FDA 21 PART 11 REQUIREMENTS FOR ELECTRONIC RECORDS

21 CFR part 11 of the federal regulations defines criteria for electronic records and digital signatures. Investigators should ensure that any software or Web application they are using for study records and data are part 11 compliant.

The main requirements of 21 CFR part 11 are:

1) Validation of systems to ensure accuracy, reliability, and consistent intended performance
2) Indexing and search functionality to allow records to be found quickly
3) Audit trail and audit history availability
4) Operational controls: documents to be reviewed by specific individuals and must meet certain criteria before being signed off
5) Individual usernames/logins and passwords for users
6) Requirements for digital signatures, including the printed name of the signer, the date and time of the signature, and the intention or purpose of the signature
7) Providing the necessary training for users to perform their assigned tasks