

21 CFR PART 11

21 CFR Part 11 governs the use of Electronic Records and Electronic Signatures (ERES). The Code of Federal Regulations (CFR) Part 11 was introduced in 1997 and is continually updated.

The regulation allows the US Food and Drug Administration (FDA) to accept regulated electronic records and signatures in place of paper records and handwritten signatures. It outlines controls for ensuring that electronic signatures and records are trustworthy, reliable, and compatible with FDA procedures and are as verifiable and traceable as their paper counterparts.

21 CFR Part 11 may be implemented through a combination of compliant software, corporate policy and/or procedures. However the regulations are implemented, they must be accompanied by supporting documentation. The implementation of any Part 11 compliant system, whether software, policy or procedure oriented, is not valid without this documentation.

Any manufacturing corporation under the scrutiny of an FDA audit will have to meet the following conditions to prove system compliance;

- ⊕ Application specific validation documentation
- ⊕ Life cycle development document set
- ⊕ Software compliance
- ⊕ Protection of records
- ⊕ Data integrity
- ⊕ Secure audit trails
- ⊕ Secure system and data access rights

Software used to implement the Food and Drug Administration regulations is the core component of a compliant system. Development of the software must be specifically aimed at satisfying the regulatory requirements. FDA specific features must include;

- ⊕ Secure audit log of all user activity and system data
- ⊕ Unique electronic signatures using two distinct components
- ⊕ Automatic signature and record linking
- ⊕ Password ageing
- ⊕ Control of unauthorised access attempts
- ⊕ Version control of electronic documents
- ⊕ Data archiving and retrieval
- ⊕ Accurate time and date stamping

Industries and organizations affected by the regulatory requirements of 21 CFR Part 11 include: medical device, pharmaceutical manufacturing and clinical trials companies. Any company supplying customers in the US is legally bound to comply with FDA regulations.

ELECTRONIC SIGNATURES

Electronic signatures can significantly increase the efficiency of a production process by working towards a paper free environment and allow instant access to historical digital data.

Electronic signatures are utilised either by means of a biometric interface or a secure password system dependent on the manufacturing environment. This signature can then be used throughout the manufacturing process to record system logon information, changes to data and settings and, most importantly, the information printed on each individual product and packing container from manufacture to dispatch.

All digital information stored can be accessed with the correct authentication to allow for internal or FDA auditing and the reconciliation and reprinting of damaged identification or packing labels.

PRISYM^{LS} has over a decade's experience supplying compliant labeling applications for life science and pharmaceutical manufacturing companies and we have been offering validated solutions for 21 CFR Part 11 since its inception. We have the experience, knowledge base and skill sets to supply and validate 21 CFR Part 11 compliant labeling solutions for any application.

For more information about 21 CFR Part 11, Electronic Signatures, FDA compliance and our range of validated labeling and tracking products and services please contact +44 (0)118 936 4400 or email info@prisymid.com

PRISYM^{LS} is a division PRISYM^{ID}.