



**U.S. FDA TITLE 21
CFR PART 11
COMPLIANCE ASSESSMENT
OF mySAP™ SUPPLIER
RELATIONSHIP
MANAGEMENT 4.0**

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SUMMARY

Based upon the interpretation of the Part 11 rule of the U.S. Food and Drug Administration's (FDA's) Title 21 Code of Federal Regulations (CFR) and the functions and features discussed within this document, SAP AG believes that version 4.0 of the mySAP™ Supplier Relationship Management (mySAP SRM) application complies technically with the intent and requirements of Title 21 CFR Part 11.



FDA TITLE 21 CFR PART 11 ASSESSMENT

Security

Version 4.0 of the mySAP SRM application is built on the SAP NetWeaver® Application Server (SAP NetWeaver AS) component. Therefore, all security features of SAP NetWeaver AS are valid for mySAP SRM 4.0.

E-Records

mySAP SRM 4.0 contains the following change-document objects: shopping basket, purchase order, contract, confirmation, and invoice.

These change-document objects contain the following information:

- Old value of an attribute of the changed business object
- New value of this attribute
- Person who changed the value (Note: user ID is written on the database, and full name of user is displayed)
- Date and time of change, that is, Coordinated Universal Time
- Action (such as create, modify, or delete)

Versions of Purchasing Documents

The SAP® Enterprise Buyer (SAP EB) component of mySAP SRM enables version management for purchasing documents. As a first step toward version management, you can display versions of **purchase orders** and **contracts**.

SAP EB creates a version in the background if you, as a purchaser, carry out one of the following actions:

- Change a posted purchase order
- Order a posted purchase order again
- Change a contract that has already been released
- Release an already-released contract again

In contrast to the change documents that retain a change history, a version displays the status of a document at a specific point in time.

Version management provides a check for you when, as a purchaser, you wish to display a purchase order in the form in which you transferred it to the vendor on a specific day. A version provides the clarity you need, for example, when negotiating a contract.

Archiving objects are available for the shopping basket of change-document objects as well as for the purchase order, contract, request for proposal, bid, confirmation, and invoice.

For restrictions that are **not critical per good manufacturing practice guidelines**, no changes are logged regarding price, condition, or related issues.

Digital Signature

You cannot configure mySAP SRM 4.0 to handle digital signatures.

Option 1 (Recommended): Encapsulated Signature Tool in SAP NetWeaver AS

This powerful tool enables SAP customers to include signature functionality in any transaction or business process within the mySAP Business Suite family of business applications. Because the tool can be integrated into any of these business applications, it enables all transactions and workflow to include signature functionality.

The tool can be used with earlier versions of SAP NetWeaver AS (formerly known as SAP Web Application Server), but only with versions 6.20 or higher. For further information, refer to the implementation guide, *Digital Signature Tool*, available in note 700495 in the SAP Notes service.

Option 2: Consulting Solution

A digital signature can easily be implemented via a **consulting solution** that has been implemented successfully with several customers. This solution leverages the capabilities of the SAP NetWeaver Exchange Infrastructure component. Implementation is performed via a separate consulting project as follows:

- The solution focuses on invoices (received from suppliers) that can be configured to handle other supplier relationship management documents as well.
- It supports the qualified as well as nonqualified digital signature process.
- The solution is owned by the SAP Consulting organization, which also offers the resources needed for its implementation.

How Does mySAP SRM 4.0 Comply with Part 11?

The following table summarizes how the SAP application complies with each requirement of Part 11 of the FDA's Title 21 CFR.

Part 11 Clause	Additional Comments
11.10(a)	All electronic records within the mySAP™ Supplier Relationship Management (mySAP SRM) application provide adequate audit trails that can be reviewed for information. These records are secured from unauthorized access.
11.10(b)	All electronic records generated in mySAP SRM are accurate, complete, and presented in a human-readable format. mySAP SRM electronic records can be printed or exported into several industry-standard formats such as ASCII.
11.10(c)	All electronic records can be maintained in the active database or archived to accommodate all required retention periods even when software is upgraded. Access to these records is secured using standard SAP® authorization profiles.
11.10(d)	Robust security administration and authorization profiles assure access to mySAP SRM. Changes to security profiles are recorded in the SAP NetWeaver® Application Server (SAP NetWeaver AS) component.
11.10(e)	The SAP Supplier Relationship Management component automatically generates all electronic records for creating, modifying, or deleting data. These records are date and time stamped and include the user ID of the individual who is logged on the system and performed the action. Electronic records also maintain the old and new values of the change and the transaction used to generate the record.

11.10(f)	Not applicable
11.10(g)	mySAP SRM and SAP NetWeaver AS execute authority checks in conjunction with robust security administration and authorization profiles to ensure only authorized individuals can access mySAP SRM and access or perform the operation at hand. SAP NetWeaver AS also records changes to authorization profiles.
11.10(h)	Not applicable
11.10(i)	The Product Innovation Lifecycle guidelines in the SAP Development Services offering require that all personnel responsible for developing and maintaining mySAP SRM 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 SAP staff involved in the development and support of all SAP software.
11.10(j)	Not applicable
11.10(k)	mySAP SRM maintains the electronic records for revision and change control according to clause 11.10(e).
11.30	For open systems, SAP NetWeaver AS supports interfaces with complementary software partners that supply cryptographic methods such as public key infrastructure technology.
11.50(a)	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by the SAP Consulting organization, or you can implement the encapsulated signature tool to satisfy the requirements.
11.50(b)	You can implement the encapsulated signature tool to satisfy the requirements, or a digital signature consulting solution offered by SAP Consulting can be implemented to satisfy the requirements.
11.70	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by SAP Consulting.
11.100(a)	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by SAP Consulting, or you can implement the encapsulated signature tool to satisfy the requirements.
11.100(b)	Not applicable
11.100(c)	Not applicable
11.200(a)(1)	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by SAP Consulting, or you can implement the encapsulated signature tool to satisfy the requirements.
11.200(a)(2)	Not applicable
11.200(a)(3)	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by SAP Consulting, or you can implement the encapsulated signature tool to satisfy the requirements.

Part 11 Clause	Additional Comments
11.200(b)	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by SAP Consulting, or you can implement the encapsulated signature tool to satisfy the requirements. SAP NetWeaver AS provides a certified interface to biometric devices such as fingerprint and retinal scanning devices. Look for certified vendors in the complementary software program published on the SAP Service Marketplace extranet.
11.300(a)	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by SAP Consulting, or you can implement the encapsulated signature tool to satisfy the requirements. SAP NetWeaver AS 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)	A digital signature consulting solution can be implemented to satisfy the requirements. It is offered by SAP Consulting, or you can implement the encapsulated signature tool to satisfy the requirements. SAP NetWeaver AS can be configured to force users to change passwords at various intervals. It also provides system checks to prevent users from repeating passwords or using combinations of alphanumeric characters that are included in the user ID. User IDs can also be invalidated – for example, when an employee leaves the company.
11.300(c)	Not applicable
11.300(d)	<p>mySAP SRM and SAP NetWeaver AS provide the following security features:</p> <ul style="list-style-type: none"> ■ When failed attempts to enter the system (via either logon or signature) exceed a certain number, the SAP software prevents further access without intervention from the security administration. Note: administrators can configure the number of failed attempts allowable. ■ When you need to bring an issue to the security administration in an immediate and urgent manner, SAP NetWeaver AS enables you to generate an express mail in the SAP software system and send it to a defined distribution list. In addition, you can interface SAP NetWeaver AS with any messaging system compliant with the messaging application program interface, enabling you to send the message externally to e-mail systems such as Microsoft Exchange or even to a paging system. <p>An electronic record of all failed attempts (for either logon or signature) is maintained in the security audit log of the SAP Solution Manager tool. SAP NetWeaver AS also generates electronic records for the locking and unlocking of users.</p>
11.300(e)	Not applicable

REFERENCES

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

- “Complying with U.S. FDA Title 21 CFR Part 11 for the Life Sciences Industry” white paper, www.sap.com/usa/solutions/grc/pdf/BWP_FDA_Title21.pdf
- SAP white papers “Financial Supply Chain Management with SAP,” “Delivering Operational Excellence with Innovation,” and “Adaptive Business Networks: A Strategy for Mastering Change and Efficiency in Manufacturing”
- *Digital Signatures in SAP Applications – SAP Best Practices Guide*
- *Digital Signature Tool*, an implementation guide available in note 700495 in SAP Notes
- FDA Title 21 CFR Part 11 Electronic Records; Electronic Signatures: Final Rule, March 1997, available at www.fda.gov/ora/compliance_ref/part11/

Authors:

Dr. Christoph Roller

Dr. Anja Modler-Spreitzer

IBU Consumer Products & Life Sciences, SAP

www.sap.com/contactsap

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