LIGHTHOUSE
WORLDWIDE SOLUTIONS

QUESTIONS TO ASK ABOUT THE APPLICATION OF 21 CFR PART 11 IN YOUR OPERATIONS

Lighthouse Worldwide Solutions

Overview

The following questions will help you ask the right questions when implementing a system that adheres to 21CFR Part 11. It is important to satisfy the requirements of this FDA code in order to enable Data Integrity and Data Traceability as well as the electronic signatures that verify the data as original, valid and accurate.

No.	21 CFR Part 11 Requirements	Yes/No
1. Validation – For Security		
1.1	Is the entire system validated?	
1.2	Is there limited system access for authorized individuals?	
1.3	Is there a process defined in which only authorized individuals can use the system, electronically sign the documents, alter them or perform other operations?	
1.4	Is there any documented training available for the system that includes on-the-job training for system users, developers, IT support staff?	
1.5	Is there a written set of policies that make individuals fully accountable and responsible for each and every action initiated by them under their electronic signatures?	
1.6	Is data encrypted within the system?	
1.7	Are digital signatures used?	
1.8	Are the system and its data fully protected with state-of-the-art encryption?	
1.9	Do you have a way to control access to, use of, and distribution of the system's operation and maintenance documentation?	
1.10	Do you have a written accountability and responsibility policy concerning actions taken under a user's login/electronic signature?	
1.11	Do you provide documented training for system users, developers, and support team members, including training on the job?	
1.12	If data can only be supplied by specific input devices, does the system validate data sources? (This implies a network of authorized input devices where the system must verify source identity/integrity/ authorization).	

2. Audit Trails – For Traceability

2.1	Does the system provide a secure, computer-generated, time-stamped audit trail (including date and time and actions such as create, modify, or delete electronic records)?	
2.2	Is previously recorded data available after every change to the record?	
2.3	Can the FDA review and copy the audit trail?t	
2.4	Does the audit trail include all necessary/relevant elements, including user ID, event sequence, original and changed values, changelog, revisions, and change controls?	
2.5	Do you have an audit trail for all documents? Note that the audit trail should be secure, computer-generated, and time-stamped, and it should record the date and time of entries and actions that affect documents/records in any way	
2.6	Can the FDA review and copy each document/record's audit trail?	
2.7	Do all signed documents/records include the signer's printed name, the date/time of signing, and the reason/meaning for the signing? Is this information visible when the document/record is displayed and/or printed?	
2.8	Do the signed electronic records contain the name, data, time stamp, and reason for signing?	
2.9	Do all signatures link to their corresponding records/documents to prevent cutting, copying, or other modifications that might allow misrepresentation?	
2.10	Have you implemented a formal change procedure for documentation within the system? Does that procedure maintain a time-stamped audit trail for all changes made by a pharmaceutical firm?	
2.11	Does each individual have his or her own unique electronic signature?	
2.12	Can you prevent signatures from being reassigned or reused?	
2.13	Do you validate identities before assigning a signature?	
2.14	Do all signatures include at least two components? Examples include ID cards and passwords or ID codes and passwords.	
2.15	Does the system require a password at each step in a multi-step/ continuous session?	
2.16	Does each signing require the execution of both components at each signing if you do not use continuous sessions?	
2.17	Would it require 2 or more people to forge an electronic signature?	

3. Electronic Signatures – For Valid Use

3.1	Are electronic signatures unique for every user?	
3.2	Is it possible to reuse or reassign the electronic signature to anyone else?	
3.3	Does each electronic signature link to its respective electronic record?	
3.4	Is the identity of an individual checked and thoroughly verified at the time of signing using an electronic signature?	

4. Record Copies

4.1	Can the system create accurate, complete paper copies of digital records/documents?	
4.2	Can the system create accurate, complete copies of records/ documents in digital form for the FDA's inspection, review, and use?	
4.3	Does the system use an established automated conversion or export process, such as PDF or XML?	
4.4	Is there a procedure defined to produce accurate and complete copies of electronic records on paper?	
4.5	Is the system capable of providing copies of records in the electronic form to serve the purpose of inspection, review, and copying by the FDA?	

5. Record Retention – For Efficiency

5.1	Have you implemented controls to help enforce the uniqueness of all identification code and password combinations? Note that this is required to help prevent code/password duplication.	
5.2	Have you implemented a procedure to periodically check the validity of all password/code combinations recorded in the system?	
5.3	Do all passwords expire periodically, requiring the creation of a new, non-duplicated password?	
5.4	Have you implemented a procedure to recall ID codes and passwords if an employee leaves or is terminated?	
5.5	Have you implemented a means to disable/invalidate ID codes and passwords if they are lost or stolen?	
5.6	Have you implemented a procedure to detect unauthorized access attempts? does that include alerting IT/security?	
5.7	Have you created a procedure for reporting multiple unauthorized access attempts, such as those that might be seen in a hacking attempt?	

5.8	Have you created a procedure to follow in the case of a lost or stolen device?	
5.9	Is there a way to disable lost or stolen electronic devices to protect access and sensitive data?	
5.10	Have you implemented controls over issuing temporary and permanent replacements?	

The above checklist represents most of the areas that should be covered in your system in order to cover 21 CFR Part 11. Equipment and Instrument suppliers supply critical systems to enable your process to capture critical facility data. It is your responsibility to ensure that the supplied equipment and instruments are 21 CFR Part 11 compliant along with internal policies and procedures that align to the end user's requirements of 21 CFR Part 11.

This checklist may be one of many tools used when reviewing the requirements of 21 CFR Part 11. To get updated information on 21 CFR Part 11 Lighthouse Worldwide Solutions always recommends going to the FDA website. Here below are some FDA links and references.

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-records-and-electronic-signatures-clinical-investigations-under-21-cfr-part-11

Part 11, Electronic Records; Electronic Signatures - Scope and Application

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application

CFR - Code of Federal Regulations Title 21

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11