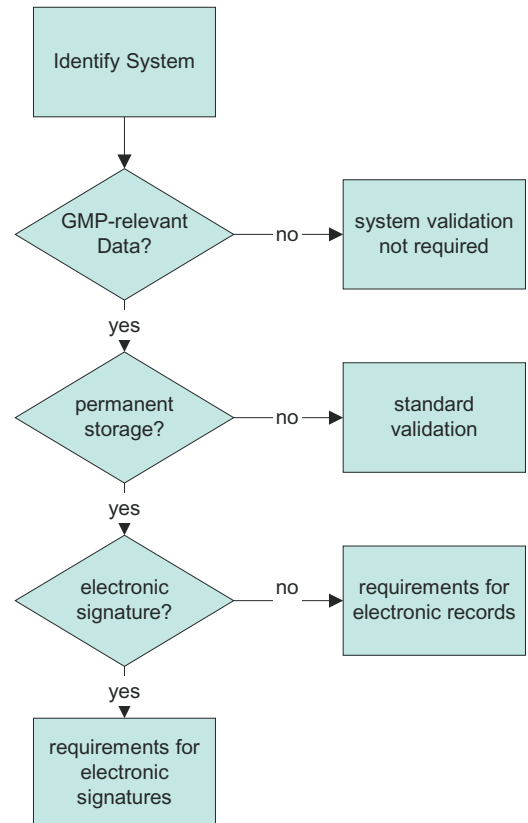
### Major Requirements for Electronic Records and Signatures

- A validated computer system must be used.
- Electronic Records must be printable.
- Access control including authorization concept are essential.
- Formal change control for system changes must be in use.
- If necessary, it must be possible to grant external auditors access to system data and validation documents.
- Full audit trail functionality must be implemented.
- Legacy Systems system must be Part 11 compliant for additional requirements for open systems exists.

### Additional Requirements for electronic signatures

- Responsibilities must be defined and set down (documentation through SOP), for those employees who can / must give electronic signatures.
- Accurate operation of electronic signature systems must be verified at regular intervals.
- Electronic signatures must be securely and inseparably connected to a data set.
- Use of the system must be registered with FDA.
- Electronic signatures are approved for certain documents only.

## Systems Classification



## Offer

Chemgineering will support you in making your systems Part 11 compliant.

- Identification of Systems requiring Part 11 compliance.
- Classification of systems according to Part 11 compliance (checklist).
- Identification of open and closed systems.
- Development of Measurement plans for Part 11 compliance achievement including SOPs.
- Implementation of these measures in your company.

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