



U.S. FDA Title 21 CFR Part 11 Compliance Assessment of SAP CRM Sales and Field Sales

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1 Summary

Based upon SAP AG's interpretation of the U.S. FDA Title 21 Code of Federal Regulations Part 11 (21 CFR Part 11) rule and the functions and features discussed within this document, SAP AG believes that the SAP CRM Sales and Field Sales software fully comply with 21 CFR Part 11.



2 U.S. FDA Title 21 CFR Part 11 Compliance Assessment

2.1 SAP CRM

SAP Customer Relationship Management (SAP CRM) is a comprehensive solution for managing your business relationships with your customers. It supports all customer-focused business areas, from marketing to sales and service, as well as customer interaction channels, such as the Interaction Center, the Internet, and mobile clients.

Sales as a key capability of SAP CRM guides you through the processing of the sale – from the first contact, to quotation and order processing, through to invoice creation. It enables you to manage your sales processes, such as your business-related tasks and appointments, as well as your customers and contact persons. It also allows you to organize and structure your sales territories, and to pursue opportunities for sales.

Field Sales for the Pharmaceutical Industry: You can use this business scenario to control field sales activities for the pharmaceuticals industry. Above all, it enables you to check which areas generate the highest sales revenue, and to plan, execute, and document calls accordingly. You can use the *SAP Enterprise Portal*, a tablet computer, or a laptop to plan, execute, and document the calls.

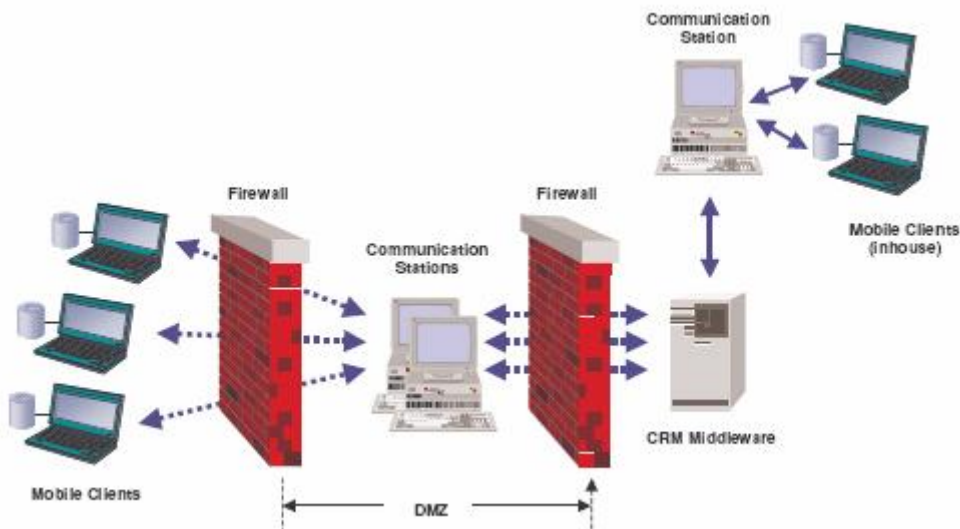
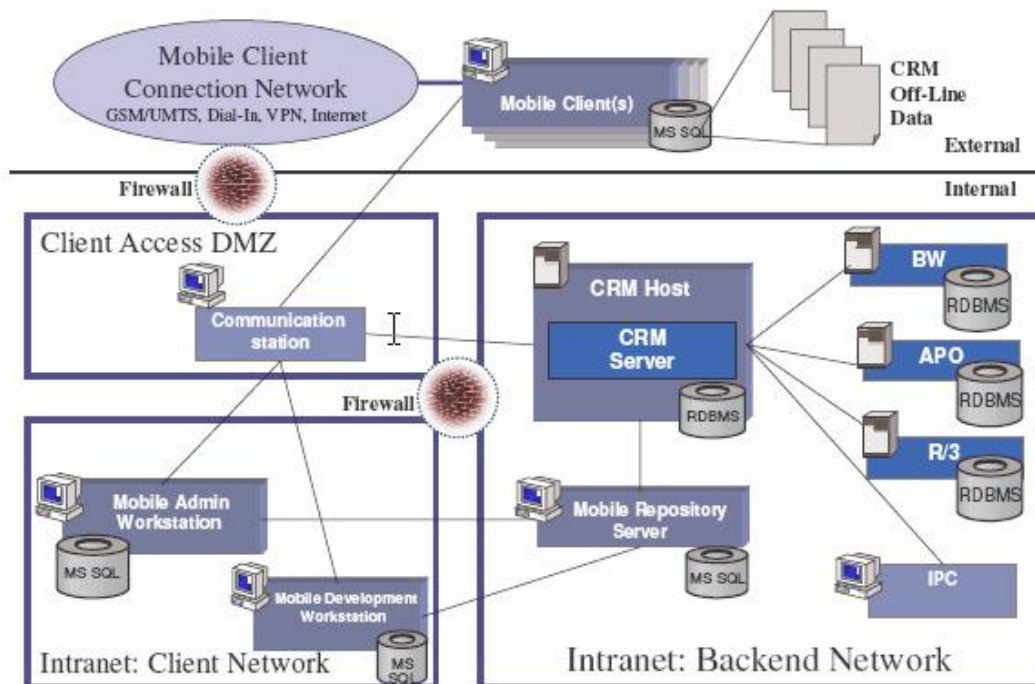
One of the main purposes of any call is to provide physicians with samples. A drug sample is a sample pack of a medicine and is intended as a lead to further prescriptions for this medicine. The physician gives the sample pack to patients at the start of therapy to cover a weekend, or to keep the costs of their treatment down, for example. Since drug samples are an incentive for physicians to meet with field sales representatives, they form an important part of pharmaceuticals marketing. The production of samples and the logistics for their distribution make up a large proportion of the marketing tasks for a medicine.

You can use the business scenario *Field Sales for the Pharmaceuticals Industry* to develop and document additional forms of contact between field sales and physicians, such as correspondence or contact by e-mail or telephone. The scenario enables you to target and consolidate your company's channels of communication and other sales departments, such as its other lines of pharmaceutical field sales.

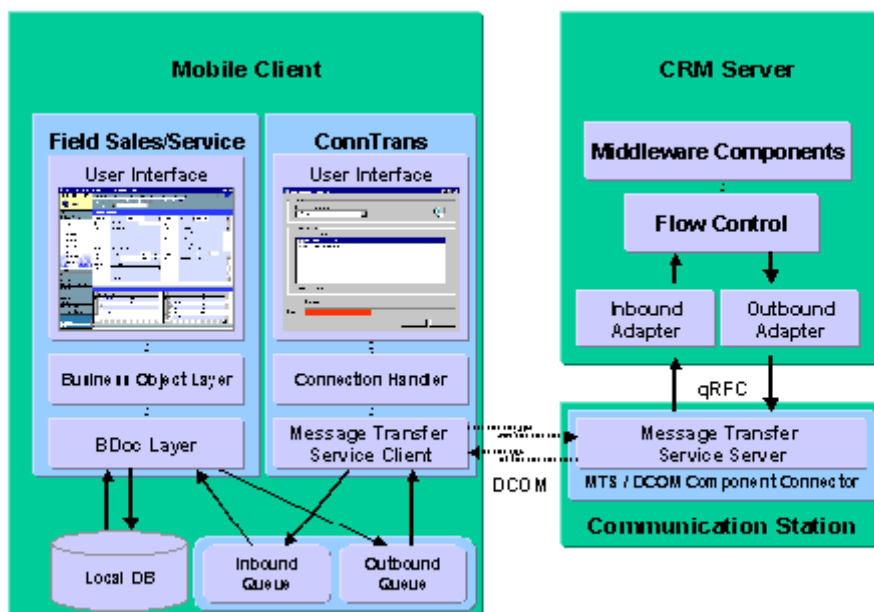
This business scenario has the following scenario variants:

- Field Sales for the Pharmaceutical Industry (Portal)
- Field Sales for the Pharmaceuticals Industry (Mobile Sales)

The SAP CRM key capability CRM Mobile Sales typically involves a special type of users: mobile users. Because of the mobility special technical equipment and communication technologies must be used. In addition mobile users need to operate off-line from the server systems and therefore the necessary data must be stored locally in the mobile device, which usually is a laptop. The following picture show a typical system landscape enabling mobile access to a SAP CRM system:



CRM Middleware links together the various types of data producers (mobile clients, ERP systems, and so on) within a CRM landscape, and provides all components with the necessary information. CRM integration services enable you to replicate, synchronize, and distribute data, for example, between a branch office and mobile field sales representatives. All Middleware Processes take place behind the firewall.



The following investigation will concentrate on Sales, Mobile Sales and Synchronization aspects (CRM Middleware) of SAP CRM 5.0 and following releases. For Part 11 Compliance of the SAP Portal scenario please see the Whitepaper "U.S. FDA Title 21 CFR Part 11 Compliance Assessment of SAP NetWeaver® Portal".

2.2 Security

SAP CRM is built on SAP NetWeaver Application Server. Therefore, all security features of SAP NetWeaver Application Server are valid for SAP CRM. For details please refer to the document "21 CFR Part 11 Compliance Assessment of SAP NetWeaver '04 Application Server".

The security guides for SAP CRM describe all relevant aspects of security for CRM Enterprise, Mobile Sales and SAP CRM powered by SAP NetWeaver as well as network and communication security (e.g. data synchronization). You can find the SAP CRM security guides on the SAP Help Portal (<http://help.sap.com>).

2.3 Electronic Records

2.3.1 FDA Requirement

FDA requires the ability to log and track changes on Business Objects and depending objects in a compliant software environment.

The computer system must provide functionality to log changes, creation and deletion applied to Business Objects and to depending objects (e.g. configuration data). The minimal necessary information the system has to provide is:

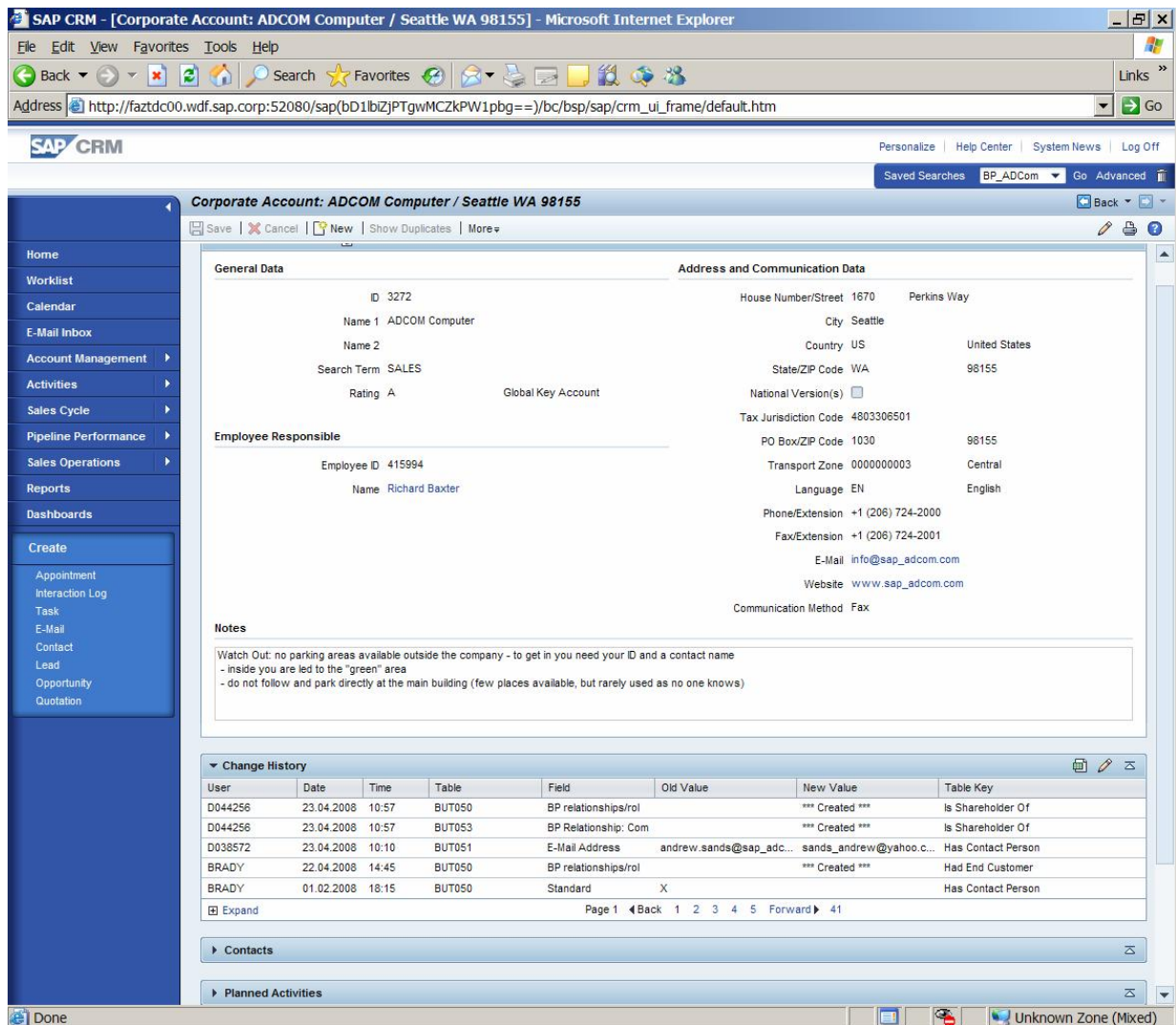
- Old value of an attribute of the changed Business Object
- New value of this attribute

- Person who changed the value
- Date and time of change (Application Server Time)
- Action (create, modify, delete)

2.3.2 Change Management and Tracking

CRM Enterprise provides change documents objects and therefore audit trail for the so-called one-order objects and one-order categories. Change documents objects are written for following one order categories: activities (representing calls in the business process), opportunities, leads, sales transactions including sales order, complaints, investigations, contracts, service transactions including service order, provider contracts and reservations. You can get a even more granular list of the concerned objects in the SAP Implementation Guide (IMG): *Customer Relationship Management → Transactions → Basic Settings → Define Transaction Types*.

Changes of the Business Partner and Products can be tracked via the change history. The assignment blocks for the change history can be made visible in the customized business role or in the personalization. It is then shown in the overview page of the activity. The following screen shots show the change history a business partner as an example:



The screenshot displays the SAP CRM interface for a Corporate Account: ADCOM Computer / Seattle WA 98155. The main content area shows the 'General Data' and 'Address and Communication Data' for the business partner. Below this, the 'Change History' section is expanded, showing a table of changes.

User	Date	Time	Table	Field	Old Value	New Value	Table Key
D044256	23.04.2008	10:57	BUT050	BP relationships/rol		*** Created ***	Is Shareholder Of
D044256	23.04.2008	10:57	BUT053	BP Relationship: Com		*** Created ***	Is Shareholder Of
D038572	23.04.2008	10:10	BUT051	E-Mail Address	andrew.sands@sap_adc...	sands_andrew@yahoo.c...	Has Contact Person
BRADY	22.04.2008	14:45	BUT050	BP relationships/rol		*** Created ***	Had End Customer
BRADY	01.02.2008	18:15	BUT050	Standard	X		Has Contact Person

The interface also includes a sidebar with navigation options like Home, Worklist, Calendar, and a 'Create' section with options like Appointment, Interaction Log, Task, E-Mail, Contact, Lead, Opportunity, and Quotation. The bottom status bar shows 'Done' and 'Unknown Zone (Mixed)'.



To show the available assignment blocks for account – the change history is not visible in the delivered standard – they must be personalized via the button with icon “pencil” in the overview page.



You can choose the assignment blocks to be displayed on the overview page. In addition, you can determine the order in which the assignment blocks are displayed. To display assignment blocks in an open state, select the indicator.

Available Assignment Blocks

Name
Addresses
Address Types
Analytics
Business Hours
Account Plans
Sales Area Data
Notes
Business Appointments
Shareholders
Industries



Displayed Assignment Blocks

Up	Down	Name	Display Expanded
		Account Details	<input checked="" type="checkbox"/>
		Change History	<input type="checkbox"/>
		Contacts	<input checked="" type="checkbox"/>
		Planned Activities	<input checked="" type="checkbox"/>
		Interaction History	<input checked="" type="checkbox"/>
		Relationships	<input type="checkbox"/>
		Attachments	<input checked="" type="checkbox"/>

Save Reset to Default Cancel

Change History							
User	Date	Time	Table	Field	Old Value	New Value	Table Key
D044256	23.04.2008	10:57	BUT050	BP relationships/rol		*** Created ***	Is Shareholder Of
D044256	23.04.2008	10:57	BUT053	BP Relationship: Com		*** Created ***	Is Shareholder Of
D038572	23.04.2008	10:10	BUT051	E-Mail Address	andrew.sands@sap_adc...	sands_andrew@yahoo.c...	Has Contact Person
BRADY	22.04.2008	14:45	BUT050	BP relationships/rol		*** Created ***	Had End Customer
BRADY	01.02.2008	18:15	BUT050	Standard	X		Has Contact Person

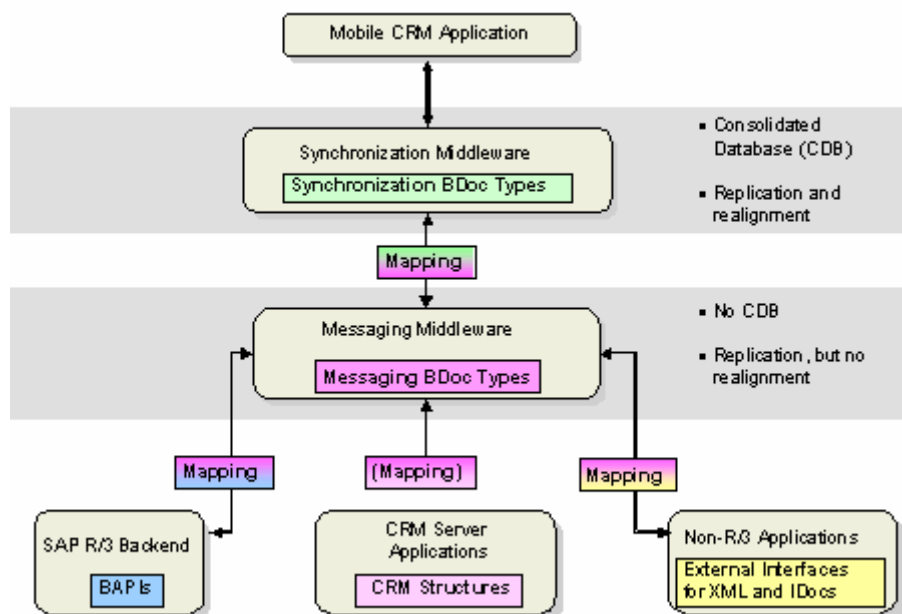
All **CRM Middleware** processes take place behind the firewall. You define distribution rules, and the mapping within the CRM Middleware. The data transfer between the sites (mobile clients) and the CRM server is done via the CRM Middleware. To set up the distribution process only system administrators access the CRM Middleware and its tools.

The data exchange between the CRM Server and the sites (mobile clients) is defined in a replication model. You define distribution rules within the CRM Middleware to determine which site receives which information. The transferred information is packed and encrypted. Business object types are represented technically by means of BDoc types. One single replication object is generated from a BDoc type using the Administration Console. The BDoc messages are passed to the server with a counter. The server receives the BDocs with a counter. When the transfer process was successful the server sends confirmation for each received BDoc to the site reducing the counter. The server processes the packages sequentially. The transfer process from the server to the sites works similarly. The transfer records are logged, but per default deleted after a certain period of time. If you need to maintain the transfer information for longer periods of time, you would have to change the default setting and take care of an appropriate

environment to maintain rapidly growing data amounts. In case of transfer errors an error log is written and the system administrator is informed automatically.

With the provided system monitoring tools you can monitor the entire data exchange via the CRM Middleware centrally or only for certain aspects. Single processes and transactions within CRM Middleware can be monitored and analyzed and logs and statistics can be generated.

Furthermore, tools for a cross-component data integrity check of master data and customizing data are available. The architecture of CRM Middleware provides SAP monitoring functionality (for example provided by the Computing Center Management System) and specific functions, for example for the message flow within the CRM Middleware.



You must be able to track record changes on the **Mobile Client** if PDMA (US Prescription Drug Marketing Act) relevant processes are impacted. This is the case if drug samples are given. A sales rep lists the samples within an activity of a physician call. The activity contains among other data the business partner (physician) data, date and time of the call and the given samples. When the sales rep changes the status of the activity to "Finished" no more changes can be done and the activity will be synchronized automatically the next time the mobile client is on line.

In case of the sales order the replication has to be triggered explicitly via pressing the button "submit". Only then the sales order data are transferred to CRM backend.

As a physician has to sign on the received drug samples the tablet PC offers the possibility of a handwritten signature captured as electronic record. Within a template can be described how the form for sample confirmation by the physician should look like. Structured (samples, lot numbers, etc.) and unstructured data (comments) can be maintained linked together with a signature (binary) element. When the sales rep opens the according form in a sales call he can enter the samples, other relevant information and the physician can sign to confirm that he received the samples. When the sales rep saves the form with the handwritten signature captured as electronic record it can't be changed any more. The signature and the information captured in the form are linked together and protected against falsification. Any attempt of violation re-



sults in an invalid signature. The form with the signature is synchronized to the CRM server the next time when the client is online.

The synchronization process itself of the mobile client to the CRM server uses in parts a general user. This is not an issue for traceability as the CRM server receives the activity, sample and sales order information together with the user name responsible and date and time of the release. After these objects had been released or finished no changes could be done on the mobile client. If changes are done on the CRM server side on those objects change document objects will be written.

2.4 Digital Signature

In case digital signature is needed within SAP CRM Enterprise processes the encapsulated signature tool in SAP NetWeaver Application Server can be implemented on a project basis. Here are some of the particulars:

- The software must consist entirely of coding from the ABAP™ programming language – which is the case for SAP CRM Enterprise – as a prerequisite for using the encapsulated signature tool. The prerequisite does not apply to user interfaces; the tool can also be utilized with user interfaces programmed in a language other than ABAP such as JAVA. In this case, security and authentication issues have to be considered carefully to avoid security gaps.
- You must have SAP NetWeaver Application Server 6.20 or higher to use the encapsulated signature tool.

For further information refer to the implementation guide titled Digital Signature-Tool (SAP note 700495).

Digital Signatures are application requirements and therefore not part of SAP CRM Middleware.

For the CRM field sales process “Sample Distribution” in Life Sciences the possibility is offered of a handwritten signature captured as electronic record as described in the chapter before.

2.5 Compliance of SAP CRM with 21 CFR Part 11

The following table summarizes how SAP CRM complies with each requirement of the 21 CFR Part 11 regulation.

Part 11 Clause	Assessment of SAP CRM
11.10(a)	<p>SAP CRM Enterprise offers change management and therefore audit trail for all one order categories which are activities, opportunities, leads, sales transactions including sales order, complaints, investigations, contracts, service transactions including service order, provider contracts and reservations. Change history for the master data such as business partner and products is available as well.</p> <p>When a PDMA critical activity is changed to status “Finished” or “Released” no changes can be done anymore. This concerns sales call activities, drug samples and sales orders. The data synchronized to the CRM server contain user information with date and time of release. In case of a change of the synchronized objects on the server side change</p>

Part 11 Clause	Assessment of SAP CRM
	document objects are written.
	The CRM Middleware takes care that all data transfer processes and the mapping are done correctly. The information flow can be monitored and the transfer protocols can be viewed.
11.10(b)	All electronic records generated in SAP CRM are accurate, complete, and presented in a human readable format. SAP CRM 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 system access. Changes to security profiles are recorded in SAP NetWeaver Application Server.
11.10(e)	<p>SAP CRM Enterprise automatically generates all electronic records for creating, modifying, or deleting data for one order objects and one order categories as well as master data such as business partner and products. 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.</p> <p>Please see clause 11.10(a) for Mobile Client and Middleware.</p> <p>When a data record is deleted the deletion flag is set first. The data record remains still in the system. When the same record is archived it's taken out of the system. The whole transaction is audited via change history.</p>
11.10(f)	SAP CRM provides status and workflow management. In this way you can enforce the proper sequence of operations as required by the applicable regulation.
11.10(g)	SAP CRM is built on SAP NetWeaver Application Server (SAP NW AS). SAP NW AS executes authority checks in conjunction with its robust security administration and authorization profiles to ensure only authorized individuals can access the system and access or perform the operation at hand. SAP NW AS also records changes to authorization profiles.
11.10(h)	The validity check of the source of data or commands from external devices and interfaces for data transferred is done via the CRM Middleware. All processes run behind the firewall.
11.10(i)	<p>The <i>Product Innovation Lifecycle (PIL)</i> for SAP development requires that all personnel responsible for developing and maintaining SAP NW Mobile 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.</p> <p>For documentation services SAP Solution Manager could be used.</p>
11.10(j)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of SAP CRM.
11.10(k)	SAP CRM Enterprise maintains the electronic records (audit trail) for revision and change control according to clause 11.10(e).

Part 11 Clause	Assessment of SAP CRM
11.30	For open systems, SAP CRM supports interfaces with complementary software partners that supply cryptographic methods such as public key infrastructure (PKI) technology.
11.50(a)	The encapsulated signature tool can be implemented in SAP CRM Enterprise to satisfy these requirements.
11.50(b)	The encapsulated signature tool can be implemented in SAP CRM Enterprise to satisfy these requirements.
11.70	The encapsulated signature tool can be implemented in SAP CRM Enterprise to satisfy these requirements.
11.100(a)	The encapsulated signature tool can be implemented in SAP CRM Enterprise to satisfy these requirements.
11.100(b)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of SAP CRM.
11.100(c)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of SAP CRM.
11.200(a)(1)	The encapsulated signature tool can be implemented in SAP CRM Enterprise to satisfy these requirements.
11.200(a)(2)	This clause covers a procedural requirement for customers and is not related to the functions or capabilities of SAP CRM.
11.200(a)(3)	SAP NetWeaver Application Server 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 SAP partners that handle security in the SAP Service Marketplace extranet.
11.300(a)	User and security administration functions of SAP CRM and SAP NW 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 configure SAP CRM and SAP NW AS to force users to change passwords at various intervals, and the software 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 SAP CRM.
11.300(d)	<p>SAP CRM and SAP NW AS provide the following features:</p> <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 NW AS generates an express mail in the SAP software system and sends it

Part 11 Clause	Assessment of SAP CRM
11.300(e)	<p>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.</p> <p>An electronic record of all failed attempts (for either logon or signature) is maintained in the security audit log of SAP NW AS. SAP NW AS also generates electronic records for the locking and unlocking of users.</p> <p>This clause covers a procedural requirement for customers and is not related to the functions or capabilities of SAP CRM.</p>

3 References

- help.sap.com: SAP NetWeaver '04 Security Guide
- help.sap.com: SAP NetWeaver 2004s Security Guide
- 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"
- Digital Signatures in SAP Applications – SAP Best Practices
- Implementation guide entitled *Digital Signature-Tool* (attached in note 700495)
- FDA Title 21 CFR Part 11 Electronic Records; Electronic Signatures: Final Rule, March 1997
- help.sap.com: Electronic Records
- help.sap.com: Customer Relationship Management, CRM Integration Services
- help.sap.com: Customer Relationship Management
- help.sap.com: Customer Relationship Management, Security Guides

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