

# Document VM3COP02.1 Organisation Who's Who VIAMED Revision ID112906

Suggested Upload Document Name: **Risk Assessment For Updating Document ID112906**

Completed by [Derek Lamb](#) 08 Sep 2023

**Reason for Risk Assessment**

updating Names

Document VM3COP02.1 Organisation Who's Who VIAMED Revision ID112906 Is linked to the Following Standards and processes

Risk Assessment ID112906	Question	Does Update Affect?	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q0	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
112906Q1	Viamed Ltd ISO13485:2016 Section: 5.1 Management commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by: a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; d) conducting management reviews; e) ensuring the availability of resources.	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
112906Q2	Viamed Ltd ISO13485:2016 Section: 5.5 Responsibility, authority and communication	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
112906Q3	Viamed Ltd ISO13485:2016 Section: 5.5.1 Responsibility and authority Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these 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
112906Q4	Viamed Ltd ISO13485:2016 Section: 5.5.2 Management representative Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes: a) ensuring that processes needed for the quality management system are documented; b) reporting to top management on the effectiveness of the quality management system and any need for improvement; c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.	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
112906Q5	Viamed Ltd ISO13485:2016 Section: 6.1 Provision of resources The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness; b) meet applicable regulatory and customer 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
112906Q6	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	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

associated with the work for which the training or other action is being provided.

112906Q7	<p>Viamed Ltd ISO13485:2016 Section: 7.3.2</p> <p>Design and development planning</p> <p>The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses.</p> <p>During design and development planning, the organization shall document:</p> <p>a) the design and development stages;</p> <p>b) the review(s) needed at each design and development stage;</p> <p>c) the verification, validation, and design transfer activities that are appropriate at each design and development stage;</p> <p>d) the responsibilities and authorities for design and development;</p> <p>e) the methods to ensure traceability of design and development outputs to design and development inputs;</p> <p>f) the resources needed including necessary competence of personnel</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q8	<p>VST Ltd ISO9001:2015 Section: 5.1.1</p> <p>General</p> <p>Top management shall demonstrate leadership and commitment with respect to the quality management system by:</p> <p>a) taking accountability for the effectiveness of the quality management system;</p> <p>b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;</p> <p>c) ensuring the integration of the quality management system requirements into the organization's business processes;</p> <p>d) promoting the use of the process approach and risk-based thinking;</p> <p>e) ensuring that the resources needed for the quality management system are available;</p> <p>f) communicating the importance of effective quality management and of conforming to the quality management system requirements;</p> <p>g) ensuring that the quality management system achieves its intended results;</p> <p>h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;</p> <p>i) promoting improvement;</p> <p>j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.</p> <p>NOTE Reference to business in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q9	<p>VST Ltd ISO9001:2015 Section: 5.3</p> <p>Organizational roles, responsibilities and authorities</p> <p>Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.</p> <p>Top management shall assign the responsibility and authority for:</p> <p>a) ensuring that the quality management system conforms to the requirements of this International Standard;</p> <p>b) ensuring that the processes are delivering their intended outputs;</p> <p>c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;</p> <p>d) ensuring the promotion of customer focus throughout the organization;</p> <p>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q10	<p>VST Ltd ISO9001:2015 Section: 6.3</p> <p>Planning of changes</p> <p>When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).</p> <p>The organization shall consider:</p> <p>a) the purpose of the changes and their potential consequences;</p> <p>b) the integrity of the quality management system;</p> <p>c) the availability of resources;</p> <p>d) the allocation or reallocation of responsibilities and authorities.</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q11	<p>VST Ltd ISO9001:2015 Section: 7.1.4</p> <p>Environment for the operation of processes</p> <p>The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.</p> <p>NOTE A suitable environment can be a combination of human and physical factors, such as:</p> <p>a) social (e.g. non-discriminatory, calm, non-confrontational);</p> <p>b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);</p> <p>c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).</p> <p>These factors can differ substantially depending on the products and services provided.</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q12	<p>VST Ltd ISO9001:2015 Section: 7.2</p> <p>Competence</p> <p>7.2 Competence</p> <p>The organization shall:</p> <p>a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

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.

No Action Required

112906Q13	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
112906Q14	VST Ltd ISO9001:2015 Section: 8.5.1 Control of production and service provision The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	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
112906Q15	Process32 MDALL Listings Complete the CMDCAS Paperwork once per year to Keep the Licence to sell in canada  NO LONGER KEEP THIS CERTIFICATE	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
112906Q16	Process34 Insurance Is Upto Date Ensure the latest version of our Insurance / master indemnity letters are up to date	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
112906Q17	Process39 Environmental Policy Document Review Ensure our Viamed Environment and WEEE Polycys are upto date and suitable for current legislation	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
112906Q18	Process5869 Legal Company Car Registration Registration of Company cars	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
112906Q19	Process6861 Management Meeting Review Weekly Meeting Non Minuted Management discussions on issues	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
112906Q20	Process7713 Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff,	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

112906Q21	<a href="#">Process7741</a> Review Ethical Policy Review the current Ethical Policy in intrastats	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
112906Q22	<a href="#">Process7837</a> Review External Parties Influencing The QMS VST / Viamed To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and 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
112906Q23	<a href="#">Process29</a> CMDCAS Updates And Licences Annual license check,  ensure no changes to Products licenced through CMDCAS,  and Issue CMDCAS a statement that No changes have occurred. NO LONGER KEEP THIS CERTIFICATE Certificate will go out of date 1st November,  Check Canadian Gazette for Latest Version of the MDR	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
112906Q24	<a href="#">Process7753</a> Management Meeting Warehouse To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse.	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
112906Q25	<a href="#">Process5874</a> Childcare Vouchers Edenred Edenred childcare voucher. these are purchased from Edenred and then the staff that are signed up for the service, salary sacrifice from their pay. Done by the Payroll people, Then childcare vouchers are sent directly to the nursery designate.It is a government scheme to help working families with childcare there are tax benefits for using the service.	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
112906Q26	<a href="#">Process5934</a> 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? 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 Action Required on Issue
112906Q27	<a href="#">Process5881</a> Training Records Review Keep Staff Training records upto date	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
112906Q28	<a href="#">Process5904</a> Taking On New Staff Check all new staff in the last 12 months have an Induction form filled in	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
112906Q29	<a href="#">Process6837</a> Personnel Requirements and Training Keep Staff Training records upto date	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
112906Q30	<a href="#">Process6877</a> Alarm Key Holders those that have keys and use the intruder alarm	Does Update Affect? No	Risk Frequency due to Update 3.Occasional Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q31	<a href="#">Process7848</a> Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards	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

112906Q32 🔗Process7891 Fire Alarm Evacuation Drill To test the evacuation of the buildings in case of fire	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q33 🔗Process7908 Private Information Data remind staff about private information data and that it needs to be looked after and securely.	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q34 🔗Process7907 Annual Review Doc Management To review which employees have Access to sensitive areas of Intrastats	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q35 🔗Process7937 Diversity Impact Assessment Diversity Impact Assessment	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q36 🔗Process7961 R D Room - Tidy, Empty Bins, Remove Cups. Caution Around Oxygen Supply To Clean Tidy the research and development rooms	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q37 🔗Process7982 Check There Are No Changes To Employment Law To Check online and see if there have been any changes to Minimum wage or employment law wee need to be aware of.	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q38 🔗Process7983 To Check On Line And See If There Have Been Any Changes To Gdpr We Need To Be Aware Of. To Check online and see if there have been any changes to GDPR we need to be aware of. Check web site for GDPR <a href="https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/whats-new/">https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/whats-new/</a>	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q39 🔗ProcessProcess 22 Company Policies Ensure the company policies are still current and upto date Current Known Risk Company shoots of in directions that are not laid out in its policys or does not meet its objectives Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q40 🔗ProcessProcess 23 Company Objectives Ensure the company Objects are still current and upto date Current Known Risk Company shots of in directions that are not laid out in its objectives Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q41 🔗ProcessProcess 26 Company Resources Overview of the Company using various data Reporting Screens Current Known Risk Not enough resources to complete tasks Current Likly 3 Current Frequency 1	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>
112906Q42 🔗ProcessProcess 27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits Current Known Risk that the task is missed that follow ups are missed Current Likly 3 Current Frequency 1	Does Update Affect? <input type="button" value="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 <div></div>	Further Action Required on Issue <div></div>

112906Q43	<a href="#">Process</a> Process 6837 Personnel Requirements and Training Keep Staff Training records upto date Current Known Risk Keep enough trained staff to perform our tasks Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q44	<a href="#">Process</a> Process 6931 Customer Complaints Review the Customer Complaints Heading Current Known Risk things are not followed up in a timely manner or are missed 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 Action Required on Issue
112906Q45	<a href="#">Process</a> Process 7048 Control of monitoring and measuring devices Control of monitoring and measuring devices Current Known Risk that equipment will be missed Current Likly 1 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q46	<a href="#">Process</a> Process 7070 Management Review To discuss any problems, to assess work load and staffing. To review issues. Current Known Risk Meetings not carried out regularly. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q47	<a href="#">Process</a> Process 7093 BSI Audits Calander Review of outstanding Audits Current Known Risk Audits dont get completed 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 Action Required on Issue
112906Q48	<a href="#">Process</a> 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 Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q49	<a href="#">Process</a> Process 7199 Non Conformities Review Viamed To review any non conformances created during the previous month, and produce a non conformance report.  Review history of non conformances and see if there has been any improvement. Current Known Risk Non conformances go unfixed Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q50	<a href="#">Process</a> 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 Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q51	<a href="#">Process</a> 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 Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q52	<a href="#">Process</a> Process 7679 Check Stock Requirements Supplier Teledyne To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q53	<a href="#">Process</a> Process 7680 Check Stock Requirements Supplier Envitec To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

112906Q54	<p>ProcessProcess 7681</p> <p>Check Stock Requirements Supplier Posey</p> <p>To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.</p> <p>Current Known Risk That a customer is told we have stock and then we are unable to ship.</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q55	<p>ProcessProcess 7682</p> <p>Check Stock Requirements Supplier Blueprint</p> <p>To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.</p> <p>Current Known Risk That a customer is told we have stock and then we are unable to ship.</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q56	<p>ProcessProcess 7686</p> <p>Thorough Checking Of Awaiting Action Tray - Priority 8s</p> <p>Check that outstanding orders with unresolved issues are being followed up and addressed</p> <p>Current Known Risk Computer/network breakdown</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q57	<p>ProcessProcess 7697</p> <p>Yearly Pricing Review</p> <p>To review the current pricing and impact of increases</p> <p>Current Known Risk Getting this wrong can interfere with sales.</p> <p>Current Likly 1 Current Frequency 2</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q58	<p>ProcessProcess 7698</p> <p>Clean Toilets</p> <p>Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively.</p> <p>Current Known Risk Dirty and unhygienic bathrooms. Inadequate supply of cleaning products.</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q59	<p>ProcessProcess 7713</p> <p>Review Roles And Responsibilitys</p> <p>Ensure All tasks allocated to active Members of staff,</p> <p>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.</p> <p>Risk of being over faced.</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q60	<p>ProcessProcess 7736</p> <p>Production Start Job List</p> <p>When a new production is needed we the production job to the list of procedures.</p> <p>Check to make sure that every new job has a procedure linked to it.</p> <p>Current Known Risk That a job will be carried out without a procedure.</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q61	<p>ProcessProcess 7737</p> <p>Production In Production List</p> <p>Review the Production List, check and list those items that were started more than 30 days ago have not been through QA.</p> <p>Audit is carried out and production is reviewed and chased at this point.</p> <p>Current Known Risk Production jobs is finished but not been QA, may get lost in the system</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>2.Remote</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q62	<p>ProcessProcess 7739</p> <p>Intrastats Amendment Log</p> <p>Intrastat Changes updates.</p> <p>Logging system to enable roll back should anything break</p> <p>Current Known Risk None, The updates are automatically logged and stored for easy retrieval.</p> <p>This process is simply to add notes to new updates</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q63	<p>ProcessProcess 7740</p> <p>Weights Per Region Needed To Submit EC Sales List</p> <p>Filling in HMRC data requires Weights and dimensions per region in the EC</p> <p>This process ensures all the data is in place for the report</p> <p>Current Known Risk Fines for late submission</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>1.Negligible</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
112906Q64	<p>ProcessProcess 7743</p> <p>Customer Complaints Paper File</p> <p>Major Customer Complaints get escalated to Paper Customer Complaints file.</p> <p>Check the File is being Maintained and any relevant documentation is in the File.</p> <p>Current Known Risk Customer Complaints could be missed or not filed correctly</p> <p>Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect?</p> <p>No</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable</p> <p>Risk Likly Due to Update</p> <p>2.Minor</p> <p>Action Required:</p> <p>No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

112906Q65	<a href="#">Process</a> Process 7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products  In order to sell in the USA / Canada Markets products need to be registered with the FDA.  Current Known Risk Its harder to initially get on teh register than maintaining it.  Inability to sell products in North America Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q66	<a href="#">Process</a> 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? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q67	<a href="#">Process</a> 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? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q68	<a href="#">Process</a> Process 7791 Price List Check Changing of the prices lists. Issue to check these are current  *Vandagraph is not an ISO company Current Known Risk That people will quote the wrong price to the customer.  Current Likly 1 Current Frequency 2	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="2.Remote"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q69	<a href="#">Process</a> 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? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q70	<a href="#">Process</a> Process 7827 Review The Quality Policy VST To review the Quality policy and check it is still valid and upto date. Current Known Risk that policy will go out of date Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q71	<a href="#">Process</a> Process 7828 Review The Quality Policy Viamed To review the Quality policy and check it is still valid and upto date. Current Known Risk That the policy will go out of date Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q72	<a href="#">Process</a> Process 7833 Importance Of Effective Quality Management To Remind Staff of the Importance of the ISO systems and they should be following the procedures Current Known Risk people may become careless Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q73	<a href="#">Process</a> Process 7834 Financial Review The review the Financial requirements Current Known Risk Non Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q74	<a href="#">Process</a> 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? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
112906Q75	<a href="#">Process</a> 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.	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>



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

Update  
1.Negligible  
Action Required:  
No Action Required

112906Q76	ProcessProcess 7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards Current Known Risk No risks Rolling issue to perform task 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 Action Required on Issue
112906Q77	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: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q78	Does AF Monitor Technical file #24 Of type 0 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: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
112906Q79	Final Notes No ISO Procedures or Process are negativly affected by updating this document with the new document proposed				

**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