

What is 21 CFR Part 11 ?

A brief note from Kevin



In simple terms, it is The FDA regulation relating to the use of Electronic Records and Electronic Signatures.

The Food and Drug Administration (FDA) published this regulation on August 20, 1997, following several years of study, to establish the criteria under which electronic records and signatures are considered equivalent to paper records and hand written signatures. Manufacturers in industries regulated by the FDA are required to maintain and submit records associated with the products they manufacture. These records contain information about the product as well as hand written signatures of the individuals who executed the process and/or authorized the execution.

With ever-greater use of information technology and computer systems at all stages of manufacture, more & more of the operating processes are being automated. As a result, key decisions and actions are being taken through electronic interfaces, with regulatory records being generated electronically.

Historically, these records have been kept in paper format and submitted for review to the FDA upon request. As computer systems became readily accepted in the manufacturing environment, the storage of these records in electronic format was explored to see whether maintenance of these records in electronic format offered volume and cost benefits over the paper equivalent.

The study early on encountered concerns about utilizing electronic media for storage of this information. Without the proper checks and balances in place it could be possible to corrupt a record without maintaining the original data or being able to discern that the data had been modified. Additionally, the handwritten signatures that were used to authorize and execute the production were legally binding to the owners of the signatures. There was no equivalent for signatures executed electronically.

The 21 CFR Part 11 regulation was therefore put in place to ensure that wherever manufacturers replaced the traditional paper records with electronic records, they implemented the systems in a manner that was equivalent. The regulation only applies where the records being maintained must be submitted for review to the FDA.

While recognizing the long -term benefits 21 CFR Part 11 will bring in permitting technological advances, industry also is faced with applying the rule to existing systems and current projects. With this comes an urgent need to improve understanding of the rule, its interpretation, and application.

Kevin's Continuing Commitments.

Kevin is committed to a defined strategy that will lower the cost of development and support for validated applications. This commitment includes the development of 21 CFR Part 11 applications, where the following functions will be addressed:

Built-in security authentication from a Windows NT Domain, where the configuration is effectively transparent to the user, if he selects to use NT authentication.

The ability to report easily on application changes and to do comparisons in order to reduce FDA validation and maintenance costs.

These functionalities are & will be available in most of our systems enabling existing applications to be continued going forward and permitting enhancements to be made to applications with reduced effort for achieving 21 CFR Part 11 compliance.

For your requirements of the following, do contact us.

VALIDATION - SCADA - DCS - PLC CONTROL - AUTOMATION - SOFTWARE

Kevin Technologies Pvt. Ltd

201, Shapath Complex, Opp. Rajpath Club, Sarkhej Gandhinagar Highway, Ahmedabad 380 015. India.

Tel: +91 79 687 2555. Fax: + 91 79 687 8930. E-Mail: info@kevintech.com.

Website : www.kevintech.com

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