

Appendix 2 – Management Review Minutes

Attendants						
Type of meeting			Date and place of the meeting			
Documents used for review						
Management review						
Review item	Input	Output	Responsible person	Execution deadline	Resources needed	Status
Quality Policy			CEO			
Risk acceptability			CEO, Management Representative			
Quality objectives						
Results of internal audits						
Results of external audits						
Customer feedback						

Commented [AES1]: Regular or Additional

Commented [AES2]: Status can be: "Conducted", "Underway"

Commented [AES3]: E.g., Quality Policy is communicated to

Commented [AES4]: E.g., Periodic review of its relevance.

Commented [AES5]: E.g., Risk policy defined in the Procedure

Commented [AES6]: E.g., Changes made in section 3.1 of

Commented [AES7]: E.g., Quality objectives are met.

Commented [AES8]: E.g.:
• Internal audit found no nonconformities

Commented [AES9]: In case of nonconformities write here the

Commented [AES10]: E.g., External audit found minor

Commented [AES11]: In case of nonconformities write here

Commented [AES12]: E.g., Registry of Customer Complaints,

Commented [AES13]: E.g., Customer satisfaction survey is

Commented [AES14]: E.g., Speed up the response time on

[organization name]

Process performance and product conformity			CEO, Management Representative			
Status of corrective and preventive actions			CEO, Management Representative			
Previous management review feedback			CEO, Management Representative			
Changes in the external environment						
Inputs from the business system						
Product quality						
Training						
Quality objectives appropriate to the organization						
Recommendations for improvement of QMS						
Improvement of product related to customer requirement						
Supplier's quality performance						

- Commented [AES15]: E.g., Processes met planned results,
- Commented [AES16]: Periodic effectiveness review should be
- Commented [AES17]: E.g., One nonconformity is repeating.
- Commented [AES18]: E.g., Initiate new corrective action.
- Commented [AES19]: E.g., All previous actions are executed
- Commented [AES20]: E.g., Initiate new corrective action.
- Commented [AES21]: E.g., changes in production process,
- Commented [AES22]: E.g., Product is compliant with
- Commented [AES23]: E.g., Maintain the defined quality of
- Commented [AES24]: Write in the status of planned trainings.
- Commented [AES25]: E.g., Periodically perform training
- Commented [AES26]: E.g., Periodically perform training
- Commented [AES27]: E.g., Provide resources needed for
- Commented [AES28]: E.g., Actions from this management

[organization name]

Improvement of product related to customer requirement			CEO, Management Representative			
Date of the next Management review:	[date]		CEO			

Commented [AES29]: E.g., All defined customers' requests are met.

Commented [AES30]: E.g., Define unexpressed requests of

Commented [AES32]: E.g., Define corrective actions necessary

Commented [AES31]: E.g., Post-market Surveillance Report,

[job title]

[name]

[signature]

Commented [AES33]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.