

# Document QC 44 MHRA / CMDCAS Risk Assessment Initial Assessment form

## Revision ID11751

Suggested Upload Document Name: **Risk Assesment For Updating Document ID11751**

Completed by [Derek Lamb](#) 19 Nov 2021

### Reason for Risk Assesment

Updated for Digital MIR reporting

Document QC 44 MHRA / CMDCAS Risk Assessment Initial Assessment form Revision ID11751 Is linked to the Following Standards and processes

Risk Assesment Question ID11751	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
11751Q0 Does this Update warrant updating Any External Parties due to any <b>Terms and Conditional Agreements</b> E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
11751Q1 Viamed Ltd ISO13485:2016 Section: 5.5 Responsibility, authority and communication	Does Update Affect? Yes ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: Needs Setting	Notes On Risk / Benefits statement if required No risk, update to method of MIR reporting	Further Action Required on Issue
11751Q2 Viamed Ltd ISO13485:2016 Section: 5.6.3 Review output	Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to:

- a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;
- b) improvement of product related to customer requirements;
- c) changes needed to respond to applicable new or revised regulatory requirements;
- d) resource needs.

Affect?

Risk Likely Due to Update

Action  
Required:  
Needs Setting

No risk, update to method of MIR reporting

11751Q3 Final Notes

No risk, update to method of MIR reporting

SAVE FORM