

## Proposed additions for the Good Distribution Practice standards

### Computer controlled systems

1. Computerized systems or devices which have software; must be validated.
2. Changing and deletion-recording (audit trail) of GMP relevant records must be categorised and set based on risk assessment. GMP relevant data change and deletion must be documented.
3. Electronic records can be signed with electronic signature and the use of it is allowed in case of:
  - Closed system, where the manual signing has been done within the corporate boundaries.
  - The appropriate record has unchangeable connection.
  - The signature can be clearly connected to the signing person
  - In case of electronic signature the unique user identification must be added (user name, password)
  - The electronic signature must consist who, when, what and what kind of level of authority was it used.