

 Responsible Office/Division	Document No.: MDSAP QMS F0005.1.001	Page: 1 of 1
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Title: MDSAP QMS Management Responsibility/Review Report Form <i>(Sample)</i>	Project Manager: Liliane Brown, USFDA	

Date: [Date]

From: [Name]

To: [Name]

Subject: [Year] Management Review of MDSAP Management System

The [annual] [biannual] management review was performed on [Date]. The purpose of this review of the MDSAP management system is to monitor and evaluate the quality and fitness for use of services to program needs. The review ensures the fitness and effectiveness of the management system.

Attendees: [List Name of Attendees]

Synopsis of findings includes:

- Suitability of policies and procedures
- Reports from managerial and supervisory personnel
- Outcome of recent internal audits
- Effectiveness of previous actions taken
- Corrective and preventive actions
- Assessments by external bodies
- Changes in the volume and type of the work
- Complaints
- Customer feedback and complaints
- Other factors, such as quality control activities, resources and training
- Changes to Regulatory requirements documented in MDSAP QMS documentation

Conclusions:

Recommendations:

Provide a statement on the overall effectiveness of the MDSAP Quality Management System (QMS).