

Using digital signatures according to FDA 21 CFR Part 11

What is 21 CFR Part 11?

The use of computer systems in branches like pharmaceuticals, biotechnology and medical technology is increasingly subject to requirements from regulating authorities. This can affect a wide range of departments like such as Manufacturing, Quality Assurance or Research and Development. In 1997, the US health authority FDA (Food and Drug Administration) defined requirements for the use of electronic records and electronic signatures. These guidelines are defined in 21 CFR (Code of Federal Regulations) Part 11. In the past, the FDA granted the companies a transition period for implementing these rules. However, it now increasingly focuses on 21 CFR Part 11 issues during inspections. The increases in warning letters as well as the statements from FDA officers show that the FDA wants to see concrete measures, not just plans. Drastic sanctions, up to a complete stop of production, are imposed upon the discovery of violations. Beside technical measures, there also are organizational measures that have to be implemented in order to achieve a 21 CFR Part 11 compliant system. Part 11 Compliance requires validation of all relevant computer systems. In order to meet all requirements concerning electronic signatures, so-called digital signatures are particularly well-suited.



What is the benefit?

The risk of having a production site shut down by a FDA inspection surely isn't acceptable for a company. The so called "21 CFR 11 compliance" of production and documentation processes is becoming a crucial criterion for a company's success. For producers of medical products or devices it is very important to be in compliance with Part 11, in order to stay internationally competitive. This is why an early implementation can be considered a competitive advantage. For the corresponding agencies, which are confronted with a growing number of submissions, this leads to a simpler and faster procession of electronic submissions. The FDA's demands for electronic signatures are made to improve quality and traceability of electronically documented processes. Furthermore there are additional advantages for companies when adopting digital signatures:

- Cost reduction
- Acceleration of processes
- Avoidance of media breaks
- Increase of process quality
- Compliancy of requirements by other authorities (e.g. finances)

Why digital signatures?

Part 11 strictly distinguishes between handwritten and electronic signatures. The term "electronic signature" is, similar to other laws, an extensive generic term. As special variants, Part 11 defines the usage of biometric attributes as well as the digital signature, based on cryptographic methods. The FDA places most emphasis on the assurance of integrity and authenticity of datasets as well as the accountability of processes. These demands for the highest level of security can be met with state-of-the-art digital signatures combined with a reliable Public Key Infrastructure (PKI). Digital signatures also meet high requirements concerning:

- Dependency on signer,
- Dependency on assertion,
- Verification,
- Protection against tempering and
- Authenticity of documents.

With this the Part 11 demands for electronic signatures, closed/open systems, signature manifestations or signature/record linking can be completely fulfilled. The FDA doesn't require electronic signatures for all data. So called predicate rules in the Good Practices (GxP) of the FDA and other acts define which documents and datasets require electronic signatures. As an alternative it is possible for such electronic datasets to be accompanied by a related handwritten (paper) signature. But such hybrid systems require a huge amount of administration effort and eliminate the advantages of a general digital signature solution. Because of the big scope of Part 11 it affects many different systems. Depending on the currently viewed process this could be DMS, ECM, ERP, EDM/PDM or workflow-systems. This is why it's often important to use interoperable document and signature formats.

How can we assist you?

To meet the Part 11-requirements it is essential to cover the tasks of conception, implementation and validation. In order to cover the topic „Electronic Signatures“ it is necessary to have competence and experience in implementing such a complex topic as „PKI / electronic signatures“. Especially the integration of digital signature mechanisms into existing or yet-to-be-realized systems isn't available as off-the-shelf product. However, it is possible with the right selection of standard products, add-on components and services to save a lot of time and money. SECARDEO has the necessary competence and experience and helps you

- analyzing application systems and defining the requirements,
- design and implement digital signature solutions for Part 11 Compliance based on standard products and add-ons,
- planning and accomplishment of validation task for Part 11 electronic signatures,
- evaluate signature products and services e.g. external trust centers,
- integration of a signature verification server for validating and auditing authenticity and authorizations
- designing and implementing a company wide PKI as a central infrastructure for digital signatures as well as
- perform seminars and workshops for Part 11 / electronic signatures

Do you need further information?

If you need further information, please contact

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