

# Document VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews and Analysis Data Revision ID53797

Suggested Upload Document Name: **Risk Assesment For Updating Document ID53797**

Completed by Derek Lamb 17 Nov 2021

## Reason for Risk Assesment

Feedback process was not fully effective as PMS procedure was not seen to be updated according applicable regulatory requirements for the CE products which are still in service.

Document VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews and Analysis Data Revision ID53797 Is linked to the Following Standards and processes

Risk Assessment Question	Does Update Risk on Update Affect	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q0 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 Risk Frequency Update due to Update Affect? 1.Improbable ▼ No ▼ Risk Likly Due to Update 1.Negligible ▼ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q1 Viamed Ltd ISO13485:2016 Section: 4.1.3 Quality management system For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes;	Does Risk Frequency Update due to Update Affect? 1.Improbable ▼ No ▼ Risk Likly Due to Update 1.Negligible ▼ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).

		Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q2	Viamed Ltd ISO13485:2016 Section: 5.6.1  General  The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.  Records from management reviews shall be maintained			
53797Q3	Viamed Ltd ISO13485:2016 Section: 5.6.2 Review input  General  The input to management review shall include, but is not limited to, information arising from:  a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.			
53797Q4	Viamed Ltd ISO13485:2016 Section: 8.1  General  The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:  a) demonstrate conformity of product; b) ensure conformity of the quality management system; c) maintain the effectiveness of the quality management system.  This shall include determination of appropriate methods, including statistical			

techniques, and the extent of their use.

53797Q5	<p>Viamed Ltd ISO13485:2016 Section: 8.2.1</p> <p><b>Feedback</b></p> <p>As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented.</p> <p>The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.</p> <p>The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.</p> <p>If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.</p>	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="Yes"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: Needs Setting"/></p> <p>Notes On Risk / Benefits statement if required</p> <p>Requirements of MDR Art. 120 Added no negative effect to the system</p>	<p>Further Action Required on Issue</p> <p>241893</p>
53797Q6	<p>Viamed Ltd ISO13485:2016 Section: 8.2.4</p> <p><b>Internal audit</b></p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p> <p>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit</p>	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: No Action Required"/></p> <p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

NOTE Further information can be found in ISO 19011.

		Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: No Action Required"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q7	Viamed Ltd ISO13485:2016 Section: 8.2.5 Monitoring and measurement of processes The organization shall apply suitable methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.	Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: No Action Required"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q8	Viamed Ltd ISO13485:2016 Section: 8.4 Analysis of data The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective,	Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: No Action Required"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue

the organization shall use this analysis as input for improvement as required in 8.5.

Records of the results of analyses shall be maintained (see 4.2.5).

53797Q9	VST Ltd ISO9001:2015 Section: 6.2.1	Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/>	Risk Likly Due to Update 1.Negligible <input type="button" value="▼"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q9	<p>The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall:</p> <ul style="list-style-type: none"><li>a) be consistent with the quality policy;</li><li>b) be measurable;</li><li>c) take into account applicable requirements;</li><li>d) be relevant to conformity of products and services and to enhancement of customer satisfaction;</li><li>e) be monitored;</li><li>f) be communicated;</li><li>g) be updated as appropriate.</li></ul> <p>The organization shall maintain documented information on the quality objectives</p>	Action Required: No Action Required			
53797Q10	<p>VST Ltd ISO9001:2015 Section: 8.5.5</p> <p>Post-delivery activities</p> <p>The organization shall meet requirements for post-delivery activities associated with the products and services.</p> <p>In determining the extent of post-delivery activities that are required, the organization shall consider:</p> <ul style="list-style-type: none"><li>a) statutory and regulatory requirements;</li><li>b) the potential undesired consequences associated with its products and services;</li><li>c) the nature, use and intended lifetime of its products and services;</li><li>d) customer requirements;</li><li>e) customer feedback.</li></ul> <p>NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.</p>	Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/>	Risk Likly Due to Update 1.Negligible <input type="button" value="▼"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q11	<p>VST Ltd ISO9001:2015 Section: 9.1.1</p> <p>General</p> <p>The organization shall determine:</p> <ul style="list-style-type: none"><li>a) what needs to be monitored and measured;</li><li>b) the methods for monitoring, measurement, analysis and evaluation needed to</li></ul>	Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/>	Risk Likly Due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

1.Negligible ▾

Action

Required:

No Action

Required

53797Q12	VST Ltd ISO9001:2015 Section: 9.1.2 Customer satisfaction The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.	Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾	Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q13	VST Ltd ISO9001:2015 Section: 9.1.3 Analysis and evaluation The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. NOTE Methods to analyse data can include statistical techniques.	Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾	Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q14	VST Ltd ISO9001:2015 Section: 9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system;	Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾	Risk Likly Due to Update 1.Negligible ▾	Notes On Risk / Benefits statement if required	Further Action Required on Issue

2) the requirements of this International Standard;  
 b) is effectively implemented and maintained.

Action  
 Required:  
 No Action  
 Required

53797Q15 VST Ltd ISO9001:2015 Section: 9.2.2

The organization shall:

- a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q16 VST Ltd ISO9001:2015 Section: 9.3.1

General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q17 VST Ltd ISO9001:2015 Section: 9.3.2

Management review inputs

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

c) information on the performance and effectiveness of the quality management system, including trends in:

- 1) customer satisfaction and feedback from relevant interested parties;
- 2) the extent to which quality objectives have been met;
- 3) process performance and conformity of products and services;
- 4) nonconformities and corrective actions;
- 5) monitoring and measurement results;
- 6) audit results;
- 7) the performance of external providers;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1);

f) opportunities for improvement.

No Action Required

53797Q18	QProcess22 Company Policies Ensure the company policies are still current and upto date	Does Risk Frequency Update due to Update Affect?	1.Improbable	Notes On Risk / Benefits statement if required	Further Action Required on Issue
		No	Risk Likly Due to Update 1.Negligible		
53797Q19	QProcess23 Company Objectives Ensure the company Objects are still current and upto date	Does Risk Frequency Update due to Update Affect?	1.Improbable	Notes On Risk / Benefits statement if required	Further Action Required on Issue
		No	Risk Likly Due to Update 1.Negligible		
53797Q20	QProcess55 Business Continuity Plan Business Continuity Plan	Does Risk Frequency Update due to Update Affect?	1.Improbable	Notes On Risk / Benefits statement if required	Further Action Required on Issue
		No	Risk Likly Due to Update 1.Negligible		

		No Action Required	
53797Q21	Process7846 ISO System Management Review Viamed To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q22	Process7834 Financial Review The review the Financial requirements	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q23	Process27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="3.Serious"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q24	Process26 Company Resources Overview of the Company using various data Reporting Screens	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="3.Serious"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>

		No Action Required	
53797Q25	QProcess38 Audits Up to Date and Confirm next years Audit schedule Management oversight of Internal Tasks and Audits Issue(s). Review the responses to Tasks and Audits. ensure they are being fulfilled and completed.	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q26	QProcess5877 Review Company Data To review the numbers of various departments. Showing increasing / reducing staff requirements	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likely Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q27	QProcess7070 Management Review To discuss any problems, to assess work load and staffing. To review issues.	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q28	QProcess5887 Review ISO/EN Documents To Keep Products and Services up-to date with current regulations and standards	Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likely Due to Update 2.Minor Action Required:	Notes On Risk / Benefits statement if required Further Action Required on Issue

		No Action Required	
53797Q29	QProcess5889 Audit And Task - Audit To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits	Does Risk Frequency Update due to Update Affect? 1.Improbable ▼ No ▼ Risk Likly Due to Update 4.Critical ▼ Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q30	QProcess6866 Internal Process Verification Complete Systems Review Review the Internal Process and Verification's are suitable for the current standards  PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20	Does Risk Frequency Update due to Update Affect? 1.Improbable ▼ No ▼ Risk Likly Due to Update 1.Negligible ▼ Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q31	QProcess7071 Post Market Surveillance The process by which re view and risk assess all product files, check that no Products / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.	Does Risk Frequency Update due to Update Affect? 3.Occasional ▼ No ▼ Risk Likly Due to Update 1.Negligible ▼ Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q32	QProcess7093 BSI Audits Calander Review of outstanding Audits	Does Risk Frequency Update due to Update Affect? 1.Improbable ▼ No ▼ Risk Likly Due to Update 1.Negligible ▼ Action Required:	Notes On Risk / Benefits statement if required Further Action Required on Issue

		No Action Required	
53797Q33	QProcess7172 CE Technical Files Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body.	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 1.Negligible <input type="button" value="▼"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q34	QProcess7138 Non Conformance Issues Any New QC21 Forms To review any new QC 21 Forms	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 3.Serious <input type="button" value="▼"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q35	QProcess7808 Ensure All Invoice Correctly Tagged To find and Tag any sales that are removed from commissions, as they are break even products for relationships purposes	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 3.Serious <input type="button" value="▼"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q36	QProcess7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems.	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 3.Serious <input type="button" value="▼"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>

		No Action Required	
53797Q37	QProcess7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats.	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q38	QProcess57 Temporary Stock Notices To Review Memos on Stock references tagged as Temporary	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q39	QProcess5854 Stock FAQ Admin List To update and maintain the Stock FAQ list	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q40	QProcess6871 ISO14001 Environmental management systems Not yet Applied Rolling Issue to see if we should apply this standard in the future	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>

		No Action Required		
53797Q41	Process7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards	Does Risk Frequency Update due to Update Affect? <input checked="" type="checkbox"/> 1.Improbable <input type="checkbox"/> No <input checked="" type="checkbox"/> Risk Likly Due to Update <input checked="" type="checkbox"/> 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q42	Process28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.	Does Risk Frequency Update due to Update Affect? <input checked="" type="checkbox"/> 1.Improbable <input type="checkbox"/> No <input checked="" type="checkbox"/> Risk Likly Due to Update <input checked="" type="checkbox"/> 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q43	Process7879 Software Validation Scheduled Tasks And Audits To check the Scheduled Tasks and Audits is working as Intended. To also Check the Out of Date documents is working as Intended.	Does Risk Frequency Update due to Update Affect? <input checked="" type="checkbox"/> 1.Improbable <input type="checkbox"/> No <input checked="" type="checkbox"/> Risk Likly Due to Update <input checked="" type="checkbox"/> 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q44	Process7876 Maintain Update Of ISO Route Maps To review Route map VIAMED 13485:2016 and VST 9001:2015  See if a new Summary sheet needs producing,	Does Risk Frequency Update due to Update Affect? <input checked="" type="checkbox"/> 1.Improbable <input type="checkbox"/> No <input checked="" type="checkbox"/> Risk Likly Due to Update <input checked="" type="checkbox"/> 2.Minor Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue

print new PDF, and upload on top of the old summary

No Action  
Required

53797Q45	QProcess7878 Review Possible Upcoming Regulation Changes Review possible legal / regulator changes that might affect Viamed / VST	Does Risk Frequency Update due to Update Affect? <input type="button" value="3.Occasional"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q46	QProcess7885 Audit 04 Accounts and Finance Carry out Audit 04 Accounts for Both VST and Viamed	Does Risk Frequency Update due to Update Affect? <input type="button" value="2.Remote"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q47	QProcess7837 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 Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q48	QProcess7888 Review Processes Linked To VOPs And Audits Ensure All Sub Processes are linked to a VOP and an Audit.	Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="3.Serious"/> Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue

		No Action Required	
53797Q49	Process7965 VST Feedback Enter Feedback from VST customer or Suppliers in the the Feedback headers Both Positive and Negative feedback to be logged	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="2.Remote"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q50	Process7964 Check Roles And Tasks For Incomplete Data To check the Roles and tasks tables for any gaps /red crosses Fill in the missing information where needed.	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="2.Remote"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q51	Process7877 Disaster Planning To Plan for disaster	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="3.Occasional"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q52	Process7980 Review Gov Website For Applicable Required Standards ISO9001 Review the Government Website For Applicable Required Standards ISO 9001 Check if any other standards have been introduced that may have an affect on the company www.gov.uk European Commission harmonised standards to check documentation upto date	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="2.Remote"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>

53797Q53	<p>ProcessProcess 11 Distribution Of Mail Distibuting incoming post to correct person Current Known Risk Royal Mail fail to deliver post Current Likly 3 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 3.Serious <input type="button" value="▼"/> Action Required: No Action Required</p>	Notes On Risk / Benefits statement if required <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	Further Action Required on Issue <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q54	<p>ProcessProcess 14 Fax Paper Ensuring that fax reports have been generated for both sent and received faxes and ensuring there is paper in the fax machine Current Known Risk Phone lines go down The paper tray is empty Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 1.Negligible <input type="button" value="▼"/> Action Required: No Action Required</p>	Notes On Risk / Benefits statement if required <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	Further Action Required on Issue <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q55	<p>ProcessProcess 15 Filing and Archiving Paperwork to be filed in the correct order Current Known Risk Paperwork is filed incorrectly Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 1.Negligible <input type="button" value="▼"/> Action Required: No Action Required</p>	Notes On Risk / Benefits statement if required <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	Further Action Required on Issue <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
53797Q56	<p>ProcessProcess 21 Office Sales Projects Ensuring office job list is being updated and completed Current Known Risk Office is short staffed or over worked Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 2.Minor <input type="button" value="▼"/></p>	Notes On Risk / Benefits statement if required <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	Further Action Required on Issue <div style="border: 1px solid black; height: 100px; width: 100%;"></div>

		Action Required: No Action Required		
53797Q57	QProcessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q58	QProcessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q59	QProcessProcess 28 Supplier Review Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.  Current Known Risk Supplier certificates go out of date, or they lose ISO standards and we're unaware Current Likly 1 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q60	QProcessProcess 36 Emailing Of Invoices Invoices are emailed to customers	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Current Known Risk Computer or network failure  
Current Likly 2 Current Frequency 1

to Update  
2.Minor  
Action  
Required:  
No Action  
Required

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53797Q61	QProcessProcess 5859 Review Un-shipped Parcels audit and snap shot - this is an audit of a part of goods out, listing of the parcels that are sat waiting on a customer response Current Known Risk Customer forgets to come back to us and parcels stay ready for shipping. As the package is already pick pack and ready to leave the building all computer traces will show as shipped. Current Likly 2 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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53797Q62	QProcessProcess 5871 Check Sale Or Returns Review the Sale or Return list in intrastats. Ensure it is up to date. Current Known Risk That goods could be sent to a customer or goods returned but the list is not updated Current Likly 2 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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53797Q63	QProcessProcess 5872 Check Sale Or Returns Export Review the Sale or Return list in intrastats. Ensure it is up to date. Current Known Risk That goods could be sent to a customer or goods returned but the list is not updated Current Likly 2 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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53797Q64	QProcessProcess 5875 Check Paypal For Orders Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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	Current Known Risk Computer/network breakdown	to Update 2.Minor	
	Current Likly 2 Current Frequency 1	Action Required: No Action Required	
53797Q65	ProcessProcess 5876 E.Commerce Cardea And Multiquote To Collect E.Commerce Cardea And Multiquote Orders Current Known Risk Orders go unnoticed Current Likly 1 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q66	ProcessProcess 5877 Review Company Data To review the numbers of various departments. Showing increasing / reducing staff requirements Current Known Risk incorrect staff levels Current Likly 3 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q67	ProcessProcess 5881 Training Records Review Keep Staff Training records upto date Current Known Risk Keep enough trained staff to perform our tasks Current Likly 2 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
53797Q68	ProcessProcess 5882 Send Post To Humanmed Humanmed post is received, it needs to be forwarded to Humanmed UK Sales Manager	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due	Notes On Risk / Benefits statement if required Further Action Required on Issue

Current Known Risk Post is not sent  
Current Likly 4 Current Frequency 1

to Update  
4.Critical  
Action  
Required:  
No Action  
Required

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53797Q69	QProcessProcess 5887 Review ISO/EN Documents To Keep Products and Services up-to date with current regulations and standards Current Known Risk Shipping products and or services with below regulations and or standards Current Likly 2 Current Frequency 2	Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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53797Q70	QProcessProcess 5889 Audit And Task - Audit To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits Current Known Risk non risk to process, Risk of not completing is Jobs / tasks can go not done Current Likly 4 Current Frequency 1	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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53797Q71	QProcessProcess 5892 Checking EBay And Amazon For Orders And Messages Checking the eBay and Amazon accounts for orders that have not been emailed to the main inbox and checking to see if there are messages or questions. Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 2	Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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53797Q72	QProcessProcess 5893 Answering Website Questions Answering any questions that are asked via the website from within Intrastats Current Known Risk Computer/network breakdown	Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
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Current Likly 1 Current Frequency 1

to Update

1.Negligible ▾

Action

Required:

No Action

Required

53797Q73  Process 5894

Checking Of Active List

Check the Active Back orders ensure no orders get missed

Current Known Risk List is not reviewed and orders do not get shipped

Current Likly 1 Current Frequency 1

Does Risk Frequency

Update due to Update

Affect? 1.Improbable ▾

No ▾ Risk Likly Due

to Update

1.Negligible ▾

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q74  Process 5895

Completing Office Job List

Ensuring that the allocated tasks are being completed

Current Known Risk Office staff are too busy

Current Likly 3 Current Frequency 1

Does Risk Frequency

Update due to Update

Affect? 1.Improbable ▾

No ▾ Risk Likly Due

to Update

3.Serious ▾

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q75  Process 5899

Proforma And Quote Chasing

Chase outstanding Quotes and Proforms

Current Known Risk Computer/network breakdown

Not chased up.

Current Likly 3 Current Frequency 1

Does Risk Frequency

Update due to Update

Affect? 1.Improbable ▾

No ▾ Risk Likly Due

to Update

3.Serious ▾

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q76  Process 5901

Link Call Log Contacts To The CRM

To link new calls to Contacts in the CRM

Does Risk Frequency

Update due to Update

Affect? 1.Improbable ▾

No ▾ Risk Likly Due

Notes On Risk / Benefits statement if required

Further Action Required on Issue

	<p>Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	<p>to Update 2.Minor</p> <p>Action Required: No Action Required</p>	
53797Q77	<p>QProcessProcess 5913 Check For Humanmed Orders In Logistics Mailbox Checking the logistics mailbox from within and the main inbox for outstanding Humanmed orders.</p> <p>Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable No</p> <p>Risk Likly Due to Update 2.Minor</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q78	<p>QProcessProcess 5943 Check Cardea And Multiquote Checking the Cardea and Multiquote websites for outstanding orders or requests</p> <p>Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable No</p> <p>Risk Likly Due to Update 2.Minor</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q79	<p>QProcessProcess 5949 Filling Credit Card Slips Inputting the accurate data on to our pre-printed credit card slips for processing on dispatch of good. Secure storing and processing</p> <p>Current Known Risk incorrect information slips left unsecured</p> <p>Current Likly 1 Current Frequency 3</p>	<p>Does Risk Frequency Update due to Update Affect? 3.Occasional No</p> <p>Risk Likly Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q80	<p>QProcessProcess 6829 Supplier Review - Outstanding orders Orders that have not been supplied in the time scale provided.</p> <p>Current Known Risk That good will be delayed and therefore not available to</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote No</p> <p>Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>

customers.

Current Likly 2 Current Frequency 2

to Update

2.Minor

Action

Required:

No Action

Required

53797Q81 QProcessProcess 6832

Supplier Review Future orders

Orders that will be placed in the future.

Current Known Risk That we will not place the correct orders and the right time.

Current Likly 2 Current Frequency 1

Does Risk Frequency Update due to Update Affect? 1.Improbable

No Risk Likely Due to Update

2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q82 QProcessProcess 6851

Review Accident Book

To look through the accident book and make sure there were no breaches of Health and Safety that were not reported.

Current Known Risk That additions to the accident book have not been reported when serious.

Current Likly 2 Current Frequency 2

Does Risk Frequency Update due to Update Affect? 2.Remote

No Risk Likely Due to Update

2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q83 QProcessProcess 6898

GHX Web Pricing

To review the GHX Web Pricing

Current Known Risk That the prices are in correct and we may have to let them have the old price if we have not up dated them

Current Likly 1 Current Frequency 2

Does Risk Frequency Update due to Update Affect? 2.Remote

No Risk Likely Due to Update

1.Negligible

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q84 QProcessProcess 6931

Customer Complaints

Review the Customer Complaints Heading

Current Known Risk things are not followed up in a timely manner or are

Does Risk Frequency Update due to Update Affect? 3.Occasional

No Risk Likely Due

Notes On Risk / Benefits statement if required

Further Action Required on Issue

missed

Current Likly 1 Current Frequency 3

to Update

1.Negligible

Action

Required:

No Action

Required

53797Q85 ProcessProcess 6954

Back Orders Review - By Customer

To check the back orders in the tray in goods out and check the active list back orders has been reviewed

Current Known Risk goods not shipped in a timely manner

Current Likly 1 Current Frequency 1

Does Risk Frequency Update due to Update Affect?

1.Improbable

No

Risk Likly Due to Update

1.Negligible

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q86 ProcessProcess 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 Risk Frequency Update due to Update Affect?

1.Improbable

No

Risk Likly Due to Update

2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q87 ProcessProcess 7071

Post Market Surveillance

The process by which review and risk assess all product files, check that no Products / Designs have changed significantly to warrant informing any notified bodies eg. MDD / BSI / CMDCAS or any other related Body.

Current Known Risk Loss of certifications

Unforeseen product risks.

Current Likly 1 Current Frequency 3

Does Risk Frequency Update due to Update Affect?

3.Occasional

No

Risk Likly Due to Update

1.Negligible

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q88 ProcessProcess 7091

Calibration Index

To ensure that all equipment that requires calibration is done.

In the correct timescale and manor.

Does Risk Frequency Update due to Update Affect?

2.Remote

No

Risk Likly Due

Notes On Risk / Benefits statement if required

Further Action Required on Issue

	<p>Current Known Risk That equipment we use to may not be calibrated when we need it.</p> <p>Current Likly 1 Current Frequency 2</p>	<p>to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	
53797Q89	<p>QProcessProcess 7199 Non Conformities Review Viamed To review any non conformances created during the previous month, and produce a non conformance report.</p> <p>Review history of non conformances and see if there has been any improvement.</p> <p>Current Known Risk Non conformances go unfixed</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likely Due to Update 2.Minor</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q90	<p>QProcessProcess 7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems.</p> <p>Current Known Risk That there are duplicate orders o the system due to errors.</p> <p>Current Likly 3 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likely Due to Update 3.Serious</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q91	<p>QProcessProcess 7671 Humanmed Non Conformances Humanmed Non Conformances</p> <p>Current Known Risk non conformations not logged.</p> <p>Current Likly 2 Current Frequency 2</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likely Due to Update 2.Minor</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q92	<p>QProcessProcess 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates.</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likely Due</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>

Current Known Risk Stock being dispatched that is pasts its date.  
Current Likly 1 Current Frequency 2

to Update  
1.Negligible ▾  
Action  
Required:  
No Action  
Required

53797Q93  ProcessProcess 7674  
Check Repairs Ready For Invoice List  
Review the repairs ready For invoice List in intrastats.  
Current Known Risk That repairs will be missed.  
Current Likly 2 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q94  ProcessProcess 7676  
PDFing Of Invoices Viamed  
Process of PDF ing Invoices into the system for easy of use in the future and  
the Emailing of Invoices to customers  
  
NO LONGER REQUIRED AS DONE BY THE SYSTEM  
AUTOMATICALLY  
Current Known Risk Incorrect name given to Invoice when saving the PDF.  
customer gets incorrect invoice.  
Current Likly 2 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q95  ProcessProcess 7678  
Check Catalog 360 Circle For Quotes And Orders  
Checking the Catalog 360 Circle website for outstanding orders or requests  
Current Known Risk Computer/network breakdown  
Current Likly 2 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q96  ProcessProcess 7683  
Check Stock For Proforma  
To check that we have stock in for customer proformas. Or review if any stock  
needs to be ordered.

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾  
No ▾ Risk Likly Due

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

	<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>to Update 2.Minor</p> <p>Action Required: No Action Required</p>	
53797Q97	<p>QProcessProcess 7684</p> <p>Repairs Ready For Quote</p> <p>Process Repairs Ready For Quote</p> <p>Current Known Risk If process does not get performed, we likely to loose customers,</p> <p>get complaints over not responding to customers returned goods</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q98	<p>QProcessProcess 7685</p> <p>Repairs Ready For Invoice</p> <p>Process Invoice for completed repairs.</p> <p>Current Known Risk repair has errors on it</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q99	<p>QProcessProcess 7686</p> <p>Thorough Checking Of Awaiting Action Tray</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 Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>
53797Q100	<p>QProcessProcess 7690</p> <p>Ship Repairs</p> <p>Review the Repairs completed shelf and ship those items that are ready for return to the customer.</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due</p>	<p>Notes On Risk / Benefits statement if required</p> <p>Further Action Required on Issue</p>

Current Known Risk That a repair will be missed  
Current Likly 2 Current Frequency 1

to Update  
2.Minor  
Action  
Required:  
No Action  
Required

53797Q101 ProcessProcess 7691  
Ship Sale Or Returns  
Review the sale or return shelf and ship those items.  
Current Known Risk Goods will be missed  
Current Likly 2 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q102 ProcessProcess 7693  
Collect Repair Filing From Warehouse  
Collect the filing form the warehouse  
Current Known Risk paperwork has been missed  
Current Likly 1 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q103 ProcessProcess 7699  
Shred Sensitive Paperwork In JL Office  
Shredding of sensitive information  
Current Known Risk Broken shredder  
Current Likly 1 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q104 ProcessProcess 7709  
Delivered not Invoiced  
Ensure invoices are generated for shipped orders  
Current Known Risk Computer/network breakdown

Does Risk Frequency  
Update due to Update  
Affect? 2.Remote  
No Risk Likly Due

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

delivery is missed and remains un invoiced.  
Current Likly 2 Current Frequency 2

to Update  
2.Minor  
Action  
Required:  
No Action  
Required

53797Q105 ProcessProcess 7712  
Review Inward Payments  
Review the payments received to ensure proformas can be shipped  
Current Known Risk Computer network breakdown  
Current Likly 3 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q106 ProcessProcess 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 Risk Frequency  
Update due to Update  
Affect? 2.Remote  
No Risk Likly Due  
to Update  
2.Minor  
Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q107 ProcessProcess 7735  
Ensure SOR`s Are Followed Up  
Ensure samples and Sale or Return items are followed up after 4 weeks for  
feedback and the item(s) is returned as appropriate  
Current Known Risk Computer/network breakdown  
Current Likly 2 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q108 ProcessProcess 7741  
Review Ethical Policy  
Review the current Ethical Policy in intrastats

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable  
No Risk Likly Due

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

Current Known Risk That something is missed that we would like to include  
Current Likly 1 Current Frequency 1

to Update  
1.Negligible ▾  
Action  
Required:  
No Action  
Required

53797Q109 QProcessProcess 7743  
Customer Complaints Paper File  
Major Customer Complaints get escalated to Paper Customer Complaints file.  
  
Check the File is being Maintained and any relevant documentation is in the File.  
Current Known Risk Customer Complaints could be missed or not filed correctly  
Current Likly 2 Current Frequency 1

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾  
No ▾ Risk Likely Due  
to Update  
2.Minor ▾  
Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q110 QProcessProcess 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 Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾  
No ▾ Risk Likely Due  
to Update  
1.Negligible ▾  
Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q111 QProcessProcess 7748  
Check Repair Orders  
Check the orders against the customer paperwork, that we have generated, for  
the repair we have received in.  
Current Known Risk That details will be incorrect and it will affect the  
customer.  
That mistakes may be missed.  
Current Likly 2 Current Frequency 1

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾  
No ▾ Risk Likely Due  
to Update  
2.Minor ▾  
Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q112 QProcessProcess 7749

Does Risk Frequency

Notes On Risk / Benefits statement if

Further Action Required

#### Check Repair Quotes

Check the quotes that we send out for the repairs we have received in.

Current Known Risk That mistakes may be missed.

That details will be incorrect and it will affect the customer.

Current Likly 2 Current Frequency 2

Update due to Update required

Affect? 2.Remote

No Risk Likly Due

to Update

2.Minor

Action

Required:

No Action

Required

on Issue

#### 53797Q113 ProcessProcess 7752

SRS Folder

Ensure all outstanding repairs are being dealt with

Current Known Risk repairs get stuck in the system

Current Likly 2 Current Frequency 1

Does Risk Frequency

Update due to Update

Affect? 1.Improbable

No Risk Likly Due

to Update

2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

#### 53797Q114 ProcessProcess 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 Risk Frequency

Update due to Update

Affect? 1.Improbable

No Risk Likly Due

to Update

3.Serious

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

#### 53797Q115 ProcessProcess 7758

Check For GHX Orders

Check the emails for orders from GHX

Current Known Risk Computer/network breakdown

Current Likly 2 Current Frequency 1

Does Risk Frequency

Update due to Update

Affect? 1.Improbable

No Risk Likly Due

to Update

2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

#### 53797Q116 ProcessProcess 7760

Does Risk Frequency

Notes On Risk / Benefits statement if

Further Action Required

<p>Send Service Offers Send letters to existing customers to remind them that a service is due on their equipment Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1</p>	<p>Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>required on Issue</p>
<p>53797Q117 ProcessProcess 7761 Send VST Delivery Notifications Emailing Notifications of shipments Current Known Risk Limited risks, and if the email fails to get delivered the customer will still receive their shipment. Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required Further Action Required on Issue</p>
<p>53797Q118 ProcessProcess 7783 PDF VST Invoices And Purchase Orders Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers  NOW DONE AUTOMATICALLY Current Known Risk Incorrect name given to Invoice when saving the PDF. customer gets incorrect invoice. Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required Further Action Required on Issue</p>
<p>53797Q119 ProcessProcess 7793 Team Review Meeting Duplicate Issue needs process removing see processid 7750 Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required Further Action Required on Issue</p>
<p>53797Q120 ProcessProcess 7795</p>	<p>Does Risk Frequency</p>	<p>Notes On Risk / Benefits statement if Further Action Required</p>

### Answering UK Web Questions

Answering any questions that are asked via the website from within Intrastats

Current Known Risk Computer/network breakdown

Current Likly 1 Current Frequency 1

Update due to Update  
Affect? 1.Improbable

No Risk Likly Due  
to Update

1.Negligible

Action

Required:

No Action

Required

on Issue

53797Q121  ProcessProcess 7797

Check Order Are Being Picked In Priority Order

Check order are being picked in order of priority and date.

Current Known Risk Orders going at before more urgent ones

Current Likly 2 Current Frequency 1

Does Risk Frequency  
Update due to Update  
Affect? 1.Improbable

No Risk Likly Due  
to Update  
2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q122  ProcessProcess 7820

North Yorkshire Council Waste Tranfer

The renewal of our waste transfer agreement with North Yorkshire County  
Counclil

Current Known Risk That we cannot get rid of waste or we have a supplier that  
takes waste but does not dispose of it in the correct legal manor.

Current Likly 1 Current Frequency 2

Does Risk Frequency  
Update due to Update  
Affect? 2.Remote

No Risk Likly Due  
to Update  
1.Negligible

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q123  ProcessProcess 7821

Controlled Waste Description And Transfer

The renewal of our waste transfer agreement with our waste disposal  
companies

Current Known Risk That we cannot get rid of waste or we have a supplier that  
takes waste but does not dispose of it in the correct legal manor.

Current Likly 1 Current Frequency 2

Does Risk Frequency  
Update due to Update  
Affect? 2.Remote

No Risk Likly Due  
to Update  
1.Negligible

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q124  ProcessProcess 7822

Does Risk Frequency

Notes On Risk / Benefits statement if

Further Action Required

Review Oxylink Stock  
To check we have the stock available to supply our customer Oxylink.

NOTE THIS PROCESS HAS BEEN STOPPED.

Part number has been superseded  
Current Known Risk The we do not have the stock needed to satisfy the orders for this customer.  
Current Likly 3 Current Frequency 1

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

on Issue

53797Q125 QProcessProcess 7826  
Goods In Processes  
To Receive Goods from Suppliers  
Current Known Risk incorrectly booked in not booked in  
Current Likly 2 Current Frequency 2

Does Risk Frequency  
Update due to Update  
Affect? 2.Remote ▾  
No ▾ Risk Likly Due to Update  
2.Minor ▾  
Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q126 QProcessProcess 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 Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾  
No ▾ Risk Likly Due to Update  
1.Negligible ▾  
Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q127 QProcessProcess 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 Risk Frequency  
Update due to Update  
Affect? 1.Improbable ▾  
No ▾ Risk Likly Due to Update  
1.Negligible ▾  
Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q128 QProcessProcess 7830

Does Risk Frequency  
Notes On Risk / Benefits statement if  
Further Action Required

#### Review Q.A. Failures Report

To review the Quantities of Failed product per Stock reference Passing through the Q.A. system

Current Known Risk No risk

Current Likly 3 Current Frequency 1

Update due to Update required

Affect? 1.Improbable   
No  Risk Likly Due to Update  
3.Serious

Action  
Required:  
No Action  
Required

on Issue

#### 53797Q129 ProcessProcess 7831

Intrastats Debtors And Creditor Figures

Intrastats Debtors And Creditor Figures

Fill in the figure in Enter Overview details from Operas and bank.

Current Known Risk Not filled in often enough

Not filled in correctly

Current Likly 3 Current Frequency 1

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

Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

#### 53797Q130 ProcessProcess 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 Risk Frequency Update due to Update  
Affect? 1.Improbable   
No  Risk Likly Due to Update  
2.Minor

Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

#### 53797Q131 ProcessProcess 7834

Financial Review

The review the Financial requirements

Current Known Risk Non

Current Likly 1 Current Frequency 1

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

Action  
Required:  
No Action  
Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q132 QProcessProcess 7837

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  
Current Known Risk External party has un-reviewed expectations  
Current Likly 1 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q133 QProcessProcess 7838

Review VIAMED Feedback - Customer Feedback Negative  
Review Customer Feedback Negative  
Current Known Risk Rolling Issues No risk to process  
Current Likly 3 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q134 QProcessProcess 7839

Review VIAMED Feedback - Customer Complaints  
To Review Viamed Customer Complaints  
Current Known Risk Rolling Issue No Risk  
Current Likly 3 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q135 QProcessProcess 7840

Review VST Feedback - Customer Feedback Negative  
To review Negative feedback form Products  
see if Non Conformance or customer Complaints need to be raised  
Current Known Risk Rolling Issue, No Risk  
Current Likly 3 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

<p>53797Q136  Process 7841</p> <p>Review VST Feedback - Customer Complaints</p> <p>To review Customer Complaints</p> <p>see if Non Conformance need to be raised</p> <p>Current Known Risk Rolling Issue, No Risk</p> <p>Current Likly 3 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="3.Serious"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>53797Q137  Process 7842</p> <p>Review VIAMED Product Feedback Negative</p> <p>To review Negative feedback form Products</p> <p>see if Non Conformance or customer Complaints need to be raised</p> <p>Current Known Risk Rolling Issue, No Risk</p> <p>Current Likly 3 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="3.Serious"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>53797Q138  Process 7843</p> <p>Review VST Product Feedback Negative</p> <p>To review Negative feedback form Products</p> <p>see if Non Conformance or customer Complaints need to be raise</p> <p>Current Known Risk Rolling Issue, No Risk</p> <p>Current Likly 3 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="3.Serious"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>53797Q139  Process 7846</p> <p>ISO System Management Review Viamed</p> <p>To Comply with Top Level</p> <p>Re-authorise the Current Audits for next 12 Months</p> <p>Cover the Agenda as Per VOP13</p> <p>Current Known Risk Failure to do may cause major non conformites in QMS System</p> <p>Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

53797Q140  Process 7847  
Health And Safety Review  
Perform HSE Risk Assessment,

Re issue Message of the Day or send company issue with regard to Employees being aware of HSE documentation / policy.  
and Location of Fire Exits and First Aid Kits.

Send new Issue to Projects Asking if New HSE implications have arisen from new products.

Review Online the Local Community Risk Register.

Check the Viamed Overall Risk Analysis Program Document in the Index to check its still current.

Current Known Risk HSE Risks to Staff and business

Current Likly 1 Current Frequency 1

Does Risk Frequency Update due to Update Affect?   Risk Likly Due to Update  Action Required: No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q141  Process 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 Risk Frequency Update due to Update Affect?   Risk Likly Due to Update  Action Required: No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q142  Process 7849  
Review Product Failures New Codes  
Review the Customer Returns and Review Product Failures New Codes  
Current Known Risk Product failures / returns do not get reviewed and a new Risk may occur  
Current Likly 1 Current Frequency 3

Does Risk Frequency Update due to Update Affect?   Risk Likly Due to Update  Action Required: No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q143  Process 7871  
Review Exclusion From Viamed 13485:2016 And VST 9001:2015  
To review the Exclusions / boundaries to ISO 13485:2016 for Viamed

Does Risk Frequency Update due to Update Affect?   Risk Likly Due

Notes On Risk / Benefits statement if required

Further Action Required on Issue

Current Known Risk Something is missed.  
Current Likly 1 Current Frequency 1

to Update  
1.Negligible ▾  
Action  
Required:  
No Action  
Required

53797Q144 QProcessProcess 7874  
Review For Latest Version Med Dev 2.12.  
To Ensure we have the latest version of Med Dev 2.12.  
and update management if its been updated  
Current Known Risk Using out of date Med Dev  
Current Likly 1 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q145 QProcessProcess 7876  
Maintain Update Of ISO Route Maps  
To review  
Route map VIAMED 13485:2016  
and VST 9001:2015  
  
See if a new Summary sheet needs producing,  
print new PDF, and upload on top of the old summary

Current Known Risk Summary sheet gets out of date.  
Current Likly 2 Current Frequency 1

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q146 QProcessProcess 7877  
Disaster Planning  
To Plan for disaster  
Current Known Risk Total failure  
Current Likly 1 Current Frequency 3

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

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

53797Q147 QProcessProcess 7878  
Review Possible Upcoming Regulation Changes

Does Risk Frequency  
Update due to Update

Notes On Risk / Benefits statement if  
required

Further Action Required  
on Issue

Review possible legal / regulator changes that might affect Viamed / VST Current Known Risk Legal / Regulatory changes stop us being able to carry out our processes as per QMS Current Likly 1 Current Frequency 3	Affect? <input type="button" value="3.Occasional"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	
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53797Q148  Process 7953 Vandagraph Delivery Notifications To Send Vandagraph Delivery notifications Current Known Risk task not carried out Current Likly 1 Current Frequency 1	Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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53797Q149 Document ID22371 Chart 36 Risk Management Existing Products Is Related to this document	Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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53797Q150 Document ID74871 Need Risks and Expectations of External Parties Viamed Is Related to this document	Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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53797Q151 Document ID22842 VM3COP00.01 Company objectives Is Related to this document	Does Risk Frequency Update due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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Affect? 1.Improbable ▼  
 No ▼ Risk Likely Due to Update  
 1.Negligible ▼  
 Action  
 Required:  
 No Action  
 Required

53797Q152 Document ID17423 VM3COP02 Organisation Responsibilities Viamed Is Related to this document

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q153 Document ID13954 VM3COP02 Organisation VST Is Related to this document

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q154 Document ID69692 VM3COP02.01 Boundaries ISO 9001:2015 VST Is Related to this document

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q155 Document ID74788 VM3COP10.02 Product Recall locate products out in the Field Is Related to this document

Does Risk Frequency Update due to Update

Notes On Risk / Benefits statement if required

Further Action Required on Issue

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

53797Q156 Document ID8106 VM3COP18 Post Market Surveillance Is Related to this document

Does Risk Frequency Update due to Update		Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable		
No	Risk Likly Due to Update		
	1.Negligible		
Action			
Required:			
No Action			
Required			

53797Q157 Document ID43166 VM3COP20.064 Atlas List Invoices of a Company Between dates Is Related to this document

Does Risk Frequency Update due to Update		Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable		
No	Risk Likly Due to Update		
	1.Negligible		
Action			
Required:			
No Action			
Required			

53797Q158 Document ID47771 VM3COP24.00 Viamed Overall Risk Analysis Program Is Related to this document

Does Risk Frequency Update due to Update		Notes On Risk / Benefits statement if required	Further Action Required on Issue
Affect?	1.Improbable		
No	Risk Likly Due to Update		
	1.Negligible		
Action			
Required:			
No Action			
Required			

53797Q159 Document ID15453 VM3COP27.12 Clinical Evaluation Risk assessment Technical Files Is Related to this document

Does Risk Frequency Update due to Update		Notes On Risk / Benefits statement if required	Further Action Required on Issue
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Affect?	1.Improbable	
No	Risk Likly Due to Update	
	1.Negligible	
Action		
Required:		
No Action		
Required		

53797Q160 Document ID16995 VM3COP27.17 Complete Auto_calender Issues Is Related to this document	Does Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q161 Document ID17082 VM3COP27.36 Auto Close Issues Is Related to this document	Does Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q162 Document ID24926 VM3COP27.38 Applying statistics to Viamed products Is Related to this document	Does Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
53797Q163 Document ID72870 VM3COP60.04 Viamed Disaster Planning Business Continuity Plan Reports Is Related to this document	Does Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Affect? 1.Improbable ▼  
No ▼ Risk Likely Due to Update  
1.Negligible ▼  
Action  
Required:  
No Action  
Required

53797Q164 Document ID74819 VM3COP60.06 BUSINESS CONTINUITY PLAN  
Contingency Plan Viamed VST Vandagraph Is Related to this document

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q165 Does Generic CE File Attached to All Technical file #2  
Of type 5 require any Notifications and/or Risk assessment updates

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

53797Q166 Final Notes

No ISO Procedures or Process  
are negatively affected by updating this document with the new document proposed

SAVE FORM