1. PURPOSE

Regulations and company policies require records to be available for up to 10 or more years. Ensuring the authenticity, reliability and long-term availability of electronic records is challenging because they can be easily altered. This procedure should help to reliably maintain and retain electronic records over the entire retention period.

2. SCOPE

Applies to the entire retention period of records as required by applicable regulations and company policies.

3. GLOSSARY/DEFINITIONS

Item	Explanation
Electronic Record	"Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system". *(Source: FDA 21 CFR Part 11)*
Processable Electronic Record	"Records in native file formats, that can be read, analyzed, interpreted, and manipulated by current and future hardware and software that can read the native file structure. File structures exportable to other file formats are typically searchable and analyzable but are not in the native file formats as created by the original software. Records that can only be viewed and/or printed are retrievable and reproducible but not processable". *(Source: PDA/ISPE GERM)*
Electronic Signature	"A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature". *(Source: FDA 21 CFR Part 11)*
Digital Signature	"An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified". *(Source: FDA 21 CFR Part 11)*

5.4. IT Department

5.4.1. Advises on procedural and technical controls for security access, long-term archiving and retrieval of data and other computer and IT related operations.

5.4.2. Reviews and approves procedures related to system security, data integrity, archiving and retrieval.

5.4.3. Develops and provides staff training on availability, functioning and proper use of security tools.

5.5. Quality Assurance

5.5.1. Advises on regulations and guidelines related to GxP and 21 CFR Part 11.

5.5.2. Reviews documentation for compliance with internal policies and regulations.

5.5.3. Organizes staff training.

5.6. Management

5.6.1. Reviews electronic records policy and procedures.

5.6.2. Provides resources for implementation of procedures.

6. FREQUENCY OF USE

When electronic records are created, processed, maintained, retained and archived.

7. PROCEDURE

7.1. Development of Electronic Records Management Policy

7.1.1. The record manager drafts a policy on management of electronic records.

Considerations for contents: