

Document VOP 12 Training Revision ID31024

Suggested Upload Document Name: Risk Assessment For Updating Document ID31024  
Completed by Derek Lamb, 25 Oct 2024

Reason for Risk Assessment

Effectiveness Assessment:

introduces a more structured approach, with error data analysis across departments, high-error reviews, and corrective actions like workload adjustments and training.  
Review and Monitoring:

adds an emphasis on continuous monitoring through error reporting systems, adopting a risk-based approach to training needs.  
Continuous Improvement:

introduces continuous improvement as a core principle, integrating feedback loops from error reports and competency assessments to refine training materials and methods, especially for new technologies or regulatory requirements.  
Language and Clarity:

Document VOP 12 Training Revision ID31024 Is linked to the Following Standards and processes					
Risk Assessment ID31024	Question	Does Update Affect	Risk On Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q0	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 Significant change to any ISO Certifications	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 Action Required on Issue
31024Q1	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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q2	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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q3	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 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.	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 Action Required on Issue
31024Q4	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? 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 Action Required on Issue
31024Q5	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? 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 Action Required on Issue
31024Q6	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? 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 Action Required on Issue
31024Q7	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? 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 Action Required on Issue
31024Q8	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 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q9	7793 Team Review Meeting Duplicate Issue needs process removing see processid 7750	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 Action Required on Issue

31024Q10	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 Action Required on Issue
31024Q11	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 coved in the training and any material used.	Does Update Affect? Yes	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 introduces a more structured approach, with error data analysis across departments, high-error reviews, and corrective actions like workload adjustments and training. Review and Monitoring: adds an emphasis on continuous monitoring through error reporting systems, adopting a risk-based approach to training needs Continuous Improvement: introduces continuous improvement as a core principle, integrating feedback loops from error reports and competency assessments to refine training materials and methods, especially for new technologies or regulatory requirements. Language and Clarity: General improvements to the document	Further Action Required on Issue
31024Q12	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 Action Required on Issue
31024Q13	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 Action Required on Issue
31024Q14	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 Action Required on Issue
31024Q15	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 Action Required on Issue
31024Q16	Process 7713 Review Roles And Responsibilities 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 Action Required on Issue
31024Q17	Process 7750 Meeting With Management Meeting between management and office team leader to discuss improvement of systems and address any issues Current Known Risk Staff being unavailable 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 Action Required on Issue
31024Q18	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 Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q19	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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q20	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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q21	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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31024Q22	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 Likely Due to Update 1.Negligible Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue

No Action  
Required

31024Q23	<div>Process 7845</div> <div>7.1.4 Environment Of Operations</div> <div>Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.</div> <div>Merged into 7729 can close the tasks</div> <div>Current Known Risk no risk. to the process,</div> <div>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.</div> <div>Current Likly 1 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>
31024Q24	<div>Does Generic CE File Attached to All Technical file #2</div> <div>Of type 5 require any Notificaiions and/or Risk assesment updates due to this update</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>
31024Q25	<div>Final Notes</div> <div>No ISO Procedures or Process</div> <div>are negatively affected by updating this document with the new document proposed</div>				

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