 Discovery Labs	STANDARD OPERATING PROCEDURE			
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	Supersedes :	SOP-QA-029-01	Next Review Date:	29.06.2022
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TITLE: QUALIFICATION OF EXTERNAL LABORATORIES				

1.0 PURPOSE:

To lay down the Procedure for Qualification of External Laboratories.

2.0 SCOPE:

This procedure is applicable for assessment and approval of external laboratories or services providers those have a potential major impact on the quality of products at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

- 3.1 Quality control and Engineering shall be responsible to prepare, maintain and update the Approved service providers list for services identified.
- 3.2 Purchase team shall identify the prospective service providers and support in facilitating assessment and audit of the site.
- 3.3 QA shall be responsible to approve the service provider's list and audit report.
- 3.4 QA shall lead the quality audit for the services identified for approval process.
- 3.5 QA shall track the completion of periodical audits, CAPA arising from the audits.


4.0 DEFINITIONS:

Nil

5.0 PROCEDURE:


- 5.1 Service providers are the external testing laboratories, external calibration agencies and external services like pest control, cleaning agencies etc..
- 5.2 Services that are considered potential major impact on product quality shall be identified and approved.
- 5.3 Identify service providers based upon the test/ calibration requirements, where such instruments/ methods is not available at in-house and / or during break down of such instruments.

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- 5.4 Purchase team shall identify the service provides based on user requirement like Quality control sample testing, pest control agencies, calibration agencies, cleaning service providers etc..
- 5.5 An assessment shall carry out to understand the service provider's ability to meet the Discovery specifications by getting the documents from the service providers.
- 5.6 Quality Assurance department shall plan the audit at external laboratory / calibration agency to evaluate for systems, procedures and compliance with coordination of respective user department. Check list format No QA029-FM119 shall be followed to accesses the Quality control testing laboratories and for external calibration agencies.
- 5.7 Get the confirmation of audit dates with the facility owner, QA along with user department (based on necessity) shall audit the facility with the help of audit checklist.
- 5.8 The key points that require consideration during audits shall include the following but not limited to:
- 5.8.1 Adequate premises, equipment, systems and services
- 5.8.2 Written procedures as applicable and records for receipt, testing, results reporting, handling deviations etc.
- 5.8.3 Calibration of instruments and calibration methods used by the agency are as per the national / international standards, if any
- 5.8.4 Adequate staff with sufficient knowledge, skills, training, experience and demonstrate overall technical competence.
- 5.8.5 Maintains appropriate technical standards and has the ability to consistently meet requirements.
- 5.8.6 Qualification & Calibration of master instruments and preventive maintenance program.
- 5.8.7 Usage of standard chemicals and licenses

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- 5.9 In case of pest control service provider, the auditor shall ensure the training of employees, chemical and their dosage and antidotes requirements and procedure for handling of rodents.
- 5.10 In case of any Non-Compliance observed in the audit, the auditor shall raise a Non-Compliance Report as per the format No. QA029-FM120, suitable CAPA shall be obtained from the service provider.
- 5.11 An audit report shall be prepared based on audit checklist and shall be submitted to Head-Quality or designee.
- 5.12 Head-Quality or designee shall evaluate the audit report and ensure that corrective and preventive actions for non-conformance are completed from respective service provider.
- 5.13 After approving the external laboratory, list of approved contract service providers shall be updated in QA029-FM098.
- 5.14 The version number shall start from 01 and shall be incremented by one.
- 5.15 The original signed copy of the list shall be available with QA. Distribute controlled copies as per requirement.
- 5.16 A contractual agreement shall be prepared and signed by both contract giver and contract acceptor as per the format No. QA029-FM094. The terms and condition like frequency of service, documents need to produce etc...shall be defined based nature of service like testing, calibrations, pest control, cleaning.
- 5.17 In case any additional tests (other than the previously audited tests) are to be carried out at the contract lab, the lab shall be re-evaluated for the competency to carry out the new test.

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- 5.18 All Quality control samples, which sent outside shall be tracked and shall maintain test sample out ward register as per the format No. QA029-FM084, for the samples and outsourced calibrated instruments record as per the Format No. QA029-FM121, for instruments sent to outside test/ calibration labs. Receive the test/ calibration (along with copies of international standards) reports.
- 5.19 Relevant department personnel shall review and accept the reports/ certificates, put reviewed stamp and sign as a part of acceptance of the same. Test reports shall attach to the concerned batch and file as per requirement.
- 5.20 The national standard certificates shall be obtained from the service provider to ensure the calibration of instruments used for testing / calibration, if required.
- 5.21 If the government agencies calibrate the instrument, such services providers need not be qualified by internal procedures.
- 5.22 **Handling of samples being sent, Receipt and Review of External Laboratory results:**
- 5.22.1 Samples shall be sent only to qualify Contract Laboratory as listed.
- 5.22.2 The required quantity of sample shall be suitable container and labeled as “Sample information label”
- 5.22.3 Communication with details of samples to be sent for analysis shall be prepared and a copy of the relevant standard test procedure shall also be enclosed along with the communication, if required.
- 5.22.4 Necessary Working standards with the complete label details shall be sent to Contract testing Laboratories along with the sample, wherever required.
- 5.22.5 Details of sample and required test shall be entered in External Laboratory Analysis provided by Contract Laboratory and enter the details in Test Samples out ward register.

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5.22.6 After receipt of Report shall be reviewed for correctness and completeness.

Reviewed Stamp shall be put on COA by QA/QC.

5.23 Re-Evaluation or Re-Qualification Frequency:

5.23.1 Once in 3 years and as and when required.

5.23.2 Whenever any lab error necessitates the re-qualification.


5.23.3 Whenever Laboratories required to be approved for carrying out new tests, based on assessment.

6.0 FORMATS / ANNEXURE(S):

- | | |
|--|---------------|
| 6.1 Test Sample Out ward Register | : QA029-FM084 |
| 6.2 External Laboratory analysis qualification checklist | : QA029-FM119 |
| 6.3 External Laboratory Non- Compliance Report | : QA029-FM120 |
| 6.4 Agreement of Contract Laboratory | : QA029-FM094 |
| 6.5 Approved contract service providers | : QA029-FM098 |
| 6.6 Out sourced calibrated instruments record | : QA029-FM121 |

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7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01-01-2014	New SOP	---
01	25-07-2017	<ol style="list-style-type: none"> SOP format changed make to inline with SOP-QA-001-05. Altogether procedure has `been rephrased for better clarity. 	CCF/GEN/17021
02	30.06.2019	<ol style="list-style-type: none"> Procedure for service provider is included in which QC samples and engineering calibration are covered. List of service providers preparation procedure included the engineering calibration. FM091 merged into FM119 FM098 is revised in line with SOP 	CCF/GEN/19026

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