

	Standard Operating Procedure cGMP Electronic Signatures		SOP Number QS-116	Revision 0
			Effective Date 04/01/22	Page Page 1 of 3
Written by/ Date <i>[Signature]</i> 03/11/22		Reviewed by/ Date <i>[Signature]</i> 03/14/22		Approved by/ Date <i>[Signature]</i> 03-15-22
Title: Quality Systems Manager		Title: Production Director		Title: VP of Quality & Regulatory Affairs

1.0 Purpose

The purpose of this procedure is to define the requirements for electronic signature recording at Ion Labs, Inc.

2.0 Scope

This procedure applies to all electronic signatures required within electronic systems used to perform cGMP functions at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of all employees who will use electronic signatures to complete an electronic cGMP record to strictly follow this procedure.
- 3.2 It is the responsibility of Quality Management to implement this procedure and to ensure that the procedure is followed.

4.0 Definitions

- 4.1 **ESCR** – Electronic System Controls and Requirements
- 4.2 **cGMP** – Current Good Manufacturing Practices
- 4.3 **CFR** – Code of Federal Regulations
- 4.4 **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

- 4.5 **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

5.0 References

- 5.1 QS-116-F1, Form, Electronic Signature Acknowledgement
- 5.2 QS-115, SOP, cGMP Electronic System Controls and Requirements

6.0 Procedure

- 6.1 Any system in which electronic signatures are to be accepted must first be validated to ensure accuracy, reliability, consistency, intended performance, and the ability to discern invalid or altered records.
- 6.2 Electronic records that are signed must adhere to all of the controls listed for electronic records. In addition, the signed electronic records must include the name of the signer, the date and time of the signature (the signer's local time), and the meaning of the signature (e.g., review, approval, authorship) (21 CFR 11.50(a)). This information must be included in any human-readable copy of the record (21 CFR 11.50(b)). Electronic signatures and handwritten signatures executed to electronic records must be linked to their respective electronic records to ensure that they cannot be falsified (21 CFR 11.70)
- 6.3 Some cGMP processes require a signature, or initials of an individual completing the process. If an electronic system is used to meet a cGMP requirement, then that system must apply electronic signatures, initials, and / or date to the transaction or record the same way paper systems would require signatures, initials, or dates. Electronic systems are capable of identifying the individual using a system based on the user name and password used to gain access to that system. Additionally, biometrics or keys may be used to identify individuals using a system.
- 6.4 For systems that utilize electronic signatures, each user of the system who will execute an electronic signature must first sign a certification declaring that his/her electronic signature

is the legally binding equivalent of his/her handwritten signature., prior to being granted the authority to perform electronic signatures. This serves to confirm that the signer accepts the significance of the electronic signature, besides being a regulatory requirement. There should be documented training of these individuals to indicate that they understand the significance of the certification.

- 6.5 This certification need not be submitted to the FDA, but must be retained and available in the event of an authority request.
- 6.6 Ion Labs employees are expected to keep passwords and other identification mechanisms confidential and secure to ensure that other individuals cannot gain access to systems or sign for activities on their behalf. The use of a username and password is considered an electronic signature and carries the same meaning as a handwritten signature on a document.
- 6.7 This requirement is communicated to Ion Labs employees during the onboarding and training process and acknowledgement of this information is documented on form QS-116-F1 Electronic Signature Acknowledgement for each employee engaged in or potentially engaged in the use of these systems.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	03/14/22	New procedure.	N/A	K. Burris



cGMP Electronic Signature Acknowledgement and Consent

Form: QS-116-F1 CCR No. N/A Revision: 0

Electronic Signature Acknowledgement and Consent

Some cGMP processes require a signature, or initials of an individual completing the process. If an electronic system is used to meet a cGMP requirement, then that system must apply electronic signatures, initials, and / or date to the transaction or record the same way paper systems would require signatures, initials, or dates. Electronic systems are capable of identifying the individual using a system based on the user name and password used to gain access to that system. Additionally, biometrics or keys may be used to identify individuals using a system.

Ion Labs employees are expected to keep passwords and other identification mechanisms confidential and secure to ensure that other individuals cannot gain access to systems or sign for activities on their behalf. The use of a username and password is considered an electronic signature and carries the same meaning as a handwritten signature on a document.

PROVISIONS

- You will protect and keep confidential usernames, passwords, etc. used to gain access to cGMP Electronic Systems
- You will not use any username and password other than your own to electronically sign a cGMP document or transaction.
- You agree that use of your username and password or any other biometric identifier or key carries the same meaning on electronic records as your handwritten signature on a document.

ACKNOWLEDGMENT

By signing this Acknowledgement and Consent for Electronic Signatures, you acknowledge that you have read and agree to the above provisions.

	Printed Name	Signature	Date
Acknowledged By			