FDA

21 CFR Part 11

FDA 21 CFR Part 11 Compliance Checklist

The 21 CFR Part 11 compliance checklist is a tool that can be used to evaluate the level of compliance with the requirements outlined in 21 CFR Part 11.

It provides a comprehensive list of questions to consider when assessing the compliance of electronic records and electronic signature systems.

Validation

Item Nr.	Question	Check?
1	Is the system validated?	☐
2	Is the system performance accurate, reliable, and consistent?	☐
3	Is the system able to identify invalid or altered records?	☐
4	Are there written policies in place that outline the accountability and responsibility of users for actions initiated under their electronic signatures?	☐
5	Are users informed and trained on the policies related to electronic signatures to prevent record and signature falsification?	☐
6	Can you provide training documentation demonstrating that individuals who develop, maintain, or use electronic record and signature systems have the required experience for their assigned tasks?	☐
7	Is there a documented process for verifying the identity of users before their electronic signature is established, assigned, or certified?	☐
8	Is the system designed to require the collaboration of two or more individuals to use an electronic signature that does not belong to them?	☐

Audit Trail

Item Nr.	Question	Check?
1	Are document management and change control procedures in place to maintain an audit trail?	☐
2	Does the system have a secure and computer-generated audit trail to record operator entries and actions that create, modify, or delete electronic records?	☐
3	Does the system record the date and time of these operator entries and actions on the audit trail?	☐
4	Do changes to records modify previously recorded information? Note that all previous information should still be accessible and not erased or hidden by changes.	☐
5	Is the audit trail documentation retrievable and available for FDA review and copying?	☐

Systems

Item Nr.	Question	Check?
1	Does the company use electronic records?	☐
2	Does the company use electronic signatures?	☐
3	Does the company use handwritten signatures executed to electronic records?	☐
4	Does the company use electronic signatures based on biometrics?	☐
5	Does the system prevent electronic signatures based on biometrics from being used by anyone other than their genuine owners?	☐

Item Nr.	Question	Check?
6	Is the system designed to ensure only authorized individuals can access it and perform actions?	☐
7	Does the system have controls to prevent unauthorized access to the operation or computer system input/output devices?	☐
8	Does an open system comply with the appropriate procedures and controls identified in section 11.10?	☐
9	Does an open system employ additional controls, such as document encryption and digital signature standards, to ensure record authenticity, integrity, and confidentiality?	☐
10	Is there a procedure to conduct device checks to ensure the data input source or operational instruction is valid?	☐
11	Does the system use operational checks to enforce actions to be executed in a predetermined sequence, if applicable?	☐
12	Are there controls in place for the distribution of system documentation?	☐
13	Is an access control procedure in place to ensure only authorized users can access system operation and maintenance documentation?	☐
14	Is there a procedure to ensure the proper use of system documentation for operation and maintenance?	☐

Copies of Records

Item Nr.	Question	Check?
1	Is the system capable of producing accurate and complete copies of electronic records?	☐

Item Nr.	Question	Check?
2	Are electronic signatures linked to their respective electronic records preventing the removal, copying, or transfer of signatures?	☐
3	Can all electronic records be provided to the FDA for inspection and review?	☐
4	Are records in the system protected from unauthorized changes by having authorization checks in place?	☐

Record Retention

Item Nr.	Question	Check?
1	Do the signed electronic records contain information that indicates the signer's printed name?	☐
2	Do the signed electronic records contain information indicating the date and time when the signature was executed?	☐
3	Do the signed electronic records contain information that indicates the meaning associated with the signature, such as review, approval, responsibility, or authorship?	☐
4	Is the level of control for signature information equivalent to that of electronic records?	☐
5	Are electronic records readily retrievable throughout their retention period?	☐
6	Is the audit trail documentation retained for the required period?	☐

Electronic Signatures

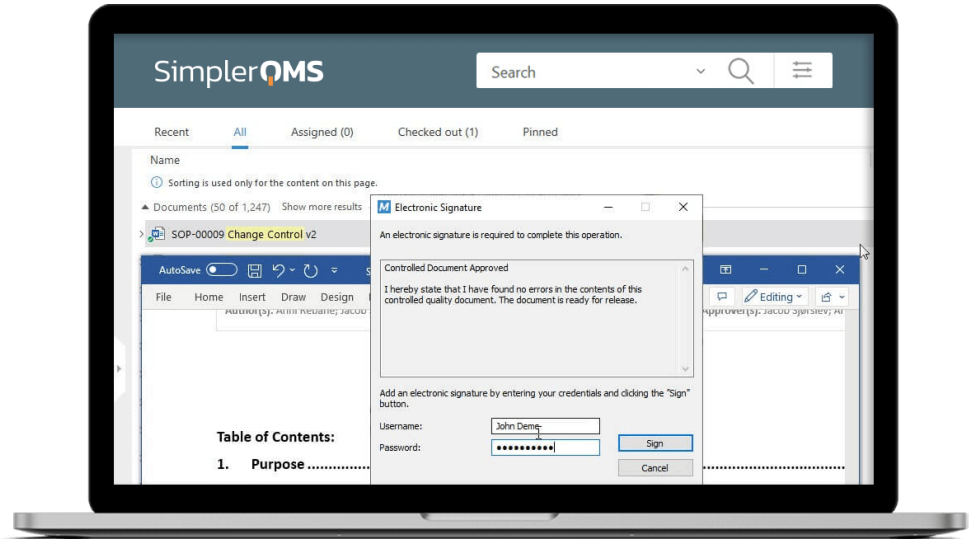
Item Nr.	Question	Check?
1	Are electronic signatures in the system restricted to authorized users only?	☐
2	Does each user have their own unique electronic signature?	☐
3	Are electronic signatures only being used by their genuine owners?	☐
4	Do electronic signatures use at least two different identification components, such as an identification code and password?	☐
5	Does the system require all electronic signature components for the first signature within a series of signatures in a single system access?	☐
6	Does the system require at least one electronic signature component for subsequent signatures?	☐
7	Does the system require all electronic signature components when a user signs during several system accesses?	☐
8	Is there a procedure to prevent signatures from being reassigned or reused?	☐
9	Did users provide a traditional handwritten signature on the Electronic Signature Agreement to acknowledge that their electronic signature is equivalent to a handwritten signature?	☐
10	Has the company ensured that everyone using electronic signatures in their system, used on or after August 20, 1997, has their certification submitted to the FDA?	☐
11	Has the company followed the submission guidelines on the FDA's web page on the Letters of Non-Repudiation Agreement to certify electronic signatures?	☐

Item Nr.	Question	Check?
12	Are the users aware FDA may require them to provide additional certification or testimony of the equivalence of an electronic signature to their handwritten signature?	☐

Access Security

Item Nr.	Question	Check?
1	Are controls in place to ensure each individual has a unique identification code and password combination?	☐
2	Is the system capable of preventing the creation of duplicate identification code and password combinations?	☐
3	Are passwords required to expire and be updated periodically?	☐
4	Are there any procedures in place to recall or revise identification codes and passwords if necessary?	☐
5	Is there a procedure to periodically check the validity of the identification code and password combinations recorded in the system?	☐
6	Are there procedures to revoke identification code and password combinations that may have been compromised?	☐
7	Is there a procedure for recalling identification codes and passwords if someone leaves the company?	☐
8	Is there a procedure to disable lost, stolen, or missing electronic devices to protect system access and sensitive data?	☐
9	Are temporary or permanent password replacements issued using appropriate and rigorous controls?	☐

Item Nr.	Question	Check?
10	Does the system detect attempts of unauthorized use of passwords and identification codes?	☐
11	Is the system security unit immediately informed of any unauthorized use attempts of passwords and identification codes?	☐
12	Is organizational management notified of any unauthorized use of passwords and identification codes, if appropriate?	☐
13	Does the company perform initial testing on devices that generate or hold identification codes or password information to ensure they function properly?	☐
14	Does the company perform periodic device testing to ensure they still function properly?	☐
15	Is there a procedure to test for unauthorized device alterations that generate or hold identification codes or password information?	☐



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