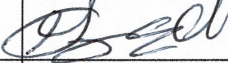
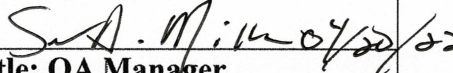
	<b>Standard Operating Procedure</b>  <b>Employee Signature Recording</b>		<b>SOP Number</b> <b>A-114</b>	<b>Revision</b> <b>4</b>
			<b>Effective Date</b> <i>05/04/22</i>	<b>Page</b> <b>1 of 4</b>
<b>Written by/ Date</b> <i>Hammis 04/18/22</i>		<b>Reviewed by/ Date</b>  <i>04/18/22</i>		<b>Approved by/ Date</b>  <i>07/27/22</i>
<b>Title: Quality Systems Manager</b>		<b>Title: Training Coordinator</b>		<b>Title: QA Manager</b>

## 1.0 Purpose

The purpose of this procedure is to establish the guidelines for the use of signatures and initials on all cGMP documents. This procedure will also establish a system for the recording of every employee's signature and initials.

## 2.0 Scope

This procedure applies to all employees at Ion Labs, Inc.

## 3.0 Responsibility

- 3.1 It is the responsibility of HR to notify Document Control and the Training Department upon the hire of a new employee, the termination of an existing employee, and for any changes to an employee's name.
- 3.2 It is the responsibility of the Department Manager and/or HR to inform Document Control and the Training Department every time an employee is transferred from one department to another. It is the responsibility of Quality and Department Managers to ensure that this procedure is followed by all employees, and that all signatures and initials recorded by employees on cGMP documents are legible and correct.
- 3.3 It is the responsibility of the Training Department to record all employee signatures and initials and forward them to Document Control.
- 3.4 It is the responsibility of Document Control to maintain on file all employee signatures and initials, and to update them as necessary.

## 4.0 Definitions

4.1 **cGMP** – Current Good Manufacturing Practices

4.2 **HR** – Human Resources

## 5.0 References

5.1 A-114-F1, Form, Employee Register

## 6.0 Procedure

6.1 Employee signatures and initials must be unique to each employee and easily identifiable.

6.1.1 The recommended format for initial use is the first letter from the employee's first name, the first letter from the employee's middle name, and the first letter from the employee's last name.

6.1.2 Duplication of initials between two or more employees is not permitted.

6.1.2.1 In the event that there is more than one employee with the same initials, other designated letters must be used to differentiate the initials of these employees.

- In the event that an employee does not have a middle name, any other combination of letters may be used, as long as the initials will be unique to the employee.

6.2 If an employee wishes to change their name, signature, or initials, HR and the Training Department must be notified immediately.

6.3 Every new employee must be trained on this procedure. At training completion, the employee's signature and initials will be recorded on Form A-114-F1 Employee Register.

- 6.3.1 Only the signature and initials recorded on the Employee Register are permitted to be written on all cGMP documents.
- 6.4 If an employee transfers from one department to another, the department manager and/or HR must notify Document Control and the Training Department of the transfer. The employee's department will be updated on the Employee Register.
- 6.5 Every time an employee enters his/her signature or initials onto the Employee Register, it must be in the presence of the Training Department or designee. Otherwise, the entries will not be valid.
- 6.6 Document Control will keep each Employee Register. These records will be kept current and secure at all times, separate from employee records.
- 6.7 Form A-114-F1 Employee Register will contain the following information:
- 6.7.1 Employee's Printed Name
  - 6.7.2 Employee's Signature
  - 6.7.3 Employee's Distinguished Initials
  - 6.7.4 Employee's Start Date
  - 6.7.5 Employee's End Date
  - 6.7.6 Department
  - 6.7.7 Transfer Date (as applicable)
  - 6.7.8 New Department (as applicable)
  - 6.7.9 Recorded By

## 7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	03/14/13	New	13-171	V. Iltcheva
2	02/12/15	Biennial review. Updated SOP format. Changed SOP title. Revised Form A-114-F1.	15-0153	K. Burris
3	01/03/19	Scheduled review: added training department to procedure. Removed unnecessary definitions.	19-0017	K. Burris
4	04/18/22	Scheduled review: Cleaned up procedure. Updated logo.	CC-22-0195	K. Burris



**Employee Register**

Form: A-114-F1

CCR No. CC-22-0195

Revision: 4

**Employee Name:**

It is a GMP requirement to have a record of each employee's signature and initials. Only the signature and initials recorded on this register are permitted to be written on GMP documents.

Your signature and/or initials on a GMP document mean that you have performed the task in accordance with documented requirements.

You are only permitted to sign or initial a document if you have been trained to perform the task.

Do not sign or initial a document if you have not performed the task.

You are not permitted to sign someone else's signature or initials.

<b>Printed Name</b>	
<b>Signature</b>	
<b>Initials</b>	

Start Date:

End Date:

Department:

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Transfer Date: \_\_\_\_\_

New Department: \_\_\_\_\_

Entered by: \_\_\_\_\_

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Transfer Date: \_\_\_\_\_

New Department: \_\_\_\_\_

Entered by: \_\_\_\_\_