Evidence Product Checklist

For the FDA Document
"FDA 21 CFR Part 11
Electronic Records; Electronic Signatures;
Final Rule"

ISBN 0-9716087-0-9

FDA Document

Checklist

Quality Records

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EVIDENCE PRODUCT CHECKLIST
For the FDA Document

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FDA 21 CFR Part 11
Electronic Records; Electronic Signatures; Final Rule
EVIDENCE PRODUCT CHECKLIST

Introduction

The process of defining what is necessary for compliance with a document such as "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule" is sometimes confusing and laborious because the directions contained in the document may be unclear or ambiguous. To aid in determining what is actually "required" by the document in the way of physical evidence of compliance, the experts at SEPT have produced this checklist. This checklist is constructed around a classification scheme of physical evidence comprised of policies, procedures, plans, records, documents, audits, and reviews. SEPT has carefully reviewed this FDA document and defined the physical evidence required based upon this classification scheme. SEPT has conducted a second review of the complete list to ensure that the document's producers did not leave out a physical piece of evidence that a "reasonable person" would expect to find. It could certainly be argued that if the document did not call it out then it is not required; however if this document were used by an enterprise to improve its software process, then it would make sense to recognize missing documents. Therefore, there are documents specified in this checklist, though not specifically called out, which are implied by "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule". These implied documents are designated by an asterisk (*) throughout this checklist. If a document is called out more than one time, only the first reference is stipulated.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the Software Detail Specification Document could be a subset of Software Design Specification. SEPT has called out these individual items separately to ensure that the organization does not overlook any facet of physical evidence. If the organization does not require a separate document, and an item can be a subset of another document or record, then this fact should be denoted in the detail section of the checklist for that item. This should be done in the form of a statement reflecting that the information for this document may be found in section XX of Document XYZ. If the organizational requirements do not call for this physical evidence for a particular project, this should also be denoted with a statement reflecting that this physical evidence is not required and why. The reasons for the evidence not being required should be clearly presented in this statement. Further details on this step are provided in the in the Detail Steps section of the introduction. The size of these documents could vary from paragraphs to volumes depending upon the size and complexity of the software project or business requirements.

This checklist is focused solely on "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule". It does not cover the requirements for any other standard unless so stated.

FDA Document Checklist for Electronic Records and Electronic Signatures

This checklist was prepared by analyzing each clause of this document for the key words that signify a:

- Policy
- Procedure
- Plan
- Records
- Document
- Audit
- Review

This checklist specifies evidence that is unique to the process necessary for electronic records and electronic signatures. After reviewing the completed document, the second review was conducted from a common sense "reasonable man" approach. If a document or other piece of evidence appeared to be required, but was not called out in the document, then it is added with an asterisk **(*)** after its notation in the checklist. The information was transferred into checklist tables, based on the type of product or evidence.

Using the Checklist

When a company is planning to use this document to ensure their compliance to FDA 21 CFR Part 11, the company should review this evidence checklist. If the company's present process does not address an evidence product delineated in this document, then this question should be asked: "Is the evidence product required for the type of product or services the business is producing?" If in the view of the company the evidence is not required, the rationale should be documented and inserted in the appropriate organizational records. This rationale should pass "*the reasonable person rule*." If the evidence is required, plans should be prepared to address the missing items.

Detail Steps

An enterprise should compare the proposed output of their project or organization against the checklist. In doing this, they will find one of five conditions that exist for each item listed in the checklist. The following five conditions and the actions required by these conditions are listed in the table below.

Condition	Action Required
1. The title of the documented evidence specified by the checklist (document, plan, etc) *agrees* with the title of the evidence being planned by the enterprise.	Record in checklist that the enterprise is *compliant.*

2. The title of the documented evidence specified by the checklist (document, etc) *disagrees* with the title of the evidence planned by the enterprise but the content is the same.	Record in the checklist the evidence title the enterprise uses and record that the enterprise is compliant, and the evidence is the *same* although the title is different.
3. The title of the documented evidence specified by the checklist (document, etc) is *combined* with another piece of evidence.	Record in the checklist the title of the evidence (document, etc) where this information is *contained*.
4. The title of the documented evidence specified by the checklist (document, etc) *is not planned* by the enterprise because it is not required.	Record in the checklist that the evidence is *not* required and the rationale for this decision.
5. The title of the documented evidence called out by the checklist (document, etc) *is not planned* by the enterprise and *should be* planned by it.	Record in the checklist when this evidence will be *planned* and reference a *plan* for accomplishing the task.

Components of the Checklist
This checklist is composed of 8 sections:

- Section 1. Introduction
- Section 2. Composites of all required and suggested "FDA 21 CFR Part 11 Electronic Records and Electronic Signatures; Final Rule" evidence products.
- Sections 3-7. Individual checklists for each evidence type.
- Section 8. "About the Author"

Product Support
All reasonable questions concerning this checklist or its use will be addressed free of charge for 60 days from time of purchase, up to a maximum of 4 hours consultation time.

Author's Qualifications
Stan Magee is president of Software Engineering Process Technology Company, a firm specializing in the implementation of software process technology for U.S. and international corporations and organizations.

Mr. Magee is convener of WG 7 (Life Cycle Management) for ISO/IEC JTC1 SC 7 (Software and Systems Engineering) standards group. He has been a U.S. delegate to the International Plenary meetings since 1986. In 1995 he was elected to the IEEE Computer Society Golden Core of 500 people who have significantly served the IEEE Society in standards development over its 50 year history.

Mr. Magee is co-author of the books, *Guide to Software Engineering Standards and Specification Documents,* Artech House Publishers, 1997, ISBN 0-89006-919-0 and *Guide to Standards and Specification Documents for Designing Web Software,* Artech House Publishers, 1998, ISBN 0-89006-819-4. In 1997 Mr. Magee was part of a "People to People" quality mission to China and lectured at Shanghai University on software quality standards. He gives seminars on meeting the requirements of international software standards for medical device firms. Mr. Magee has over 35 years experience in the software field and is considered an expert in the area of software life cycle methodology. He is active on many governmental, educational and professional boards, and holds BS from the School of Engineering from Oregon State University and an MBA in International Business from the University of Puget Sound.

Warranties and Liability

Software Engineering Process Technology (SEPT) makes no warranties implied or stated with respect to this checklist, and it is provided on an "*as is*" basis. SEPT will have no liability for any indirect, incidental, special or consequential damages or any loss of revenue or profits arising under, or with respect to the use of this document.

Section 2

Product Checklist for "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule,"--Checklist by Clause

FDA 21 CFR Part 11 Electronic Records and Electronic Signatures; Final Rule	**POLICY** and PROCEDURES	PLANS	RECORDS	DOCUMENTS	**AUDIT**S and REVIEWS
11.0 General Provisions					
11.1 Scope					
11.2 Implementation					
11.3 Definitions					
11.10 Controls for Closed Systems	• Creation, Maintenance and Deletion of Electronic Records in a Closed System Procedure • **Electronic Record Keeping and Electronic Signatures Policy** • Electronic Record Keeping and Electronic Signatures System Change Control Procedure	• Electronic Record Keeping and Electronic Signatures Training Plan • Electronic Records and Signatures Validation and Test Plan • Security Plan*	• Audit Trail Records • Electronic Record Keeping and Electronic Signatures Training Records • Electronic Records • System Validation and Test Records	• Electronic Record Keeping and Electronic Signatures System Document	• Creation, Maintenance and Deletion of Electronic Records in a Closed System Procedure Review* • Electronic Record Keeping and Electronic Signatures Policy Review* • **Electronic Record Keeping and Electronic Signatures System Audit***

*Suggested Item

Section 2

Product Checklist for "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule,"--Checklist by Clause

FDA 21 CFR Part 11 Electronic Records and Electronic Signatures; Final Rule	**POLICY** and PROCEDURES	PLANS	RECORDS	DOCUMENTS	**AUDIT**S and REVIEWS
11.10 Controls for Closed Systems (Cont. 1)	• Electronic Record Keeping and Electronic Signatures System Document Procedure • Electronic Record Keeping and Electronic Signatures System Documentation Change Control Procedure • Electronic Record Keeping and Electronic Signatures Training Procedure				• Electronic Record Keeping and Electronic Signatures System Change Control Procedure Review* • Electronic Record Keeping and Electronic Signatures System Document Procedure Review* • Electronic Record Keeping and Electronic Signatures System Document Review*

*Suggested Item

Section 2

Product Checklist for "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule,"--Checklist by Clause

FDA 21 CFR Part 11 Electronic Records and Electronic Signatures; Final Rule	**POLICY** and PROCEDURES	PLANS	RECORDS	DOCUMENTS	**AUDIT**S and REVIEWS
11.10 Controls for Closed Systems (Cont. 2)	• Electronic Records System Equipment Checking and Operations Procedure • Electronic Records System Revision and Change Control Procedure • Electronic Records System Security Procedure* • Records (Human Readable and Electronic) Copying and Archive Procedure				• **Electronic Record Keeping and Electronic Signatures System Documentation Audit*** • Electronic Record Keeping and Electronic Signatures System Documentation Change Control Procedure Review* • Electronic Record Keeping and Electronic Signatures Training Plan Review*

*Suggested Item

Section 2

Product Checklist for "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule,"--Checklist by Clause

FDA 21 CFR Part 11 Electronic Records and Electronic Signatures; Final Rule	**POLICY** and PROCEDURES	PLANS	RECORDS	DOCUMENTS	**AUDIT**S and REVIEWS
11.10 Controls for Closed Systems (Cont. 3)					• Electronic Record Keeping and Electronic Signatures Training Procedure Review* • Electronic Records and Signatures Validation and Test Plan Review* • Electronic Records System Equipment Checking and Operations Procedure Review*

*Suggested Item

Section 2

Product Checklist for "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule,"--Checklist by Clause

FDA 21 CFR Part 11 Electronic Records and Electronic Signatures; Final Rule	**POLICY** and PROCEDURES	PLANS	RECORDS	DOCUMENTS	**AUDIT**S and REVIEWS
11.10 Controls for Closed Systems (Cont. 4)					• Electronic Records System Revision and Change Control Procedure Review* • Electronic Records System Security Procedure Review* • Records (Human Readable and Electronic) Copying and Archive Procedure Review* • Security Plan Review*

*Suggested Item

Section 2

Product Checklist for "FDA 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule,"--Checklist by Clause

FDA 21 CFR Part 11 Electronic Records and Electronic Signatures; Final Rule	**POLICY** and PROCEDURES	PLANS	RECORDS	DOCUMENTS	**AUDIT**S and REVIEWS
11.10 Controls for Closed Systems (Cont. 5)					• Training Records Review*
11.30 Controls for Open Systems	• Creation, Maintenance and Deletion of Electronic Records in an Open System Procedure			• Digital Signature Standards List Document	• Creation, Maintenance and Deletion of Electronic Records in an Open System Procedure Review* • Digital Signature Standards List Review*
11.50 Signature Manifestations			• Signature Manifestation Records • Valid Electronic Signature Records		• Signature Manifestation Records Review
11.70 Signature/Record Linking			• Signature/ Record Linking Records		

*Suggested Item