

Management Review for Medical Devices

7.4 Management Review Outputs

The documented output of the Management Review details the assessment and lists all agreed follow up actions discussed during the Management review. It should be highlighted if there had been identified any needs to improve the Quality System as well of any needs to improve product and services to meet current customer requirements and increase customer satisfaction.

These improvements are either identified as corrections, Corrections Actions and Preventive Actions (CAPA) or as additional proposals for quality objectives and KPIs.

7.5 Management Review Report and Follow up

The Management Review Report in a summary report, which should include the following:

- Date and Participants of the Management Review
- All presented information attached (Reports, PowerPoint slides)
- Conclusion about the follow up status from last Management Review
- An executive summary of all reviewed data and presentations
- All results and conclusions of the Management Review
- A list of all agreed actions discussed during the Management Review
- A conclusion on any averse product or quality trends
- A final conclusion on the assessment of all results and the performance and efficiency of the established Quality System

This report must be signed and approved by the Quality Head and the Site Head company head as a minimum. An authorized copy of this report should be distributed to all Management Committee members and to the participants of the Management Review meeting.

8 ATTACHMENTS

Attachment 1: Management Review Flow chart (1 page)

9 SOP DISTRIBUTION

In this paragraph the customer should indicate the persons and department with authorized copies of this SOP

SOP Authorized Copy Number	Department	Name
01	Sample Production	Mr. Sample
02		

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SOP	XX_WWW_ZZZ_YYYY	1.0	Approved	8/10