

Intertek Alchemy

Platform Validation

21 CFR Part 11 Compliance Statement

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1 OVERVIEW

1.1 BACKGROUND

21 CFR Part 11 is the Food and Drug Administration (FDA) regulation that relates to the use of electronic records and electronic signatures.

1.2 OBJECTIVE

This document outlines the mechanisms used in validation of the applicable components of the Intertek Alchemy platform to meet the requirements of 21 CFR Part 11. Intertek Alchemy makes every effort to meet all necessary regulatory requirements in this regard. It must be understood, however, that certain activities, such as certification of electronic signatures to the FDA, and requisite SOPs are the responsibility of the customer.

1.3 SCOPE

Part 11 requires FDA regulated industries to implement a broad set of operational, business specific, and information security controls (i.e., policies, procedures, and processes) for ensuring the confidentiality, integrity, and availability (CIA) of electronic records and all other applicable data. The Alchemy Platform components known as Playbook, Player, Coach, and Manager meet the 21 CFR Part 11 requirements for closed systems.

2 TERMS AND DEFINITIONS

The below terms are used in the document. The Terms and Definitions section is here to provide standardization across meaning and how terms are to be interpreted.

Term	Definition
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.
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.
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.

3 STANDARD FOR COMPLIANCE

The table below lists the compliance requirements as outlined by 21 CFR Part 11 and Intertek Alchemy validation mechanism.

21 CFR 11 Section	Brief Description of Requirement	Intertek Alchemy Platform Compliant?
11.10 Controls for Closed Systems		
11.10 (a)	Systems Validation	Yes
11.10 (b)	Copies of records are complete and accurate	Yes
11.10 (c)	Records are protected	Yes
11.10 (d)	Access is limited to authorized individuals	User's SOP
11.10 (e)	There are secure computer-generated, time-stamped audit trails	Yes
11.10 (f)	Operational system checks are used for sequencing	N/A
11.10 (g)	Authority checks are in place	Yes
11.10 (h)	Device checks are used	N/A
11.10 (i)	Education, training, and experience suitable for use of the system	User's SOP
11.10 (j)	Accountability and responsibility for electronic signatures is determined	User's SOP
11.10 (k) (1)	Distribution, use of, and access to documentation are controlled	User's SOP
11.10 (k) (2)	Modifications to documentation has clear audit trail	Yes
11.50 Signature Manifestations		
11.50 (a) (1)	Signed electronic records include printed name of signer	Yes
11.50 (a) (2)	Signed electronic records include time & date of execution	Yes
11.50 (a) (3)	Signed electronic records include meaning of signature	Yes
11.50 (b)	Signatures have same controls as electronic records	Yes
11.70 Signature / Record Linking		
11.70	Electronic signatures are linked to their records	Yes
11.100 General Requirements		
11.100 (a)	Signatures are unique to one individual	Yes
11.100 (b)	Procedure in place to verify individual's identity	User's SOP
11.100 (c)	Declaration of equivalence to handwritten signature on file	User's SOP
11.200 Electronic Signature Components and Controls		
11.200 (a) (1)	Two distinct identification components are used	Yes
11.200 (a) (1) (i)	All components on first signing, at least one component on subsequent signings within same session are used	Yes
11.200 (a) (1) (ii)	All components on signings in separate sessions are used	Yes
11.200 (a) (2)	Used only by their genuine owner	User's SOP
11.200 (a) (3)	Misuse requires collaboration of two (2) or more individuals	Yes
11.300 Controls for Identification Codes / Passwords		
11.300 (a)	Identification code/password combination are unique	Yes
11.300 (b)	Checked, recalled, or revised on a periodic basis	Yes
11.300 (c)	Loss management procedures for Identification cards or other devices	User's SOP
11.300 (d)	Transaction safeguards in place to detect, prevent, and report misuse	Yes

4 STATEMENT OF COMPLIANCE

We recommend that each user retain a copy of this procedure in validation files as part of regulatory documentation. Intertek Alchemy has made every effort to understand and interpret the meaning and intent of the 21 CFR Part 11 regulations. We have drawn upon the advice and expertise of multiple sources, private industry and governmental. We believe that with proper due diligence in using the Intertek Alchemy Platform, the customer will be in full compliance.

5 CUSTOMER RESPONSIBILITY

The Chart below outlines where compliance accountability rests with the end user or Alchemy customer.

21 CFR 11 Section	Brief Description of Requirement	User SOP
11.10 Controls for Closed Systems		
11.10 (d)	Access is limited to authorized individuals	Alchemy requires that credentials be entered when accessing records in Manager, and when facilitating training in Playbook and Coach. The Alchemy customer must ensure windows credentials are in place and SOPs are followed when accessing Alchemy Player
11.10 (i)	Education, training, and experience suitable for use of the system	Describe how facilitators and administrators are trained to use the Alchemy platform
11.10 (j)	Accountability and responsibility for electronic signatures is determined	Describe how the employee database is set up and maintained
11.10 (k) (1)	Distribution, use of and access to documentation are controlled	Describe the access levels set up within the facility or organization for use of the Alchemy platform
11.100 General Requirements		
11.100 (b)	Procedure in place to verify individual's identity	Describe the enrollment process used within the facility and any tie-in to the plant employee Roster
11.100 (c)	Declaration of equivalence to handwritten signature on file	Describe how the Alchemy enrollment process ties into the Employee's training record
11.200 Electronic Signature Components and Controls		
11.200 (a) (2)	Used only by their genuine owner	Describe how the facility ensures employees do not take training under another Employee's name

11.300 Controls for Identification Codes / Passwords		
11.300 (c)	Loss management procedures for Identification cards or other devices	If using badge readers, describe the process within the facility to manage badges that are lost
11.300 (e)	Periodic testing of identification cards or other devices	Describe the process for testing that badge readers are working correctly on a periodic basis.

****Please Note: Compliance with 21 CFR 11 can only be achieved when using the Intertek Alchemy Platform as recommended.**