



ASSUREONTM

FDA & Assureon

Compliance by Nexsan

Rule 21 CFR part 11

Electronic Discovery The US Food and Drug Administration (FDA) introduced 21 CFR part 11, entitled "Electronic Records; Electronic Signatures," in 1997. The rule determines the requirements of computerized systems that need to be fulfilled in order to permit electronic signatures and electronic records in lieu of traditional paper-based records and hand-written signatures.

Who Needs to Comply?

Many industries are subject to FDA regulations. For example, the biotechnology, pharmaceutical, personal care, medical devices, food and beverage industries are required to document and acknowledge conditions and events at several points during the manufacturing process to ensure that exact manufacturing procedures are followed.

Tamper proof Records

Below are excerpts from FDA 21 CFR part 11 that refer to requirements that a compliant storage solution should address. Following each excerpt is a brief description of how Nexsan Assureon addresses that particular requirement.

Electronic Records 11.10 Controls for closed systems.

"Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, Such procedures and controls shall include the following:

Information Integrity Guaranteed with Digital Fingerprint Technology

"(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records."

Assureon provides audit trails detailing user access and any file changes and takes care of creating original and duplicate copies of files when they are modified. Assureon digital fingerprint technology provides the proof that an organization's files have not been back-dated, tampered with or destroyed.

Integrated Retention Management System

"(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period. "

Assureon has an integrated retention management system which allows a company to apply their retention policies on any document without the necessity of implementing a third-party document management system.

Protect Your Business Records & Meet FDA Compliance Obligations Electronic Records

Authorized Access to Information

“(d) Limiting system access to authorized individuals.”

Assureon uses Microsoft’s Authentication System and optionally, security certificates and smart cards, to verify a client’s identity. Once authenticated, policies set within Assureon and published to Microsoft’s Active Directory are used to determine if a client has the required permissions to access the resources they are requesting.

Audit Trail Uses a Secure Time Source

“(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records.”

Assureon uses a secure digital time source to record when and by whom a document is placed under management, modified or accessed.

Encryption and Digital Signature for Security

“11.30 Controls for open systems. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.”

Assureon has the option to encrypt any document, using the Advanced Encryption Standard (AES). The Assureon digital signature process uses two cryptographic hashes combined with a digital time stamp to assure the authenticity and integrity of the document.

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