1. **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.

1. **SCOPE:**

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

1. **RESPONSIBILITY:**
   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.
  1. Top Management:
* To ensure that the planning of QMS is carried out in order to meet the quality objectives.
  1. To ensure that the integrity of the QMS is maintained when changes are planned and implemented.

1. **Definitions:**

Nil

1. **PROCEDURE :**
   1. MRM will be chaired by Managing Director / Chairman or his nominee with following members;
      1. Director – Operations / Technical.
      2. Head – Production / Warehouse / Engineering & Maintenance / QC / QA / HR / other departmental personnel (if applicable).
   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.
   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.
   4. MRM will be conducted by considering following points :
      1. To review the process at regular intervals to assess the suitability, adequacy and effectiveness of QMS.
      2. Scope for improvement in QMS.
      3. Review on Non-conformances (NC) during internal audits / External audits.
      4. Review on Customer feedback / Complaints.
      5. Review on Process Performance and Product conformity.
      6. Review on Status of Corrective and Preventive actions.
      7. To take follow – up actions from previous MRM.
      8. Changes that could affect the QMS.
      9. Recommendations for improvement.
   5. Minutes of last meeting shall be reviewed / discussed and progress shall be evaluated before discussion of new points.
   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.
   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)”.
   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

1. **Formats/ Annexure(s):**
   1. Management Review Meeting Schedule : QA034-FM158
   2. Management Review Meeting Circular : QA034-FM159
   3. Minutes of Management Review Meeting : QA034-FM160
2. **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 |