

Document VM3COP12.01 Viamed Policy on End User Training UK Revision ID23571

Suggested Upload Document Name: **Risk Assesment For Updating Document ID23571**

Completed by [Catrin Hird](#) 29 Mar 2022

Reason for Risk Assesment

Document VM3COP12.01 Viamed Policy on End User Training UK Revision ID23571 Is linked to the Following Standards and processes

Risk Assesment Question ID23571	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further on Issue
23571Q0 Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements 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 on Issue
23571Q1 Viamed Ltd ISO13485:2016 Section: 6.2 Human resources Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel performing work affecting product quality; b) provide training or take other actions to achieve or maintain the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) maintain appropriate records of education, training, skills and experience (see 4.2.5). NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.	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 on Issue
23571Q2 Viamed Ltd ISO13485:2016 Section: 7.2.1 Determination of requirements related to product The organization shall determine: a) requirements specified by the customer, including the requirements for delivery and postdelivery activities; b) requirements not stated by the customer but necessary for specified or intended use, as known; c) applicable regulatory requirements related to the product; d) any user training needed to ensure specified performance and safe use of the medical device; e) any additional requirements determined by the organization	Does Update Affect? Yes	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 on Issue
23571Q3 VST Ltd ISO9001:2015 Section: 7.1.2 People The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.	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 on Issue
23571Q4 VST Ltd ISO9001:2015 Section: 7.1.4 Environment for the operation of processes The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. NOTE A suitable environment can be a combination of human and physical	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible	Notes On Risk / Benefits statement if required	Further on Issue

factors, such as:

- a) social (e.g. non-discriminatory, calm, non-confrontational);
- b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
- c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

Action
Required:
No Action
Required

23571Q5	VST Ltd ISO9001:2015 Section: 7.2 Competence 7.2 Competence The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.	Does Update Affect? <input checked="" type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible	Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q6	VST Ltd ISO9001:2015 Section: 7.3 Awareness The organization shall ensure that persons doing work under the organization's control are aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements.	Does Update Affect? <input checked="" type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible	Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q7	7845 7.1.4 Environment Of Operations Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. Merged into 7729 can close the tasks	Does Update Affect? <input checked="" type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible	Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q8	7833 Importance Of Effective Quality Management To Remind Staff of the Importance of the ISO systems and they should be following the procedures	Does Update Affect? <input checked="" type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 2.Minor	Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q9	7750 Meeting With Management Meeting between management and office team leader to discuss improvement of systems and address any issues	Does Update Affect? <input checked="" type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious	Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q10	7793 Team Review Meeting Duplicate Issue needs process removing see processid 7750	Does Update Affect? <input checked="" type="checkbox"/> No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible	Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues

23571Q11	7883 Appraisal to review the staff, give feedback and discuss issues	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q12	5934 Staff Training To check that any training that has been done is valid and then checked off the training record. Including enough detail to describe what has been covered in the training and any material used.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q13	Process 7120 General Maintenance Requirements Review any General Maintenance required on the physical Site(s) Current Known Risk no risks Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q14	Process 7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems. Current Known Risk That there are duplicate orders o the system due to errors. Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q15	Process 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates. Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q16	Process 7698 Clean Toilets Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively. Current Known Risk Dirty and unhygienic bathrooms. Inadequate supply of cleaning products. Current Likly 1 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q17	Process 7713 Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff, Current Known Risk That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further on Issues
23571Q18	Process 7750 Meeting With Management Meeting between management and office team leader to discuss improvement of systems and address any issues	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update	Notes On Risk / Benefits statement if required	Further on Issues

Current Known Risk Staff being unavailable
Current Likly 3 Current Frequency 1

3.Serious
Action
Required:
No Action
Required

23571Q19 Process 7753
Management Meeting Warehouse
To discuss any problems, to assess work load and staffing.
To review issues with regard the Warehouse.
Current Known Risk Meetings not carried out regularly.
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk Frequency due to Update 1.Improbable
Risk Likly Due to Update 3.Serious
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if required

Further on Issu

23571Q20 Process 7759
Health Declaration Sheet
Information from the staff that would be used in case of emergency health issue. These are filled in by staff and filled securely.
Current Known Risk That information is not up to date or received.
Current Likly 1 Current Frequency 3

Does Update Affect? No
Risk Frequency due to Update 3.Occasional
Risk Likly Due to Update 1.Negligible
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if required

Further on Issu

23571Q21 Process 7793
Team Review Meeting
Duplicate Issue needs process removing
see processid 7750
Current Known Risk Computer/network breakdown
Current Likly 1 Current Frequency 1

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 on Issu

23571Q22 Process 7806
Watering Plants
To water the plants and ensure their survival
Current Known Risk Dead plants.
Current Likly 1 Current Frequency 1

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 on Issu

23571Q23 Process 7836
Central Heating For Winter
Reset the Heating for Winter
Current Known Risk Building too hot / cold
Current Likly 1 Current Frequency 1

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 on Issu

23571Q24 Process 7845
7.1.4 Environment Of Operations
Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

Merged into 7729 can close the tasks
Current Known Risk no risk. to the process, however risk maybe some problems may be brought up that are better left un-brought up, which may result in loss of staff while dealing with a problem that is suddenly brought to light that was better not addressed.

Current Likly 1 Current Frequency 1

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 on Issu

23571Q25 Does Generic CE File Attached to All Technical file #2
Of type 5 require any Notificaions and/or Risk assesment updates due to this update

Does Update Affect? No
Risk Frequency due to Update 1.Improbable
Risk Likly Due to Update 1.Negligible
Action
Required:

Notes On Risk / Benefits statement if required

Further on Issu

No Action
Required

23571Q26 Final Notes

SAVE FORM

 Only saves your progress in filling in above Questions - No feed back to pressing save form button
Once Form Complete Print Page to PDF (Landscape mode prefereable), go back to document upload page and upload to risk assesment button