



# *FDA 21 CFR Part 11 compliance checklist*

*FDA Title 21 CFR Part 11 lays out the FDA's requirements for the integrity, quality and compliance of electronic records and signatures. The administration of data and documentation is a critical component of a life science quality management system – use this checklist to work through each requirement of FDA 21 CFR Part 11 and embed complete compliance.*

## Validation

Item number	Requirement	Complete?
1	Is the system validated?	<input type="checkbox"/>
2	Is it possible to discern invalid or altered records?	<input type="checkbox"/>
3	Are the records readily retrievable throughout their retention period?	<input type="checkbox"/>
4	Is system access limited to authorized individuals?	<input type="checkbox"/>
5	If the sequence of system steps or events is important, is this enforced by the system (process control system)?	<input type="checkbox"/>
6	Does the system ensure that only authorized individuals can use it, electronically sign records, alter a record, or perform other operations?	<input type="checkbox"/>
7	If it is a requirement of the system that input data or instructions can only come from certain input devices (e.g. terminals) does the system check the validity of the source of any data instructions received? (Note: This applies where data or instructions can come from more than one device, and therefore the system must verify the integrity of its source, such as a network of weight scales, or remote, radio controlled terminals).	<input type="checkbox"/>
8	Is there documented training, including on the job training for system users, developers, IT support staff?	<input type="checkbox"/>
9	Is there a written policy that makes individuals fully accountable and responsible for actions initiated under their electronic signatures?	<input type="checkbox"/>
10	Is the distribution of, access to, and use of systems operation and maintenance documentation controlled?	<input type="checkbox"/>
11	Is data encrypted?	<input type="checkbox"/>
12	Are digital signatures used?	<input type="checkbox"/>

## Audit trailing

Item number	Requirement	Complete?
1	Is there a secure, computer-generated, time-stamped audit trail that records the date and time of operator entries and actions that create, modify, or delete electronic records?	<input type="checkbox"/>
2	Upon making a change to an electronic record, is previously recorded information still available (i.e. not obscured by the change)?	<input type="checkbox"/>
3	Is an electronic records audit trail retrievable throughout the record's retention period?	<input type="checkbox"/>
4	Is the audit trail available for review and copying by the FDA?	<input type="checkbox"/>
5	Does the audit trail include the User ID, sequence of events (in particular scenarios or instances), original and new values (Backups of any modified or deleted records), a change log, and revision and change controls?	<input type="checkbox"/>
<b>Do signed electronic records contain:</b>		
6	The printed name of the signer?	<input type="checkbox"/>
7	The date and time of signing?	<input type="checkbox"/>
8	The meaning of the signing (such as approval, review, etc.)?	<input type="checkbox"/>
9	Is the above information shown on displayed and printed copies of the electronic record?	<input type="checkbox"/>
10	Are signatures linked to their respective electronic records to ensure that they cannot be cut, copied, or otherwise transferred by ordinary means for the purpose of falsification?	<input type="checkbox"/>
11	Is there a formal change control procedure for system documentation that maintains a time-sequenced audit trail for those changes made by the pharmaceutical organization?	<input type="checkbox"/>
12	Are electronic signatures unique to an individual?	<input type="checkbox"/>
13	Are electronic signatures ever reused by or reassigned to anyone else?	<input type="checkbox"/>

- |    |   |                          |
|----|---|--------------------------|
| 14 | Is the identity of an individual verified before an electronic signature is allocated?  | <input type="checkbox"/> |
| 15 | Is the signature made up of at least two components, such as an identification code and password, or an id card and password?   | <input type="checkbox"/> |
| 16 | Has it been shown that biometric electronic signatures can be used only by their genuine owner?   | <input type="checkbox"/> |
| 17 | When several signings are made during a continuous session, is the password executed at each signing? (Note: Both components must be executed at the first signing of a session.) | <input type="checkbox"/> |
| 18 | If signings are not done in a continuous session, are both components of the electronic signature executed with each signing?   | <input type="checkbox"/> |
| 19 | Are non-biometric signatures only used by their genuine owners?   | <input type="checkbox"/> |
| 20 | Would an attempt to falsify an electronic signature require the collaboration of at least two individuals?  | <input type="checkbox"/> |



## Record copying

Item number	Requirement	Complete?
1	Is the system capable of producing accurate and complete copies of electronic records on paper?	<input type="checkbox"/>
2	Is the system capable of producing accurate and complete copies of records in electronic form for inspection, review, and copying by the FDA?	<input type="checkbox"/>
3	Is the system using established automated conversion or export methods (PDF, XML, or SGML)?	<input type="checkbox"/>



## Record retention

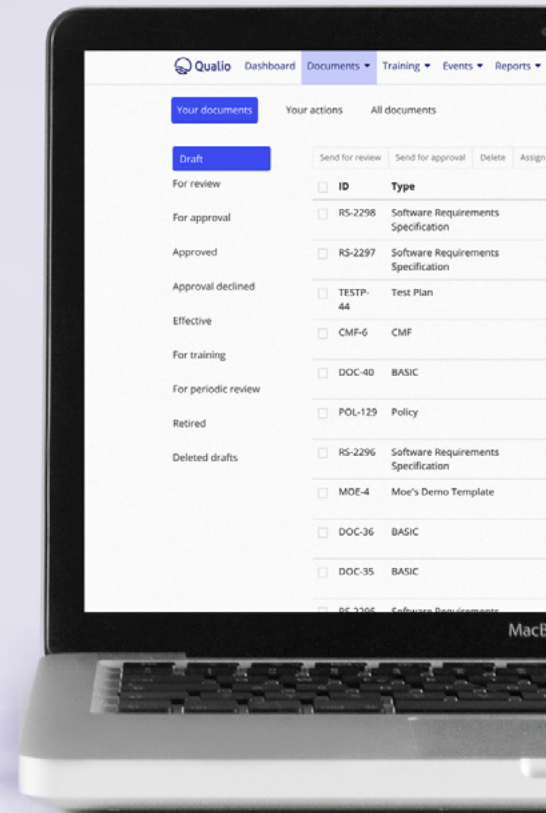
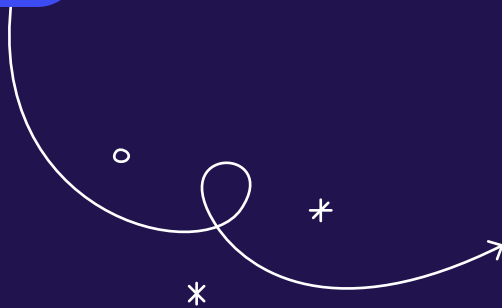
Item number	Requirement	Complete?
1	Are controls in place to maintain the uniqueness of each combined identification code and password, such that no individual can have the same combination of identification code and password?	<input type="checkbox"/>
2	Are procedures in place to ensure that the validity of identification codes is periodically checked?	<input type="checkbox"/>
3	Do passwords periodically expire and need to be revised?	<input type="checkbox"/>
4	Is there a procedure for recalling identification codes and passwords if a person leaves or is transferred?	<input type="checkbox"/>
5	Is there a procedure for electronically disabling an identification code or password if it is potentially compromised or lost?	<input type="checkbox"/>
6	Is there a procedure for detecting attempts at unauthorized use and for informing security?	<input type="checkbox"/>
7	Is there a procedure for reporting repeated or serious attempts at unauthorized use to management?	<input type="checkbox"/>
8	Is there a loss management procedure to be followed if a device is lost or stolen?	<input type="checkbox"/>
9	Is there a procedure for electronically disabling a device if it is lost, stolen, or potentially compromised?	<input type="checkbox"/>
10	Are there controls over the issuance of temporary and permanent replacements?	<input type="checkbox"/>
11	Is there initial and periodic testing of tokens and cards?	<input type="checkbox"/>
12	Does this testing check that there have been no unauthorized alterations?	<input type="checkbox"/>



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