

	<b>Standard Operating Procedure</b> <b>cGMP Electronic System</b> <b>Controls and Requirements</b>	SOP Number QS-115	Revision 0
		Effective Date 02/18/21	Page Page 1 of 5
Written by/ Date <i>K. Bunn 12/08/20</i>	Reviewed by/ Date <i>David Wagon 12-8-20</i>	Approved by/ Date <i>[Signature] 12-08-20</i>	
Title: Quality Systems Manager	Title: IT Director <i>[Signature]</i>	Title: VP of Quality & Regulatory Affairs	

## 1.0 Purpose

This procedure defines the controls and requirements for Electronic Systems used to perform cGMP functions.

## 2.0 Scope

This procedure only applies to Electronic Systems used to perform cGMP functions. This procedure may be used to control and add requirements to non-cGMP systems at the discretion of Ion Labs management. Separate procedures may be written to cover other details of specific systems. If those specific SOPs conflict with this SOP, the more specific SOP will have precedence.

## 3.0 Responsibility

- 3.1 It is the responsibility of Ion Labs management to:
- 3.1.1 Be familiar with this SOP.
  - 3.1.2 Identify electronic systems that perform cGMP functions and register those systems with Quality.
  - 3.1.3 Participate with Quality in defining requirements as described in this SOP.
- 3.2 It is the responsibility of Quality to:
- 3.2.1 Review and reject or approve requirements and controls for each registered system covered under the scope of this SOP.
- 3.3 It is the responsibility of Document Control to:
- 3.3.1 Assign and log system numbers.
  - 3.3.2 File and retain forms, protocols, reports, and risk assessments associated with each systems and this SOP.

## 4.0 Definitions

- 4.1 **CFR** – Code of Federal Regulations
- 4.2 **Electronic Signature** – Symbols or other data in digital form attached to other electronic data, transactions, or processes that are logically associated with a single individual (i.e. signatory)
- 4.3 **Electronic System** – A physical connection of components or parts that gathers various amounts of information together of fulfills an electronic request

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- 4.4 **ESCR** – Electronic system control and requirements
- 4.5 **cGMP** – Current Good Manufacturing Practices
- 4.6 **Validation** – confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled (21 CFR 820.3)

## 5.0 References

- 5.1 QS-115-F1, Form, cGMP ESCR System Log
- 5.2 QS-115-F2, Form, cGMP ESCR Checklist
- 5.3 QS-115-F3, Form, cGMP ESCR Electronic Signature Acknowledgement
- 5.4 QS-115-F4, Form, cGMP ESCR Backup Requirements
- 5.5 21 CFR Part 11
- 5.6 C-105, SOP, Protocol and Report Document Requirements
- 5.7 QS-114, SOP, Quality Risk Management
- 5.8 D-105, SOP, Out of Specification/Out of Trend Investigation

## 6.0 Procedure

- 6.1 Overview
    - 6.1.1 This SOP defines the requirements and controls that should accompany cGMP electronic systems and provides a mechanism to document specific controls and requirements for each individual system.
  - 6.2 System Numbers
    - 6.2.1 Document Control is responsible for assigning a unique number to each system applicable to this SOP. DC assigns numbers in the following format:
      - 6.2.1.1 SYS – [Year] – [###]
        - SYS = abbreviation for “System” that uniquely identifies the number as a system number rather than other types of numbers used at Ion Labs.
        - [Year] = the last two digits of the year that the system number is assigned.
        - [###] = a sequential number representing the count of numbers assigned to that event type for the given year starting at 001.
- Example:** the third system number issued in 2020 would be assigned SYS-20-003.
- Example:** the fifth system number issued in 2021 would be assigned SYS-21-005.

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### 6.3 System Log

6.3.1 DC maintains a log of each system number issued. At a minimum, the following information will be maintained in the log:

6.3.1.1 System number

6.3.1.2 System description

6.3.1.3 Logged by initials and date

6.3.2 DC may choose to include additional information in the log. DC may use form QS-115-F1 to create the log to record assigned system numbers and maintain those numbers.

### 6.4 System Documentation and Checklist

6.4.1 This SOP defines a number of controls and requirements for cGMP electronic systems and provides forms and/or references systems that are used to document controls or requirements specific to each system. This documentation provides a mechanism to review and approve system settings and requirements and provides an approved source to audit the system against.

6.4.2 This documentation should be summarized on form QS-115-F2 ESCR Checklist for each system, and should be filed in document control by system number. If desired, documents may be filed in an alternate system (i.e. the report or protocol system) with only the cross reference to those documents provided on form QS-115-F2.

6.4.3 The ESCR Checklist, form QS-115-F2, may be updated at any time. The signatures and dates on the checklist are not required at the time documents are generated, but are rather an indication of the time and date that the listed item is verified as current. Over time, the checklist may be updated to reference the most current status of the system, and previous versions of the form may be archived and also filed in document control by system number.

### 6.5 System Validation IQ/OQ/PQ

6.5.1 Use SOP C-105 to generate one or more protocols and/or reports to document the validation assessment of the system. Reference applicable protocol and report number(s) on form QS-115-F2 (ESCR Checklist).

### 6.6 System Usernames, Passwords, and Electronic Signatures

6.6.1 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.

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- 6.6.2 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.
- 6.6.3 This requirement is communicated to Ion Labs employees during the onboarding and training process and acknowledgement of this information is documented on form QS-115-F3 for each employee engaged in or potentially engaged in the use of these systems.

6.7 Password Requirements

- 6.7.1 Some systems allow configuration of password requirements. For example, the number of characters required in a password, or the types of characters required in a password may be configurable. If applicable, the configured requirements for a password may be defined and documented on form QS-115-F2 (ESCR Checklist).

6.8 User Roles and Permissions

- 6.8.1 Many electronic systems allow the assignment of permissions to users. This may be accomplished by directly assigning permissions to each user, and / or may be accomplished by defining a role with specific permissions associated with that role, and then assigning a role to each user. In most cases, the permissions given to a user are critical to the management of an electronic system and are required to maintain data integrity.
- 6.8.2 Where applicable, the assignment of permissions to roles and users as well as the assignment of roles to users should be documented and approved by at least two signatures one of which is a member of the Quality department. Often, this documentation may be produced from a system report generated by the electronic system.
- 6.8.3 Use SOP C-105 to generate one or more reports to document the assignment of permissions to roles, as well as the assignment of roles and permissions to users. As applicable attach system reports to this report. Reference this report number on form QS-115-F2 ESCR Checklist.

6.9 System Backup

- 6.9.1 Electronic data generated to meet a cGMP requirement must be maintained for the period of time required by the applicable regulations and / or applicable Ion Labs SOPs. A data backup plan should be determined and documented for each applicable system.
- 6.9.2 For simple backup plans, use form QS-115-F4 to document the backup plan and file the completed form in document control by system number. For more complex backup plans, use SOP C-105 to generate one or more reports to document the plan, or write a specific SOP to delineate the backup procedure. Reference either the form, report number(s), or SOP number(s) on form QS-115-F2 ESCR Checklist.

6.10 System Audit Trail

6.10.1 Use a system specific SOP to delineate audit trail use and review, or use SOP C-105 to generate one or more reports to document the assessment of audit trail use requirements. Reference the SOP or report number(s) on form QS-115-F2 ESCR Checklist.

**7.0 Revision History**

Revision	Date	Description of Changes	CCR #	By
0	12/08/20	New.	N/A	K. Burris





**cGMP ESCR Checklist**

Form: QS-115-F2

CCR No. N/A

Revision: 0

**Effective Date**

**System Information**

<b>System #</b>	
<b>System Name</b>	
<b>System Description</b>	

<b>Checklist Item</b>	<b>References / Comments</b>	<b>Verified By Initials / Date</b>
<b>User Requirements</b>		
<b>IQ / OQ / PQ Validation</b>		
<b>Password Requirements</b>		
<b>Defined user roles and associated permissions</b>		
<b>Assignment of either role or permissions to individual users.</b>		
<b>Backup Requirements</b>		
<b>System Audit Trail review and use requirements</b>		



**cGMP ESCR Electronic Signature Acknowledgement and Consent**

Form: QS-115-F3

CCR No. N/A

Revision: 0

## Electronic Signature Acknowledgement and Consent

### BACKGROUND

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			



**cGMP ESCR System Backup Requirements**

Form: QS-115-F4

CCR No. N/A

Revision: 0

**Effective Date**

**System Information**

<b>System #</b>	
<b>System Name</b>	
<b>System Description</b>	

This form serves as a mechanism to define and approve the backup plan associated with this system. Use the detail section below to define the plan and add attachments as necessary.

**Details**

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**Additional Attachments**

<b>Attachment Description</b>	<b># of Pages</b>

<b>Name</b>	<b>Printed Name</b>	<b>Signature</b>	<b>Date</b>
<b>Completed By</b>			
<b>Approved By QC Doc Control (DC)</b>			