

**Sec. 11.30
 Controls for open systems**

Persons who use open systems (Open system refers to an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.) to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt.

FDA Regulation

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

(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. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

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

Wintility Pro

Tracking function that records date and time of document creation, modification and deletion as well as user responsible for each action and present document location.

Wintility Pro works with all documents in their original format. With the new Wintility Guard module, finalized documents can be kept in a secure area that prohibits any alterations or unauthorized access using any other application.

The user permissions and rights system allows for security at the document level as well as the group and single user level. Administrators can assign passwords, user profiles and send information to the Wintility Guard secured area.

Sec. 11.30
Controls for open systems

FDA Regulation

(d) Limiting system access to authorized individuals.

(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. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

Wintility Pro

Along with the above mentioned, Wintility Pro offers a workflow function that encrypts documents and restricts unauthorized user access.

Wintility Pro offers document tracking functions, a workflow summary sheet and customizable version control to handle the entire audit trail.

Sec. 11.30
Controls for open systems

FDA Regulation	Wintility Pro
<p>(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.</p>	<p>The Wintility Pro workflow lets administrators define the appropriate steps, revisors and dates for a form, document or process. These steps can be saved, altered and/or reused. Revisors are automatically notified through e-mail or instant message and can access previous alterations, and general and personal instructions for each document. All external links and additional document links can be easily added.</p>
<p>(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>	<p>Wintility Pro has security at all levels - user passwords, system user profiles, object permissions and secured servers for approved documentation.</p>
<p>(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.</p>	<p>Through Wintility Pro, administrators can determine which users have the right to add documents to a specified area through user permissions. However, the hardware remains the responsibility of the company.</p>

Sec. 11.30
Controls for open systems

FDA Regulation

(i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

(j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature Falsification.

Wintility Pro

PX Technologies offers full support to users as well as instructional materials. Our service providers can be contacted for any additional Wintility Pro training.

User passwords, usernames and personal profiles are deterrents to falsifying electronic records. Usernames and passwords are unique to each user. The written policies concerning document and signature falsification remain the responsibility of the company.

Sec. 11.30
Controls for open systems

FDA Regulation

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(k) Use of appropriate controls over systems documentation including:

(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

Wintility Pro gives you control to:

(1) Lock and distribute any type of document.

(2) Standardize open, name/number, revise and save procedures. These can be reused at any time.

**Sec. 11.50
Signature Manifestations**

FDA Regulation

(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

- (1) The printed name of the signer;
- (2) The date and time when the signature was executed; and
- (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

(c) Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

To learn more visit: www.fda.gov.

Wintility Pro

In partnership with Adobe, PX Technologies integrates with Adobe PDF –Entrust to meet the FDA electronic signature requirements. For more information, see: www.wintility.com/Adobe_Entrust.pdf.