



**U.S. FDA TITLE 21
CFR PART 11 COMPLIANCE
ASSESSMENT OF SAP®
LEARNING SOLUTION**

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SUMMARY

Based upon SAP AG's interpretation of the Part 11 rule and the functions and features discussed within this document SAP AG believes that SAP® Learning Solution fully complies with U.S. FDA Title 21 Code of Federal Regulations (CFR) Part 11.



U.S. FOOD AND DRUG ADMINISTRATION (FDA) TITLE 21 CFR PART 11 ASSESSMENT

SAP Learning Solution

SAP Learning Solution provides a comprehensive, enterprise-learning platform that allows you to manage and integrate business and learning processes – and support all methods of learning beyond e-learning or classroom training. SAP Learning Solution is fully integrated with the SAP ERP application and includes an intuitive learning portal, a powerful learning management system with an authoring environment to structure content and author tests, and content management functionality enabling synchronous and asynchronous collaboration.

SAP Learning Solution offers back-office functionality for competency management and comprehensive assessment for performance management. It also provides strong analytical functionalities, including support for ad hoc reporting. The solution uses a comprehensive learning approach to deliver knowledge to all stakeholders and tailors learning paths to an individual's educational needs and personal learning style.

The document is valid for SAP Learning Solution 3.00 in SAP ERP 2004 and following releases.

FDA Regulations for Training

21 CFR Part 820.25 Personnel QSR

[This section provides quality system regulations (QSR) on training as follows.]

Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented. In addition:

- 1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.
- 2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

21 CFR Part 211

[This section provides the following in relation to training.]

- 211.25a
Training in current good manufacturing practices (cGMP) shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them.
- 211.34
Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof. Training shall be documented.

Security

SAP Learning Solution 3.00 in SAP ERP 2004 and following releases are built on top of the SAP NetWeaver® technology platform. Therefore, all security features of the SAP NetWeaver Application Server (SAP NetWeaver AS) component are valid for SAP Learning Solution. For details, please refer to the white paper “U.S. FDA Title 21 CFR Part 11 Compliance Assessment of SAP NetWeaver.”

E-Records

FDA Requirement

The FDA requires the ability to log and track changes on business objects and dependent objects in a compliant software environment.

The computer solution must provide functionality to log changes, as well as creation and deletion applied to business objects and depending objects (for example, configuration data). The minimal necessary information the system has to provide is:

- Old value of an attribute of the changed business object
- New value of this attribute
- Person who changed the value
- Date and time of change (SAP Learning Solution uses Coordinated Universal Time [UTC] and application server time)
- Action (create, modify, delete)

Change Management and Audit Trail in SAP Learning Solution

According to the FDA requirements for training described before, personnel development is the area that is critical for GMP compliance and 21 CFR Part 11. Therefore, in SAP Learning Solution, change documents can be written for all personnel development objects. In all personnel development tables used by SAP Learning Solution the data elements are already activated by default and can be configured by the customer. The report “Display Change Documents” (RHCDOC_DISPLAY) allows you to report on the change documents. The report contains all relevant data asked for by the FDA requirement for electronic records. The change documents can be archived with the standard archiving tool in SAP software (transaction SARA).

Digital Signature

SAP Learning Solution offers digital signature functionality where required by the FDA regulation: The student has to confirm his or her participation in a course. The digital signature software asks the student for user and password information. The e-signature functionality validates against the back-end user ID in the SAP ERP Central Component (SAP ECC) component. So the student needs a user ID for SAP ECC.

SAP Learning Solution provides these reports for digital signature verification: *Participant List* (RHTEILN_LSO) and *Bookings per Participant* (RHBUCH00_LSO).

Digital signature functionality is implemented in SAP Learning Solution using the secure store and forward (SSF) mechanism, an interface that allows the system supporting SAP software to protect data and documents using digital signatures and encryption.

The data is protected even if it leaves the system. It may be saved independently on data carriers or transmitted over communication paths without affecting protection. Protection is provided using an external security product that is available to SAP software using the SSF interface. The SSF interface makes use of Public-Key Cryptography Standards (PKCS).

In the standard delivery of SAP Learning Solution, the interface is implemented to validate against the back-end user, a business object in SAP ECC that collects information on a given learner.

Secure store and forward mechanisms provide you with the means to secure data and documents in SAP software as independent data units. By using SSF functions, you can “wrap” data and digital documents in secure formats before they are saved on data carriers or transmitted over (possibly) insecure communication links. Once you save the data in a secure format in SAP software, it remains in its secured format even if you export it out of the system.

SSF mechanisms use digital signatures and digital envelopes to secure digital documents. The digital signature uniquely identifies the signer, is not forgeable, and protects the integrity of the data. Any changes made to data after a digital signature is applied result in an invalid digital signature for the altered data. The digital envelope ensures the contents of the data are only visible to the intended recipient(s).

Secure store and forward mechanisms are useful in those application areas where an increased level of security exists pertaining to:

- Specific and unique identification of persons or components (for example, in workflow processes)
- Nonrepudiation or proof of obligation (for example, in signing of paperless contracts)
- Authenticity and integrity of data (for example, in saving audit logs)
- Sending or storing of confidential data

By using interfaces in SAP software such as SAP Learning Solution to connect SSF products, you can replace paper documents and handwritten signatures with automated processes and digital documents that are secured with digital signatures and digital envelopes.

Constraints

Third-Party Security Product

Secure store and forward requires the use of a third-party security product to provide its functionality. As the default provider, we deliver the SAP security library (SAPSECULIB) with SAP software. The SAPSECULIB, however, is limited to providing digital signatures only. For digital envelopes, encryption, or crypto hardware (for example, smart cards, or crypto boxes), you need to use an external security product that has been certified by SAP. For a product to be certified by SAP, it must support the PKCS #7 Cryptographic Message Syntax Standard. For information about products designed for use with SAP software, see the listing of complementary software offerings at www.sap.com/partners/directories/index.epx.

Public-Key Infrastructure

To effectively use the secure store and forward mechanisms discussed you need to have an established public-key infrastructure (PKI). The PKI ensures that you can validate and trust the digital signatures, certificates, and certification authorities (CAs). A PKI is often, although not necessarily, supported by external security products available on the market. Although SAP software does not provide a PKI directly, it does support PKIs provided by various security products.

Depending on the security product used, you can establish a PKI in one of many ways. You may want to create your own PKI and CA that you link to your customers, or you and your customers may want to agree on a common trust center. A common trust center is a third-party instance that both you and your customers can trust to validate and authenticate your PKI participants. Using a common trust center can solve many of the currently open questions regarding the establishment of a PKI.

Compliance of SAP Learning Solution with FDA Title 21 CFR Part 11

The following table summarizes how SAP Learning Solution complies with each requirement of Part 11.

Part 11 Clause	SAP Assessment of SAP® Learning Solution
11.10(a)	According to FDA regulations for training, good manufacturing practices (GMP) compliance is necessary to address "training needs" (personnel development). Change documents can be written for personnel development objects, and therefore a complete audit trail is available. The audit trail records are secured from unauthorized access.
11.10(b)	All electronic records generated in SAP® Learning Solution are accurate, complete, and presented in a human readable format. Electronic records in SAP Learning Solution can be printed or exported into several industry-standard formats such as Adobe PDF and XML.
11.10(c)	All electronic records can be maintained in the active database to accommodate all required retention periods even when software is upgraded. Access to these records is secured by authorization profiles.
11.10(d)	Robust security administration and authorization profiles assure system access. You record changes to security profiles in the SAP NetWeaver® Application Server component.
11.10(e)	According to FDA regulations for training, GMP compliance is necessary to address "training needs" (personnel development). Change documents can be written for personnel development objects, and therefore a complete audit trail is available. The audit trail records contain all data demanded by the regulation and are secured from unauthorized access.
11.10(f)	You can control the processing statuses of objects in SAP Learning Solution using status and workflow management, and so enforce the proper sequence of operations as required by the applicable regulation.
11.10(g)	SAP NetWeaver Application Server executes authority checks in conjunction with its robust security administration and authorization profiles to ensure only authorized individuals can access the system, electronically sign a record, and access or perform the operation at hand. SAP NetWeaver Application Server also records changes to authorization profiles.
11.10(h)	Input devices such as terminals, as well as remote logons are maintained through the same SAP security administration software and require authorization profiles for connection to the SAP ERP application. In addition, SAP ERP manages and controls device checks (for example, device type and device status) to verify the validity of the information source via classification software in SAP ERP.
11.10(i)	The product innovation life cycle for SAP development requires that all personnel responsible for developing and maintaining SAP products have the education, training, and experience to perform their assigned tasks. A wide range of additional education and training offerings and regular assessments of individual training requirements ensure a process of continuous learning for staff involved in the development and support of all SAP software.

11.10(j)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.10(k)	SAP ERP maintains the electronic records (audit trail) for revision and change control according to clause 11.10(e).
11.30	For open systems, SAP NetWeaver Application Server supports interfaces with complementary software partners that supply cryptographic methods such as public-key infrastructure technology.
11.50(a)	Within SAP Learning Solution, electronic records of electronic or digital signatures executed within this system contain the printed name of the signer, the system date and time when the signature was executed, and the meaning (such as review, approval, responsibility, or authorship) associated with the signature.
11.50(b)	Within SAP Learning Solution, the signature records are displayed or printed with the associated electronic record.
11.70	Within SAP Learning Solution, electronic signatures are linked to their respective electronic records. This linking and the electronic signature cannot be deleted, copied, changed, or falsified.
11.100(a)	SAP Learning Solution enforces uniqueness and prevents re-allocation of an electronic signature or deletion of information related to the signature once it has been used.
11.100(b)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.100(c)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.200(a)(1)	SAP Learning Solution requires two distinct components – a user ID and a password – to perform an electronic signature. By design, SAP NetWeaver Application Server does not support continuous sessions where only a single component is necessary subsequent to the first signing.
11.200(a)(2)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.200(a)(3)	SAP Learning Solution user- and security-administration functions ensure that the attempted use of an individual's electronic signature by someone other than the genuine owner requires the collaboration of two or more individuals.
11.200(b)	SAP NetWeaver Application Server provides a certified interface to biometric devices such as fingerprint and retinal scanning devices. Look for products that have been certified by SAP in the SAP Service Marketplace extranet. Implementation of biometric devices for use with SAP Learning Solution requires a customer-specific implementation.
11.300(a)	SAP NetWeaver Application Server user and security administration functions provide the necessary controls to ensure that no two individuals have the same combination of identification code (user ID) and password.

11.300(b)	You can configure SAP NetWeaver Application Server to force users to change passwords at various intervals. It provides system checks to prevent users from repeating passwords or using combinations of alphanumeric characters that are included in the user ID. You can also invalidate user IDs, for example, when an employee leaves the company.
11.300(c)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.
11.300(d)	SAP NetWeaver Application Server fulfills this requirement and behaves as demanded by the requirement.
11.300(e)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of the computer system.

REFERENCES

For more information, look up the following references, many of which are found in the SAP Service Marketplace extranet (authorization required):

- help.sap.com: *SAP NetWeaver '04 Security Guide*
- help.sap.com: *SAP NetWeaver 2004s Security Guide*
- help.sap.com: *Digital Signatures and Encryption*
- SAP white paper: “Complying with U.S. FDA Title 21 CFR Part 11 for the Life Sciences Industry”
- SAP white paper: “SAP NetWeaver: Providing the Building Blocks for Effective Governance, Risk, and Compliance Management”
- SAP white paper: “U.S. FDA Title 21 CFR Part 11 Compliance Assessment of SAP NetWeaver”
- SAP Best Practices, Digital Signatures in SAP Applications. SAP Web Application server 640, SAP AG, 2003
- Implementation guide titled *Digital Signature Tool* (attached in SAP Note 700495)
- FDA Title 21 CFR Part 11 Electronic Records; Electronic Signatures: Final Rule, March 1997
- help.sap.com: *Learning Solution*
- SAP Learning solution brief: “SAP Learning Solution: Preintegrated with mySAP ERP”

Authors:

Dr. Anja Modler-Spreitzer and Dr. Christoph Roller

Industry Business Unit, Consumer Products & Life Sciences, SAP