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Med-Info

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21 CFR Part 11

This Med-Info applies to:

- organizations that utilize electronic records in their quality management system
- manufacturers that develop/produce devices for electronic record creation

Background

Title 21 of the Code of Federal Regulations, Part 11 ("21 CFR Part 11") defines legal criteria under which the Food and Drug Administration ("FDA") considers electronic records, electronic signatures, and handwritten signatures executed on electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Ensuring compliance of the electronic records with 21 CFR Part 11 is the responsibility of the organization that utilizes electronic records for the documentation of quality-related product information/data.

The manufacturers that develop/produce devices generating electronic records need to provide the technical means to support 21 CFR Part 11 compliance (as far as applicable to the device).

When is 21 CFR Part 11 applicable to a device?

21 CFR Part 11 applies

- if a device is utilized for generating electronic records for the documentation of quality-related information/ data on products regulated by the FDA (e.g. medical devices, pharmaceutical products, etc.); and
- if the (FDA-regulated) product is to be placed on the United States market.

Which guidances provide support with the interpretation of 21 CFR Part 11 requirements?

The following FDA guidances provide further information on FDA Regulation 21 CFR Part 11:

- "Guidance for Industry: Part 11; Electronic Records; Electronic Signatures – Scope and Application"
- "Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures – Glossary of Terms"
- "Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures – Electronic Copies of Electronic Records"
- "Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures – Validation"
- "Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures Maintenance of Electronic Records"
- "Guidance for Industry: Computerized Systems Used in Clinical Investigations"

What does 21 CFR Part 11 require?

21 CFR Part 11 defines requirements for electronic records and electronic signatures to ensure they are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. 21 CFR Part 11 defines the following major requirements:

1) Controls for closed systems

Major requirements

- Validation of the device/system to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records
- Provision of the ability to generate accurate and complete copies of records in both human readable and electronic form
- Protection of records to enable their accurate and ready retrieval throughout the record's retention period
- Limitation of system access to authorized individuals
- Use of secure, computer-generated, and time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records
- Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate
- Use of authority checks
- Use of device (e.g. terminal) checks

2) Controls for open systems

Major requirements

- Employment of procedures and controls designed to ensure the authenticity, integrity and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such controls shall include those identified for closed systems and additional measures such as document encryption and use of appropriate digital signature standards

3) Signature manifestation

Major requirements

- Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:
  - the printed name of the signer
  - the date and time when the signature was executed
  - the meaning (such as review, approval, responsibility, or authorship) associated with the signature

  This information shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

4) Signature/record linking

Major requirements

- Electronic signatures and handwritten signatures executed on electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred so as to falsify an electronic record by ordinary means.

5) Electronic signatures

Major requirements

- Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
- Specific requirements for electronic signatures not based upon biometrics

What does this mean for you as a manufacturer?

The requirements of the FDA regulation have to be considered by manufacturers of electronic record-generating devices to provide the responsible organization with all technical means necessary for 21 CFR Part 11 compliance, as far as applicable to the respective device. The requirements applicable to the device need to be identified and related device requirements (both technical means and descriptive information in the accompanying device documentation) are to be specified. The extent of documentation and the required effectiveness of the means provided should be based on risk management. The correct and effective implementation of the means provided needs to be tested by the manufacturer.

How can TÜV SÜD Product Service help you?

TÜV SÜD Product Service offers a comprehensive portfolio of services:

- training in the requirements and challenges of the FDA regulation
- gap analysis of existing processes and device documentation regarding 21 CFR Part 11
- independent (spot-check) testing of implemented technical means related to 21 CFR Part 11
- auditing (e.g. as part of the medical device Single Audit Program MDSAP)

Your contact partner at TÜV SÜD Product Service can provide further information.

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