

FDA 21 CFR Part 11 – Electronic Records Validation, Integrity And Compliance

The global pandemic has now forced us to “work from home” on a regular basis. Consequentially, we find electronic documents and records to be a lot more prevalent than they were; electronic signatures are a way of acceptance in day-to-day operations. Therefore, it is very critical for organisations to reconsider 21 CFR part 11 requirements and assure data integrity & compliance.

21 CFR Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any record requirements set forth in agency regulations. Electronic signatures and their associated electronic records meet the requirements of this part. The agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings as required by agency regulations, unless specifically excepted by regulation(s) effective on or after August 20, 1997. Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection¹.

This checklist will help your organisation check if they comply with FDA 21 CFR Part 11 requirements.

Regulations	Requirement	Compliant	Noncompliant
Does your organisation have procedures (including record system) and controls designed (controls for closed systems) Ref. 21 CFR Part 11, Sec. 11.10	a. to ensure the authenticity, integrity, confidentiality of electronic records		
	b. to assure the signer cannot readily repudiate the signed record as not genuine		
	c. includes validation of systems to ensure accuracy, reliability and consistent intended performance		
	d. to generate accurate and complete copies of records in both human readable and electronic form		
	e. to ensure protection of records; accurate and ready retrieval throughout the records retention period		
	f. to restrict system access by unauthorized individuals		
	g. includes use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries		
	h. to ensure for new changes, it shall not obscure previously recorded information		
	i. to assure that audit trail documentation shall be retained for a minimum predefined period as required for electronic records		
	j. to use authority checks that only authorized individuals can use the system, electronically sign, access the operation or computer system input or output device		
	k. to use device checks to determine the validity of the source of data input or operational instructions		
l. includes a system to trace individuals responsible for signature falsification			

¹ 21 CFR Part 11 - ELECTRONIC RECORDS; ELECTRONIC SIGNATURES, Subpart A - General Provisions Sec. 11.1 Scope.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11&showFR=1> last access on April 24th 2021

	m. to use controls over systems documentation including adequate controls over the distribution of, access to, and use of documentation		
	n. to assure the persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience		

Regulations	Requirement	Compliant	Noncompliant
Does your organisation have revision and change control procedures (controls for closed systems) Ref. 21 CFR Part 11, Sec. 11.10	a. to ensure adequate controls over the distribution of, access to and use of documentation		
	b. to maintain an audit trail that notes time-sequenced development and modification of system documentations		

Regulations	Requirement	Compliant	Noncompliant
Does your organisation have procedures including record system and controls designed (controls for open systems) Ref. 21 CFR Part 11, Sec. 11.30	a. to document encryption and use of digital signatures so that record authenticity, integrity, and confidentiality are maintained Note: To comply with requirements stated in 21 CFR Part 11, Sec 11.30; one has to meet the regulations under 21 CFR Part 11, Sec 11.10 additionally.		

Regulations	Requirement	Compliant	Noncompliant
Does your organisational procedures incorporate details to ensure that signed electronic records shall contain Ref. 21 CFR Part 11, Sec. 11.50 (Signature manifestations)	a. the printed name of the signer		
	b. the date and time when the signature was executed		
	c. the meaning (such as review, approval, responsibility, or authorship) associated with the signature		
	d. human readable form of the electronic record		

Regulations	Requirement	Compliant	Noncompliant
Does your organisation have procedures to linked electronic signatures and handwritten signatures executed to electronic records Ref. 21 CFR Part 11, Sec. 11.70 (Signature/record linking)	a. to ensure that the signatures cannot be excised, copied, or transferred to falsify an electronic record by other means		

Regulations	Requirement	Compliant	Noncompliant
Organisations using electronic signatures that are not based upon biometrics shall Ref. 21 CFR Part 11, Sec. 11.200 (electronic signature components and controls)	a. employ at least two distinct identification components - identification code and password		
	b. ensure signatures shall be used only by the authorized owners		
	c. be administered to ensure that an attempt to use electronic signature by anyone other than the authorized owners requires collaboration of two or more individuals.		

Regulations	Requirement	Compliant	Noncompliant
Organisations using electronic signatures based upon biometrics shall be designed Ref. 21 CFR Part 11, Sec. 11.200 (Electronic signature components and controls)	a. to ensure that they cannot be used by anyone other than the authorized owners		

Regulations	Requirement	Compliant	Noncompliant
When an individual executes a series of signings during a single, continuous period of controlled system access Ref. 21 CFR Part 11, Sec. 11.200 (Electronic signature components and controls) Note: e-signatures not based on Biometric	a. the first signing shall be executed using all electronic signature components		
	b. subsequent signings shall be executed by using at least one electronic signature component that is only executable by and designed to be used only by the individual		

Regulations	Requirement	Compliant	Noncompliant
When an individual executes one or more signings not performed during a single, continuous period of controlled system access Ref. 21 CFR Part 11, Sec. 11.200 (Electronic signature components and controls) Note: e-signatures not based on Biometric	a. each signing shall be executed using all of the electronic signature components.		

Regulations	Requirement	Compliant	Noncompliant
Persons who use electronic signatures based upon the use of identification codes in combination with passwords shall employ controls to ensure their security and integrity which shall include Ref. 21 CFR Part 11, Sec. 11.300 (controls for identification codes/passwords)	a. maintaining the uniqueness of each combined identification code and password		
	b. identification of code and password issuances which are periodically checked, recalled, or revised		
	c. loss management procedures to electronically deauthorize lost or potentially compromised tokens		
	d. use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes		
	e. detection and reporting of any unauthorized attempt to use the system security		
	f. initial and periodic testing of devices to ensure that they function properly and have not been altered in an unauthorized manner		

In March 1997, FDA issued the final part 11 regulations that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, were intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect public health .

DISCLAIMER: This checklist does not create nor confer any rights towards any person or organisation and does not enforce to abide by this document. It is only intended to support organisations or individuals using this checklist to meet requirements of 21 CFR Part 11. Should you have an alternative method or procedure meeting the requirements of the applicable statutes and regulations, you may adopt the same in addition to this.

For further queries or support, please contact: marketing@compliancequest.com

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