



**U.S. FDA TITLE 21  
CFR PART 11  
COMPLIANCE ASSESSMENT  
OF THE INTERACTION CENTER  
OF SAP® CRM**

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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 interaction center (IC) component of the SAP® Customer Relationship Management (SAP CRM) 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 IC of SAP CRM 5.0 is built on the SAP NetWeaver® Application Server (SAP NetWeaver AS) component. Therefore, all security features of SAP NetWeaver AS are valid for the IC.

For either IC logon option – via IC WinClient or via a URL call of business server pages (BSPs) IC WebClient – SAP CRM supports the ability to change passwords. In addition, SAP CRM supports other processes, such as setting the frequency for automatic password changes, electronic logs, and so on, via SAP NetWeaver AS.

The user logs on to the IC with a user ID and password. Separately, the user logs on to SAP CRM with a user ID and password.

Direct access from the IC of SAP CRM to the mySAP™ ERP application is possible via SAP NetWeaver AS and requires a trusted system connection (see the SAP Notes service, note 128447).

Direct access from the IC of SAP CRM to SAP R/3® 4.6C and SAP R/3 Enterprise software is possible via an application programming interface (API) and requires a trusted system connection (see note 128447).

### E-Records

SAP NetWeaver AS creates electronic records for all processes, and you can track a complete call. These records are stored in change documents, and you can enforce creation of the records in the customizing process as mandatory. This is a back-end-based process. If the user changes the data later on, change history is available.

Because SAP CRM 5.0 is connected to the IC, SAP CRM always uses the same data model for sales order, activity, and lead, which all have change documents associated with them.

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 (full name and user ID)
- Date and time of change, in terms of Coordinated Universal Time (UTC)
- Action (create, modify, or delete)

### Archiving

Archiving objects are available for the change documents.

### Digital Signature

You cannot configure the IC to handle digital signatures.

Nevertheless, you can easily implement digital signature functionality via the encapsulated signature tool in SAP NetWeaver AS, with help from the SAP Consulting organization.

You can integrate the tool into any business area in the mySAP Business Suite family of business applications.

All transactions and workflow of mySAP Business Suite can include signature functionality with the encapsulated signature tool. You must have release 6.20 or higher of SAP NetWeaver AS (formerly named SAP Web Application Server) for use of the encapsulated signature tool. For further information, refer to the implementation guide titled *Digital Signature Tool* (see “References” below).

Note that the IC uses the SAP NetWeaver 2004s platform.

**How the IC of SAP CRM 5.0 Complies with FDA Title 21 CFR Part 11**

The following table summarizes how the (IC) component of SAP CRM 5.0 complies with each requirement of Part 11.

<b>Part 11 Clause</b>	<b>SAP Assessment of the IC Component of SAP® CRM 5.0</b>
11.10(a)	All electronic records within the interaction center (IC) of the SAP® Customer Relationship Management (SAP CRM) 5.0 component provide adequate audit trails that you can review for information. The IC secures these records from unauthorized access.
11.10(b)	All electronic records generated in the IC are accurate, complete, and presented in a human-readable format. Electronic records from the IC 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. You can secure access to these records using standard authorization profiles of SAP software.
11.10(d)	Robust security administration and authorization profiles assure system access. The SAP NetWeaver® Application Server (SAP NetWeaver AS) component records the changes to security profiles.
11.10(e)	The IC 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 to 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 the IC of SAP CRM 5.0.
11.10(g)	The IC of SAP CRM 5.0 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 software 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 the IC of SAP CRM 5.0.
11.10(i)	The product innovation life cycle (PIL) for SAP development requires that all personnel responsible for developing and maintaining the IC of SAP CRM 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 the IC of SAP CRM 5.0.
11.10(k)	The IC maintains the electronic records (audit trail) 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 the IC of SAP CRM 5.0.
11.100(c)	This is not applicable to the IC of SAP CRM 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 the IC of SAP CRM 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.

Part 11 Clause	SAP Assessment of the IC Component of SAP CRM 5.0
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 the IC of SAP CRM 5.0.
11.300(d)	<p>The IC of SAP CRM 5.0 and SAP NetWeaver AS provide the following features:</p> <ul style="list-style-type: none"> <li>■ 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.</li> <li>■ 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 program interface (MAPI) to SAP NetWeaver AS to send the message externally to e-mail systems such as Microsoft Exchange or even a paging system.</li> <li>■ 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.</li> </ul>
11.300(e)	This is not applicable to the IC of SAP CRM 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](http://www.sap.com/usa/solutions/grc/pdf/BWP_FDA_Title21.pdf))
- *Solution Management Guide: SAP CRM 5.0*
- *Security Guide SAP: CRM 5.0*
- *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 20, 1997 ([www.fda.gov/ora/compliance\\_ref/part11/](http://www.fda.gov/ora/compliance_ref/part11/))

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