| Discovery Labs | STANDARD OPERATING PROCEDURE | | | |
|---|---|---|---|---|
| | SOP No.: | SOP-QC-039-03 | Effective Date: | 02.06.2017 |
| | Supersedes : | QC-039-02 | Next Review Date: | 01.06.2020 |
| | Department: | Quality Control | Page: | 1 of 2 |
| **TITLE: AUDIT TRIAL** | | | | |

**1.0 PURPOSE:**

To define a procedure for Audit Trail Systems

**2.0 SCOPE:**

2.1 This procedure is limited to those instruments that are undertaken for Audit trail activation in Quality Control Department.

**3.0 RESPONSIBILITY:**

3.1 Analyst-QC is responsible to follow this SOP.

3.2 Head-QC/Designee is responsible for ensuring implementation of this SOP.

3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.

**4.0 DEFINITION:**Nil

**5.0 PROCEDURE:**

5.1 Audit trail shall be verified for individual system (HPLC/GC) by monitoring instrument activity log once in a month (month first week) by the administrator.

5.2 In audit trail record following information should be recorded;

5.2.1 Date and time

5.2.2 Name of the person making change

5.2.3 Original and changed value

5.2.4 Reason for change made

5.2.5 Invalid attempts to log on the system should also be recorded in audit trail.

5.3 Audit trail records the changes made in electronic documents. According to the 21 CFR part 11, a system having audit trail should include the following:

5.3.1 Records should be protected and ensure their accuracy and ready retrieved throughout the storage period.

5.3.2 Access to system should be limited to the authorized persons only.

| | Prepared by | Reviewed by | Approved by |
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5.3.3 System should record the date and time of used entries and action, modifications and deletion of records in system. These records should be shown during the review of system.

5.4 Review the audit trail through Audit trial review check list.

**6.0 FORMATS / ANNEXURE(S):**

6.1 Audit trial review check list : QC039-FM116

**7.0 CHANGE HISTORY:**

| Revision No. | Effective Date | Details of Revision | Ref CCF No. |
|---|---|---|---|
| 00 | 01.08.2015 | New SOP introduced. | -- |
| 01 | 01.08.2016 | 1. User and administration privileges are defined.<br>2. User ID activation and deactivation form are introduced. | -- |
| 02 | 01.10.2016 | 1. One new level is reviewer is incorporated.<br>2. Level names are modified as Analyst level, Reviewer level, Executive/In charge/Manager level and Administrator level.<br>3. List of Users format is incorporated. | -- |
| 03 | 02.06.2017 | 1. SOP format changed make to inline with SOP-QA-001-05.<br>2. User privileges procedure was removed from this SOP and prepared separately as Management of Open Lab Software.<br>3. Audit trial review check list (QC039-FM116) format introduced. | CCF/GEN/ 17015 |

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