SCITECX LAB AB

Application Note EN
code e004

21 CFR Part 11 FDA COMPLIANT

HYCLAS AIR SAMPLER COMPLIANCE TO 21CFR PART 11 REQUIREMENTS

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INTRODUCTION

The 21 CFR Part 11 rule states that the FDA view is that the risk of falsification, misinterpretation, and change (without leaving evidence) within the GMP environment are higher with electronic records than paper records, and therefore specific controls are required.

The electronic record in the HYCLAS system is based on a Secured PDF file, controlled such that, once created, it cannot be modified. This unmodifiable nature of the electronic records allows them to be printed and signed with full assurance that they represent a true representation of collected data.

21 CFR part 11 EXPLAINED

In order to understand how the HYCLAS products comply to with 21 CFR Part 11, it is useful to start explaining the regulation itself. The 21 CFR 11 is composed of few pages and split into three subparts:

- Subpart A : ***General Provisions***
- Subpart B : ***Electronic Records with 4 sections***
  - Section 11.10 : Controls for Closed System
  - Section 11.30 : Controls for Open System
  - Section 11.50 : Signature Manifestations
  - Section 11.70 : Signature Record Linking
- Subpart C : ***Electronic Signatures***

Subpart A is not highly relevant for HYCLAS system but it includes three key definitions:

- ***Closed system*** : An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system;
- ***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;
- ***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.

These definitions are clearly defining which part of the 21 CFR part 11 apply to the HYCLAS products:

- Subpart A : The data in the HYCLAS system are classified as electronic records
- Subpart B :
  - Section 11.10 : Applies because HYCLAS is a closed system;
  - Section 11.30 : Do not applies because related to Open System only;
  - Section 11.50 : Do not applies because electronic signatures are not implemented into HYCLAS system;
  - Section 11.70 : Do not applies because electronic signatures are not implemented into HYCLAS system;
- Subpart C : Do not applies because electronic signatures are not implemented into HYCLAS system.

The Section 11.10 is therefore the part of 21 CFR part 11 regulation that is related to the HYCLAS data storage system. The following table analyze step by step the conformity of the HYCLAS system to each specific the requirements of the Section 11.10.

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21CFR Part 11 Assestment

Subpart B - Electronic Records

Section 11.10 : *Controls for Closed Systems*

No.	21 CFR Part 11 Clause	HYCLAS conformity
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. Such procedures and controls shall include the following:		
a)	Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	Even though validation is a customer responsibility, HYCLAS team can offer support for Installation (IQ) and Operation Qualification (OQ) protocols.
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.	HYCLAS samplers generates reports that are accurate, complete and easy to read.
c)	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	Only data that has been already exported can be deleted. A confirmation is required before the final deletion, in this way the administrator is aware that a "True Copy" of data to be deleted is available. Alarm at 80% of memory space.
d)	Limiting system access to authorized individuals.	Authority checks are enforced through usernames and passwords that grant system access with user profiles that define access rights within the system. Two profile access through 6 digits password. USER: 25 accounts (from U01 to U25) can run and select volume. ADMIN: 5 accounts (from A01 to A05) can modify date and time, configure, export data and audit trail, delete data and reset passwords.

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No.	21 CFR Part 11 Clause	HYCLAS conformity
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.	Audit trail is available, every time a parameter is modified the audit trail records the modification (progressive number, date, time, user, value modified). Alarm at 80% of memory space.
f)	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	The HYCLAS sampler have complete description on the use of the device. However specific Standard Operating Procedures (SOP) to guide the operator are available.
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.	Authority checks are dependent upon security features built into the system as software functions. However, actually fulfilling this requirement is dependent on a user procedure to define user roles so that access rights can be correctly assigned. A general security policy is implemented in the air sampler, password complexity (6 digits, password aging (6months), and automatic logout after 30 sec.
h)	Use of device (e.g. terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	HYCLAS samplers generates reports that identifie each device and are proof of validity of the source.
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.	Training requirements are responsibility of the user.
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.	HYCLAS system is a hybrid system where electronic signatures are not implemented. The system output printed records must be signed
k)	Use of appropriate controls over systems documentation including:	Operational procedures are responsibility of the user.
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.	