Archiving, records retention, compliance and governance

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AthenaArchiver: 21 CFR 11

This guidance describes how AthenaArchiver meets the U.S. Food and Drug Administration's (FDA's) current requirements regarding the scope and application of Title 21 Code of Federal Regulations Part 11 (21 CFR 11) Electronic Records; Electronic Signatures.

The FDA mandates that companies using electronic signatures and records (in place of handwritten signatures and paper records) must follow 21 CFR 11 guidelines. When applying electronic records to automated systems, operators need to show who did what, when, where, and why. When applying electronic signatures to electronic records, an operator's user name and password must be captured as an electronic signature, which then becomes part of the electronic record.

AthenaArchiver unlocks the full potential of 21CFR compliance and more by:

- Providing a single storage center to manage data throughout the entire company
- Managing the life cycle of data, time-stamping and expiring the data as necessary
- Providing an extremely scalable email archiving architecture
- Delivering benchmark levels of security, traceability, and accountability
- Relieving production servers from storing years of historical email data
- Enhancing internal evaluation and quality control
- Improving the efficiency of FDA reporting, reviews and approvals

Requirements	FDA Perspective	How Athena Complies
Validation	The Agency intends to exercise enforcement discretion regarding the specific Part 11 requirements for validation of computerized systems (§ 11.10(a) and corresponding requirements in § 11.30). Persons must still comply with all applicable predicate rule requirements for validation (e.g., 21 CFR 820.70(i)).	• Provides automatic verification of the accuracy and completeness of stored messages and attachments, ensuring that stored messages are true copies of the original message.
Audit Trail	The Agency intends to exercise enforcement discretion regarding the specific Part 11 requirements related to computer-generated, time-stamped audit trails (§ 11.10 (e), (k)(2) and any corresponding requirement in §11.30). Persons must still comply with all applicable predicate rule requirements related to documentation of, for example, date (e.g., § 58.130(e)), time, or sequencing of events.	• Provides automatic verification of complete and accurate storage of messages, with audit trail of process. • Provides audit trail of all activities related to the message, such as access attempts, in a separate database.
Legacy Systems	The Agency intends to exercise enforcement discretion with regard to legacy systems that otherwise met predicate rule requirements prior to August 20, 1997, the effective date of Part 11. This means that the Agency will not normally take regulatory action to enforce compliance with any part 11 requirements. However, all systems must comply with all applicable predicate rule requirements and should be fit for their intended use.	• Provides an extremely scalable architecture. • Works with MS Exchange mail server, and also with virtually every other email server.

Requirements	**FDA Perspective**	**How Athena Complies**
Copies of Records	The Agency intends to exercise enforcement discretion with regard to the specific Part 11 requirements for generating copies of records (§ 11.10 (b) and any corresponding requirement in §11.30). You should provide an investigator with reasonable and useful access to records during an inspection. All records held by you are subject to inspection in accordance with predicate rules (e.g., §§ 211.180(c),(d) and 108.35(c)(3)(ii)).	• Produces copies of records held in common portable formats. • Uses established automated conversion or export methods, where available, to make copies in a more common format (including EML). • Makes stored messages immediately available to authorized users for access and display – both locally and via the web. • Enables exact copies of messages to be reproduced as necessary. • Creates a searchable index for all stored email. Indexes are also retained on each unit of storage media for the messages and attachments stored on that unit. • Indexes allow searching by a wide variety of criteria, including the full text of the message body and attachments. • Can make a duplicate copy of each index entry for storage on a duplicate piece of storage media (just as for messages).