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Discovery Labs	

STANDARD OPERATING PROCEDURE				
SOP No.:	SOP-QA-034-01	Effective Date:	01.01.2018	
Supersedes:	SOP-QA-034-00	Next Review Date:	31.12.2020	
Department:	Quality Assurance	Page:	1 of 3	

#### TITLE: MANAGEMENT REVIEW MEETING

#### 1.0 PURPOSE:

To lay down the procedure for conducting Management Review Meeting (MRM) to ensure suitability, adequacy and effectiveness of Quality Management System (QMS) by top management in coordination with Management Representative.

#### 2.0 SCOPE:

This SOP provides guidelines for conducting the MRM at Discovery Laboratories Pvt. Ltd.

#### 3.0 RESPONSIBILITY:

## 3.1 Head-QA:

- To review the QMS for adequacy and compliance.
- To ensure that the processes needed for the QMS are established, implemented and maintained.
- To report to the top management on the performance of the QMS and any need for improvement.

## 3.2 Top Management:

- To ensure that the planning of QMS is carried out in order to meet the quality objectives.
- 3.3 To ensure that the integrity of the QMS is maintained when changes are planned and implemented.

#### **4.0 DEFINITIONS:**

Nil

#### 5.0 PROCEDURE:

- 5.1 MRM will be chaired by Managing Director / Chairman or his nominee with following members;
  - 5.1.1 Director Operations / Technical.
  - 5.1.2 Head Production / Warehouse / Engineering & Maintenance / QC / QA / HR / other departmental personnel (if applicable).

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	Y. Samatha	G. Swapna	Ch. Mahendar Reddy
Department	Quality Assurance	Quality Assurance	Quality Assurance



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#### TITLE: MANAGEMENT REVIEW MEETING

- 5.2 Management Review Meeting Schedule (QA034-FM158) will be prepared annually by Management Representative (Head-QA) and it will be approved by Managing Director / Chairman.
- 5.3 Management Representative (Head-QA) shall communicate the Date and Time after consultation with Top management to all the team members at site through Management Review Meeting Circular (QA034-FM159) for once in three months.
- 5.4 MRM will be conducted by considering following points :
  - 5.4.1 To review the process at regular intervals to assess the suitability, adequacy and effectiveness of QMS.
  - 5.4.2 Scope for improvement in QMS.
  - 5.4.3 Review on Non-conformances (NC) during internal audits / External audits.
  - 5.4.4 Review on Customer feedback / Complaints.
  - 5.4.5 Review on Process Performance and Product conformity.
  - 5.4.6 Review on Status of Corrective and Preventive actions.
  - 5.4.7 To take follow up actions from previous MRM.
  - 5.4.8 Changes that could affect the QMS.
  - 5.4.9 Recommendations for improvement.
- 5.5 Minutes of last meeting shall be reviewed / discussed and progress shall be evaluated before discussion of new points.
- 5.6 Outcome of the MRM shall include decisions and actions related to improvement of the effectiveness of QMS, improvement of product related to customer requirements and resource needs.
- 5.7 Management Representative (Head-QA) shall circulate drawn conclusions and action items to all the team members at site through "Minutes of Management Review Meeting (QA034-FM160)".

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# 5.8 MRM numbering shall be as follows;

## MRM /YYXX

Where MRM: Management Review Meeting

XX : Sequence numbering of MRM conducted during the year

YY : Last two digits of the calendar year

# 6.0 FORMATS/ ANNEXURE(S):

Management Review Meeting Schedule : QA034-FM158
Management Review Meeting Circular : QA034-FM159
Minutes of Management Review Meeting : QA034-FM160

## 7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.04.2017	New SOP	
01	01.01.2018	SOP format changed make to inline with SOP-QA-01-05	CCF/GEN/ 17037

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