



Electronic Document and Record Compliance for the Life Sciences

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Organizations dedicated to the life sciences have the conflicting needs of ever shorter development cycles, while maintaining strict compliance to US and International regulations. The need for speed and efficiency is driven by competitive market demands; the failure to meet compliance standards can result in costly delays and even penalties.

In order to maintain compliance, organizations are put under intense pressure to process vast amounts of paper and electronic data. This information is related to each minute phase of the development, testing, and submission phases of product development, and extend fully to the end-of-life of the product.

In addition, if the flow of information is not efficient, the organization can be exposed to huge litigation risks. This risk is often engendered by a lack of proper management of the massive volumes of information.

To avoid or minimize these risks, life sciences organizations should adopt new information management strategies. The clear and proven path is the electronic record and document content management system. These systems enable the organization to manage their information throughout project inception, creation, review, processing, transmission, storage, as well as the archiving and dissemination phases. This approach offers a systematic and procedurally sound approach to the unique needs of product development and life cycle management in the life sciences. N2 Workflow and Document Content Management from SoluSoft is a proven, state-of-the-art solution for information management in the life sciences.

N2 from SoluSoft

The N2 Workflow and Document Management System can help your business comply with FDA regulations as well as improve process efficiency and auditability. The FDA defines electronic signature usage in 21 CFR Part 11. Additionally 21 CFR parts 210 and 211 define the rules around the use of documents and data in electronic formats and the special rules around change control processes and data security. Compliance with these regulations is compulsory and failure to comply can result in harsh penalties. These regulations define the requirements for records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in FDA regulations. The technical and procedural controls are a part of the Current Good Manufacturing Practices (CGMP) for information access, change management, tracking, notification, training, work flow and administrative controls on authentication, authorization and integrity of records.

Benefits of Compliance

1. **Authentication:** Authorized users allowed access to electronic information
2. **Authorization:** Only authorized individuals can access certain or complete parts of the information universe
3. **Change Control:** Ability to track changes to electronic and printed document records (i.e., changes were made by: who, what, when, and why?)
4. **Retrieval Tracking:** Monitor and track the retrieval of the information
5. **Workflow:** Proactively manage the information life cycle from inception, creation, review, process, transmission, storage, archiving, and dissemination

6. **Record Authenticity:** Digital signature provided to maintain document authenticity and integrity
7. **Long Term Storage:** Provide archiving, retention and purge capability
8. **Protected Transmission:** Information transmitted from authors to CRO, to technicians, to reviewers, and to consultants is protected via encryption

Business Benefits

1. Elimination and minimization of regulatory risks, fines and process delays
2. Increase in credibility due to regulatory compliance
3. Minimization or elimination of patent violations
4. Organization and management of structured and unstructured information
5. Enforcement of the best practices to protect the intellectual property of the organization

SoluSoft N2 WDMS Compliance with 21CFR Part 11

#	21 CFR Part 11 Compliance Requirement	Type of Requirement	SoluSoft N2 21CFR Part 11 Compliance
1	<p>§11.1 (b) This section applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations.</p>	Technical	N2 captures changes, user id, date time when any record is created, modified, maintained, archived, retrieved or transmitted. The modified record will be archived with a newer version and recorded with changes.
2	<p>§11.10 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, and to ensure that the signer cannot readily repudiate the signed record as not genuine.</p>	Technical Procedural	N2 provides authentication and authorization. The authorization uses roles and access control list to protect and prevent access to unauthorized records or documents. The roles and ACLs are created as per company rules and regulations and business procedures. Digital signature will provide strong non repudiation to maintain authenticity of records.
3	<p>§11.10 (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.</p>	Administrative Procedural Technical	SoluSoft provides total validation services by performing systems audit in the following areas: Installation, Configuration, Operational, and Integrity to ensure accurate, reliable and consistent performance.
4	<p>§11.10 (b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency</p>	Technical	N2 provides reports in various graphical formats like bar, line, or pie charts that are both in human readable and electronic form that can be printed or saved for inspection, review, copying or email.
5	<p>§11.10 (c) Protection of records to enable their accurate and ready retrieval throughout the records retention period</p>	Technical	N2 provides authentication and authorization. The authorization uses roles and access control list to protect and prevent access to unauthorized records or documents irrespective of if the record is archived or not.
6	<p>§11.10 (d) Limiting system access to authorized individuals</p>	Technical	N2 provides user authentication internal to N2 with user ID and password to restrict unauthorized access. External authentication is provided using LDAP

7	<p>§11.10 (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.</p>	Technical	N2 history capture changes, user id, date time when any record is created, modified, maintained, archived, retrieved or transmitted. The delete are logical delete. Purge utility will purge the records that meet predefined business criteria.
8	<p>§11.10 (f) Closed Systems Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.</p>	Technical	N2 regular maintenance can be enforced by system administration for procedural and technical system check.
9	<p>§11.10 (g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.</p>	Technical Procedural	N2 provides authentication and authorization. The authorization uses roles and access control list to protect and prevent access to unauthorized records or documents. The roles and ACLs are created as per business rules and regulations and business procedures to allow authorized user to electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.
10	<p>§11.10 (h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.</p>	Technical Procedural	N2 will only import data via import utility that keeps import logs. User input is all tracked and recorded.
11	<p>Part C: Electronic Signatures and Encryption Such procedures and controls shall include those identified § 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.</p>	Technical	Digital Signature and Document Encryption will be provided to ensure record and document authenticity, integrity and confidentiality.