Document Audit 06 Calibration VIAMED Revision ID164190

Suggested Upload Document Name: **Risk Assesment For Updating Document ID164190**
Completed by Derek Lamb 18 Nov 2024
Reason for Risk Assesment

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Added question to check for calibrate on date, stickers
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Document Audit 06 Calibration VIAMED Revision ID164190 Is linked to the Following Standards and processes

Risk Assesment ID164190	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q0	Does this Update warrant updating Any External Parties due to any **Terms and Conditional Agreements** E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required		
164190Q1	Viamed Ltd ISO13485:2016 Section: 4.1 Quality management system	Does Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required		
164190Q2	Viamed Ltd ISO13485:2016 Section: 7.5.1 Control of production and service provision Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.	Does Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required		
164190Q3	Viamed Ltd ISO13485:2016 Section: 7.6 Control of monitoring and measuring equipment The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.5); b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded (see 4.2.5); c) have identification in order to determine its calibration status; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage. The organization shall perform calibration or verification in accordance with documented procedures. In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.5). The organization shall document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be	Does Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required		

maintained (see 4.2.4 and 4.2.5).
NOTE Further information can be found in ISO 10012.

164190Q4	Viamed Ltd ISO13485:2016 Section: 8.2.4 Internal audit The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. 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 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 Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q5	Viamed Ltd ISO13485:2016 Section: 8.5.1 General The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.	Does Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q6	Process7048 Control of monitoring and measuring devices Control of monitoring and measuring devices	Does Update Affect? No	Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q7	Process7091 Calibration Index To ensure that all equipment that requires calibration is done. In the correct timescale and manor. Make sure all equipment has a date of calibration on it	Does Update Affect? No	Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q8	Process7998 Verification Calibrated Equipment Verify Equipment used is logged and up to date in the ISO calibration Index and that they have a date of calibration sticker on it.	Does Update Affect? No	Risk Freqency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q9	ProcessProcess 7048 Control of monitoring and measuring devices Control of monitoring and measuring devices Current Known Risk that equipment will be missed Current Likly 1 Current Frequency 2	Does Update Affect? No	Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q10	ProcessProcess 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates. Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2	Does Update Affect? No	Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
164190Q11	ProcessProcess 6850 Current Stock Levels Review current stock levels Current Known Risk If the levels are incorrect or we have a shortages then customers will not receive their goods in a timely manor. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

164190Q12 ProcessProcess 6838
Opera Negative Stock
To find and correct opera when it reads Negative stock values.

NOT REQUIRED ANYMORE
Opera
Current Known Risk Damage Opera.
Current Likly 1 Current Frequency 1

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

164190Q13 ProcessProcess 5858
Opera Stock Adjustments
Opera Counts bulk stock in and issues stock out against orders.
Multiple processes cause stock to be used internally,
Opera requires a weekly update to bring the stock count into line with whats been used outside the invoicing systems

NO LONGER REQUIRED, New system live counts these now
Current Known Risk Stock valuations will get inaccurate if the process is not performed.

Current Likly 2 Current Frequency 1

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

164190Q14 ProcessProcess 5935
Stock Allocations
To allocate stock that has not automatically be linked to a repair or invoice.

No longer required with replacement order system
Current Known Risk Items that should be linked to a invoice are not in the allocations list.
That items are allocated incorrectly on the list.
Current Likly 2 Current Frequency 1

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

164190Q15 ProcessProcess 6945
Missing Stock or Adjustments
To synchronise Opera stock Count against Intrastats internal movement of stock, E.G. Items that wont uniquely appear on an opera order - such as production parts.

TASK IS NO LONGER REQUIRED
Current Known Risk Opera and Intrastats go out of sync
Current Likly 1 Current Frequency 1

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

164190Q16 ProcessProcess 6955
Production Requirements
To set production job for any stock item that is needed for customer back order, warehouse requests or marketing
Current Known Risk that jobs will not be added and customers orders will be delayed
Current Likly 2 Current Frequency 1

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

164190Q17 ProcessProcess 7689
Move Stock From QA Shelf To Stock Shelf Monday
Move Stock From QA Shelf To Stock Shelf
Current Known Risk That stock is not replaced so it will take longer to pick goods for orders.
Current Likly 2 Current Frequency 1

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

164190Q18 ProcessProcess 7694
Move Stock From QA Shelf To Stock Shelf Tuesday
Move Stock From QA Shelf To Stock Shelf
Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. The stock is not on the correct shelf.
Current Likly 2 Current Frequency 1

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to Update 2.Minor
Action Required: No Action Required
Notes On Risk / Benefits statement if required
Further Action Required on Issue

164190Q19 ProcessProcess 7695
Top Up Quick Shipping Shelves
Move Stock From QA Shelf To Quick Shipping Shelves
Current Known Risk That stock is not replaced so it will take longer to pick goods for orders.
Current Likly 1 Current Frequency 1

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

164190Q20 ProcessProcess 8057
Emergency Services Show
Emergency Services Show
Emergency Services Show - September.

Can we get a list of what stock and leaflets etc we need getting ready for this. This needs to be given to the marketing and warehouse teams for stock and ordering, well in advance please.
Current Known Risk missed booking or supplies
Current Likly 1 Current Frequency 1

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to Update 1.Negligible
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Further Action Required on Issue

164190Q21 Final Notes

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