



U.S. FDA TITLE 21 CFR PART 11 COMPLIANCE ASSESSMENT OF SAP® SRM

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SUMMARY

On the basis of the interpretation of the FDA Title 21 CFR Part 11 rule of the U.S. Food and Drug Administration and the functions and features discussed within this document, SAP AG believes that the SAP® Supplier Relationship Management (SAP SRM) 5.0 component technically complies with the intent and requirements of FDA Title 21 CFR Part 11.



FDA TITLE 21 CFR PART 11 ASSESSMENT

Security

The SAP SRM 5.0 component is built on the SAP NetWeaver® Application Server (SAP NetWeaver AS) component. Therefore, all security features of SAP NetWeaver AS are valid for SAP SRM 5.0.

E-Records

SAP SRM 5.0 contains the following change document objects: shopping basket, purchase order, contract, request for proposal, bid, 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 (user ID written on the database and full name of user displayed)
- Date and time of change, in terms of Coordinated Universal Time (UTC)
- Action (create, modify, or delete)

Versions of Purchasing Documents

The SAP Enterprise Buyer component of SAP SRM provides you with version management for purchasing documents. As a first step, you can display versions of purchase orders and contracts.

SAP Enterprise Buyer creates a version 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 as a purchaser, for example, if you wish to display a purchase order in the form in which you transferred it to the vendor on day X. A version provides clarity in areas such as negotiations on a contract.

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

For restrictions that are not critical as per good manufacturing practice (GMP) guidelines, SAP Enterprise Buyer does not log changes regarding price, condition, or related issues.

Digital Signature

You cannot configure SAP SRM to handle digital signatures.

Encapsulated Signature Tool in SAP NetWeaver AS

The powerful encapsulated signature tool in SAP NetWeaver AS enables you to include signature functionality in any transaction or business process within the mySAP™ Business Suite family of business applications.

The tool can be integrated into any business area in mySAP Business Suite.

The encapsulated signature tool enables all transactions and work flow in mySAP Business Suite to include signature functionality. You must have release 6.20 or higher of SAP NetWeaver AS (formerly named SAP Web Application Server). For further information, refer to the implementation guide titled *Digital Signature Tool*. (See “References” below.)

How SAP SRM 5.0 Complies with Part 11

The following table summarizes how SAP SRM 5.0 complies with each requirement of Part 11.

SAP® SRM 5.0: Part 11 Compliance

| Part 11 Clause | SAP Assessment of SAP® SRM 5.0 |
|----------------|---|
| 11.10(a) | All electronic records within SAP SRM provide adequate audit trails that you can review for information. SAP SRM secures these records from unauthorized access. |
| 11.10(b) | All electronic records generated in SAP SRM are accurate, complete, and presented in a human-readable format. SAP SRM electronic records can be printed or exported into several industry-standard formats, such as ASCII. |
| 11.10(c) | You can maintain all electronic records in the active database or archive the records to accommodate all required retention periods, even when the software is upgraded. Access to these records is secured by standard authorization profiles of SAP software. |
| 11.10(d) | Robust security administration and authorization profiles assure system access. Changes to security profiles are recorded in SAP NetWeaver® AS. |
| 11.10(e) | SAP SRM automatically generates all electronic records for creating, modifying, or deleting data. These records are date stamped and time stamped and include the user ID of the individual who is logged on the system and who 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) | This is not applicable to SAP SRM. |
| 11.10(g) | SAP SRM and SAP NetWeaver AS execute authority checks in conjunction with the robust security administration and authorization profiles of SAP NetWeaver AS to ensure that only authorized individuals can access the system and access or perform the operation at hand. SAP NetWeaver AS also records changes to authorization profiles. |
| 11.10(h) | This is not applicable to SAP SRM 5.0. |
| 11.10(i) | The product innovation life cycle (PIL) for SAP development requires that all personnel responsible for developing and maintaining SAP 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 staff involved in the development and support of all SAP software. |
| 11.10(j) | This is not applicable to SAP SRM 5.0. |
| 11.10(k) | SAP 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 (PKI) technology. |

| | |
|--------------|--|
| 11.50(a) | 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. |
| 11.70 | You can implement the encapsulated signature tool to satisfy the requirements. |
| 11.100(a) | You can implement the encapsulated signature tool to satisfy the requirements. |
| 11.100(b) | This is not applicable to SAP SRM 5.0. |
| 11.100(c) | This is not applicable to SAP SRM 5.0. |
| 11.200(a)(1) | You can implement the encapsulated signature tool to satisfy the requirements. |
| 11.200(a)(2) | This is not applicable to SAP SRM 5.0. |
| 11.200(a)(3) | You can implement the encapsulated signature tool to satisfy the requirements. |
| 11.200(b) | 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 SAP-certified security partners in the SAP Service Marketplace extranet. |
| 11.300(a) | You can implement the encapsulated signature tool to satisfy the requirements. The user and security administration functions of SAP NetWeaver AS 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 implement the encapsulated signature tool to satisfy the requirements. You can configure SAP NetWeaver AS to force users to change passwords at various intervals, and the component 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 is not applicable to SAP SRM 5.0. |
| 11.300(d) | SAP SRM 5.0 and SAP NetWeaver AS provide the following features: <ul style="list-style-type: none"> ■ When the number of failed attempts (for either logon or signature) is exceeded, the SAP software prevents the user from further access, without intervention from the security administration. Note that the number of failed attempts allowed is configurable. ■ SAP NetWeaver AS generates an express mail in the SAP software system and sends it to a defined distribution list to notify the security administration in an immediate and urgent manner. In addition, you can interface any messaging system compliant with the messaging application programming interface (MAPI) to SAP NetWeaver AS to send the message externally to e-mail systems such as Microsoft Exchange or even a paging system. ■ An electronic record of all failed attempts (for either logon or signature) is maintained in the security audit log of SAP NetWeaver AS. SAP NetWeaver AS also generates electronic records for the locking and unlocking of users. |
| 11.300(e) | This is not applicable to SAP SRM 5.0. |

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)
- “Financial Supply Chain Management with SAP” (white paper, www.sap.com/solutions/business-suite/erp/financials/pdf/BWP_WP_FSCM.pdf), “Delivering Operational Excellence with Innovation” (white paper, www.sap.com/solutions/esa/pdf/BWP_Delivering_Operational_Excellence.pdf), and “Adaptive Business Networks: A Strategy for Mastering Change and Efficiency in Manufacturing” (white paper, www.sap.com/solutions/business-suite/scm/pdf/BWP_WP_Adaptive_Bus_Networks_Mfg.pdf)
- *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 (www.fda.gov/ora/compliance_ref/part11/)

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