



**U.S. FDA TITLE 21
CFR PART 11
COMPLIANCE ASSESSMENT
OF SAP NetWeaver®
EXCHANGE INFRASTRUCTURE**

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CONTENTS

- Summary 4

- U.S. Food and Drug Administration (FDA) Title 21 CFR Part 11 Assessment 5
 - Security5
 - E-Records5
 - Archiving5
 - Digital Signature5
 - Compliance of SAP NetWeaver XI with 21 CFR Part 116

- References 7

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 NetWeaver® Exchange Infrastructure (SAP NetWeaver XI)'04 component and the SAP NetWeaver 7.0 technology platform technically comply with the intent and requirements of 21 CFR Part 11.



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

Security

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

E-Records

E-records are objects from the application domain and therefore not part of SAP NetWeaver XI. SAP NetWeaver XI does not own business e-records (unless messages processed by SAP NetWeaver XI are regarded as such).

If SAP NetWeaver XI is used for application-to-application, business-to-business communication, the sending application has to ensure there is linkage between changes to business objects and resulting messages sent out. If messages are changed in the course of processing on the integration server in SAP NetWeaver XI (that is, due to routing and mapping), versions of the message are kept, allowing the reproduction of the message changes. Coordinated Universal Time (UTC) is used for date and time stamp of the messages.

Principal propagation functionality available with SAP NetWeaver XI '04 support package (SP)19 and SAP NetWeaver XI 7.0 SP10 allows the propagation of a user identity from one application through the integration server into another application, and is used in the latter for authentication and authorization checking. SAP NetWeaver XI supports principal propagation for its native protocol, SOAP, and the remote function call (RFC) adapter. The native protocol for SAP NetWeaver XI can be applied with the ABAP™ programming language and Java applications via generated proxies in SAP NetWeaver XI that send and receive messages to and from SAP NetWeaver XI. Also, the adapters enable use of SOAP and allow for RFCs to be sent and received by SAP NetWeaver XI.

User identities can be only forwarded via the proprietary authentication mechanism of the SAP assertion ticket. This means that third-party solutions cannot create but may be enabled to handle SAP assertion tickets.

Archiving

The following is true regarding archiving in SAP NetWeaver XI:

- Archiving functionalities are provided for messages.
- Each messaging component – the integration server (written in ABAP) and the adapter engine (written in Java 2 Platform, Enterprise Edition) – offers archiving possibilities in different variants.
- All message versions that document message processing are archived by the integration server.
- Only one message version is archived by the adapter engine.
- Both components allow for archiving of the line format when message-level security (encryption, signature) is used.
- The archiving interface of the integration server is the archive development kit.
- The archiving interface of the adapter engine supports Web-based distributed authoring and versioning (WebDAV).

Digital Signature

Digital signatures are application requirements and therefore not part of SAP NetWeaver XI.

Compliance of SAP NetWeaver XI with 21 CFR Part 11

The following table summarizes how SAP NetWeaver XI complies with each requirement of Part 11.

Part 11 Clause	SAP Assessment of SAP NetWeaver® XI
11.10(a)	Not applicable (N/A). The SAP NetWeaver® Exchange Infrastructure (SAP NetWeaver XI) component does not own business electronic records (unless messages processed by SAP NetWeaver XI are regarded as such).
11.10(b)	You can display and save content of single messages. Only single messages can be read via an archive monitor and be printed out and exported from this monitor. Reading, printing, and exporting of archived messages are not mass enabled.
11.10(c)	Archiving functionalities are provided for messages.
11.10(d)	<p>End users typically do not have access to SAP NetWeaver XI as it typically facilitates information exchange between different computer systems.</p> <p>Dedicated roles with specific authorization profiles are defined for configuration, administration, and monitoring in SAP NetWeaver XI. Access to message payload can be further restricted.</p> <p>Robust security administration and authorizations assure secure system access. Changes to authorizations are recorded in the SAP NetWeaver Application Server (SAP NetWeaver AS) component.</p>
11.10(e)	<p>Typically, SAP NetWeaver XI uses an anonymous, artificial "technical user" for processing messages. If "principal propagation" is used, the identity of the user initiating a message exchange can be reproduced.</p> <p>Audit trail information cannot be changed by ordinary means.</p> <p>Changes to a record result in the creation of a new record version: previous values remain available.</p>
11.10(f)	Not applicable (N/A)
11.10(g)	<p>SAP NetWeaver XI builds on functionalities in SAP NetWeaver AS to define user roles and authorization profiles.</p> <p>SAP NetWeaver AS 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 AS also records changes to authorizations.</p>
11.10(h)	N/A

11.10(i)	The product innovation life cycle for SAP development requires that all personnel responsible for developing and maintaining SAP NetWeaver AS 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)	N/A.
11.10(k)	N/A
11.30	For open systems, SAP NetWeaver AS supports interfaces with complementary software partners that supply cryptographic methods.
11.50(a)	N/A
11.50(b)	N/A.
11.70	N/A
11.100(a)	N/A
11.100(b)	N/A
11.100(c)	N/A
11.200(a)(1)	N/A
11.200(a)(1)	N/A
11.200(a)(2)	N/A
11.200(a)(3)	N/A
11.200(b)	N/A
11.300(a)	N/A
11.300(b)	SAP NetWeaver AS can be configured to force users to change passwords at various intervals and 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)	N/A
11.300(d)	<p>The SAP NetWeaver Portal component provides the following features to satisfy 11.300(d):</p> <ul style="list-style-type: none"> ■ When the number of failed attempts (for either logon or signature) is exceeded, SAP NetWeaver AS prevents the user from further access without intervention from security administration. Note that the number of failed attempts allowed is configurable. ■ SAP NetWeaver AS generates and sends a message to a defined distribution list to notify the security administration "in an immediate and urgent manner." In addition, any Message Application Program Interface (MAPI)-compliant messaging system can be interfaced to SAP NetWeaver AS to send this message externally to e-mail solutions such as Microsoft Exchange Server or even a paging system. ■ SAP NetWeaver maintains an electronic record of all failed attempts (for either logon or signature) in the security audit log and Java log. SAP NetWeaver AS also generates electronic records for the locking and unlocking of users.
11.300(e)	N/A

REFERENCES

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

- SAP Library: *SAP NetWeaver Application Server Java Security Guide*
- SAP Library: *SAP NetWeaver Application Server ABAP Security Guide*
- SAP Library: *SAP NetWeaver '04 Security Guide*
- SAP PRESS Book *SAP Exchange Infrastructure*
- SAP Exchange Infrastructure documentation (help.sap.com)
- SAP white paper: “Complying with U.S. FDA Title 21 CFR Part 11 for the Life Sciences Industry”
- SAP white paper: “U.S. FDA Title 21 CFR Part 11 Compliance Assessment of SAP NetWeaver”
- *Digital Signatures in SAP Applications: SAP Best Practices Guide*
- SAP Note 700495: attachment, *Digital Signature Tool – implementation guide*
- SAP white paper: “SAP NetWeaver: Providing the Building Blocks for Effective Governance, Risk, and Compliance Management”
- FDA Title 21 CFR Part 11 Electronic Records; Electronic Signatures: Final Rule, March 1997

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