

MANAGEMENT REVIEW VIAMED 11/10/2017

a. Follow-up actions from previous reviews

Didnt have a previous review in this form, was covered by the individual meeting reviews.
As per ISO Audit, this form needs discussing once per year.

b. Customer feedback

Positive feedback reviewed

102592	Sarah Walton	08/09/17	Steve Nixon	Feedback			
		102562	Katie Evans	08/09/17	Steve Nixon	EBME Forum - 2004	
		99739	Derek Lamb	31/07/17	Steve Nixon	Feedback - Humanmed UK	
		99738	Derek Lamb	31/07/17	Sophie Lines	Feedback - Humanmed UK	
		99737	Derek Lamb	31/07/17	Sarah Walton	Feedback - Humanmed UK	
		99736	Derek Lamb	31/07/17	Katie Evans	Feedback - Humanmed UK	
		99735	Derek Lamb	31/07/17	Jonathan Connor	Feedback - Humanmed UK	
		99734	Derek Lamb	31/07/17	John Lamb	Feedback - Humanmed UK	
		99733	Derek Lamb	31/07/17	Jean Lamb	Feedback - Humanmed UK	
		99732	Derek Lamb	31/07/17	Helen Lamb	Feedback - Humanmed UK	
		99731	Derek Lamb	31/07/17	Emma Clark	Feedback - Humanmed UK	
		99730	Derek Lamb	31/07/17	Emily Hanson	Feedback - Humanmed UK	
		99729	Derek Lamb	31/07/17	Catrin Hird	Feedback - Humanmed UK	
		99728	Derek Lamb	31/07/17	Catherine Spence	Feedback - Humanmed UK	
		99727	Derek Lamb	31/07/17	Callum Watson	Feedback - Humanmed UK	
		99726	Derek Lamb	31/07/17	Derek Lamb	Feedback - Humanmed UK	

		97369	Steve Hardaker	23/06/17	Zoey Teal	Positive customer comments	
		97368	Steve Hardaker	23/06/17	Steve Nixon	Positive customer comments	
		97367	Steve Hardaker	23/06/17	Sophie Lines	Positive customer comments	
		97366	Steve Hardaker	23/06/17	Sarah Walton	Positive customer comments	
		97365	Steve Hardaker	23/06/17	Ryan Swaine	Positive customer comments	
		97364	Steve Hardaker	23/06/17	Robert Connor	Positive customer comments	
		97363	Steve Hardaker	23/06/17	Philip Crossley	Positive customer comments	
		97362	Steve Hardaker	23/06/17	Michael Green	Positive customer comments	
		97361	Steve Hardaker	23/06/17	Linda Shearing	Positive customer comments	
		97360	Steve Hardaker	23/06/17	Katie Evans	Positive customer comments	
		97359	Steve Hardaker	23/06/17	Jonathan Connor	Positive customer comments	
		97358	Steve Hardaker	23/06/17	John Lamb	Positive customer comments	
		97357	Steve Hardaker	23/06/17	Helen Lamb	Positive customer comments	
		97356	Steve Hardaker	23/06/17	Emma Clark	Positive customer comments	
		97355	Steve Hardaker	23/06/17	Emily Hanson	Positive customer comments	
		97354	Steve Hardaker	23/06/17	Catrin Hird	Positive customer comments	
		97353	Steve Hardaker	23/06/17	Catherine Spence	Positive customer comments	
		97352	Steve Hardaker	23/06/17	Callum Watson	Positive customer comments	
		97351	Steve Hardaker	23/06/17	Derek Lamb	Positive customer comments	
		92340	Katie Evans	06/04/17	Steve Nixon	Last Minute Urgent Order	

		90624	Steve Hardaker	07/03/17	Derek Lamb	Yorkshire Ambulance feedback	
		90623	Steve Hardaker	07/03/17	Steve Nixon	Yorkshire Ambulance feedback	
		78378	Steve Hardaker	05/09/16	Steve Nixon	Feedback re fast delivery of large order	
		78377	Steve Hardaker	05/09/16	Sarah Walton	Feedback re fast delivery of large order	
		78376	Steve Hardaker	05/09/16	Sarah Hawker	Feedback re fast delivery of large order	
		78375	Steve Hardaker	05/09/16	Katie Evans	Feedback re fast delivery of large order	
		78374	Steve Hardaker	05/09/16	Jonathan Connor	Feedback re fast delivery of large order	
		78373	Steve Hardaker	05/09/16	Helen Lamb	Feedback re fast delivery of large order	
		78372	Steve Hardaker	05/09/16	Emma Clark	Feedback re fast delivery of large order	
		78371	Steve Hardaker	05/09/16	Emily Hanson	Feedback re fast delivery of large order	
		78370	Steve Hardaker	05/09/16	Derek Lamb	Feedback re fast delivery of large order	
		78369	Steve Hardaker	05/09/16	Catherine Spence	Feedback re fast delivery of large order	

Negative Feed Back Reviewed

		103818	Derek Lamb	26/09/17	Derek Lamb	Gemco - semi-lost automotive customer	
		103816	Steve Hardaker	26/09/17	Derek Lamb	Gemco - semi-lost automotive customer	
		103815	Steve Hardaker	26/09/17	Steve Nixon	Gemco - semi-lost automotive customer	
		103141	Steve Hardaker	18/09/17	Derek Lamb	Prosol automotive feedback	
		103140	Steve Hardaker	18/09/17	Steve Nixon	Prosol automotive feedback	
		102332	Steve Hardaker	06/09/17	Steve Nixon	Stock levels for R-22MEDV	
		102331	Steve Hardaker	06/09/17	Jonathan Connor	Stock levels for R-22MEDV	

	100067	Steve Hardaker	04/08/17	Jonathan Connor	Oxygen sensor heat-sealing failures	
	100066	Steve Hardaker	04/08/17	Derek Lamb	Oxygen sensor heat-sealing failures	
	100065	Steve Hardaker	04/08/17	Steve Nixon	Oxygen sensor heat-sealing failures	
	99907	Ryan Swaine	02/08/17	Steve Nixon	Intermed - New Zealand	
	86338	Ryan Swaine	03/01/17	Ryan Swaine	Flowsensor H Tender - Poland	

Product Feed back

V1000 Keypad failures, being investigated by supplier of keypads,

The Tom thumb with stuck gauge, no actual fault was found in the building and wer replaced it

Pricing on Warmers

c. Results of internal audits / Mini Audits

Agree to continue with current audit plan,

Are upto date this year in the current form, follow up actions have been completed.

In light of the rolling audits some question can possibly be removed from the tick sheets, and additions of the rolling audits added, to confirm they are being performed at individual process level.

discussed the Management review of mini rolling audits and showed the current outstanding follow on issues

06 Oct 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
05 Oct 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
05 Oct 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
05 Oct 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
03 Oct 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	1 Review
02 Oct 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	1 Review
30 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
28 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
27 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
26 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
22 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
21 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	
16 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	1 Review
11 Sep 2017	Derek Lamb	Show Processes Signed Off	Show Mini Audits Signed Off	

d. Process and product performance.

Product performance is excellent very low returns rate, non issues with getting the goods to the customers, debtors are good, no over due debtors (aside from the erroneous 30.17)

e. Preventive and corrective actions.

Discussed the computer system in barcode tracking and preventing stock going where it shouldnt, and qa/production not being possible unless trained.

Discussed the current non conformance system and the monthly non conformance review followup issue. And the monitoring of order errors.

Also Demonstrated the management review of internal processes and outstanding processes.

f. Possible system changes.

Discussed the roles titles and responsibility's and audits

g. Recommendations or improvement

discussed but overall happy with the current system and the new role and titles, with further processes being broken down and added

h. Any other business

non

1. Contract review / Picking, Packing & Despatch

No issues found in the processing of the products

2. Purchasing controls

Director signs most orders, and only utilising 2 suppliers (Viamed and envitec)

3. Supplier / subcontractor performance

Supplier review is up to date,

Teledyne in the past few months has caused endless problems, and the loss of some customers. Making moves to potentially get automotive sensors from our second source, but that could cause future problems in relationship with teledyne.

4. Storage & Stock control

Storage space should open up as we sell the remaining discontinued products

5. Customer complaints

		103014 Derek Lamb	15/09/17	Derek Lamb	CCR150 R-30V oxygen sensors leaking gas	
		102482 Steve Hardaker	07/09/17	Derek Lamb	CCR150 R-30V oxygen sensors leaking gas	

	 102480	Steve Hardaker	07/09/17	Derek Lamb	R-30V oxygen sensors leaking gas	
	 92679	Steve Nixon	11/04/17	Steve Hardaker	Ceratherm 600-3 Serial No. 516-3-0514	
	 92678	Steve Nixon	11/04/17	Jonathan Connor	Ceratherm 600-3 Serial No. 516-3-0514	
	 92677	Steve Nixon	11/04/17	Derek Lamb	CCN149 Ceratherm 600-3 Serial No. 516-3-0514	

The R-30V issues is almost fully closed just waiting on confirmation of actual serial numbers involved. But its already been determind there is no end user risk via the manufacturer.

CCN149, could be closed already, but I wanted to keep the Issue alive a little longer to see if we have any more reports. Again was stated no end user risk.

6. Calibration

Calibration index upto date.

7. Documentation & records

Intrastats controlled, BSI not happy with virtual documents not having revision codes on them, but have modified the front screen to make clear internal documents - print outs are not to be used.

8. Training

Training records now mostly computer controlled, certainly for the day to day use of processes, QA, Production etc.. training record required before the task can be performed. Mention we had a problem of Helen auditing the training records, when she maintains them and how I had to redo the audit.

9. Review of responsibilities

Reviewed the Organisation chart ID21556, MD is still responsible for MHRA/Product notifications, and the Notified body for QMS notifications.

Explained the new roles titles and processes system, Follow up Issue :105111 and related issues to look over in more detail and come back if any further processes require task/audits, and happy with allocations of staff

10. Resources required

Reviewed the analysis of data screens, discussed changes in staff likely and the new member of the warehouse team.

11. New products etc.

Mainly discussed potential upcoming Bluepoint products, and changing of our labels to blue points on the stock we currently have.

13. Quality planning

Reviewed the new Scopes and certificates in readiness for BSI visit in the near future.

14. Achievement of Quality Policy

Showed the QA fails screen,

Showed the Audit of Audits screen for processes and tasks, and the weekly management review of processes.

Confirmed the Quality policy is ok, now the references to the standards have been updated

15. Advisory notices & recalls

No Recalls.

16. Vigilance system

Happy with the current monitoring of product and product returns. and QA reports.

Check the time Non Conformance Issues are reviewed

1507712474	Non Conformance Issues	11/10/17	Derek Lamb	Derek Lamb, Helen Lamb, Jean Lamb, John Lamb, Steve Nixon,
1506800988	Non Conformance Issues	30/09/17	Derek Lamb	Derek Lamb, Helen Lamb,
1493906850	Non Conformance Issues	04/05/17	Derek Lamb	Derek Lamb,
1487064519	Non Conformance Issues	14/02/17	Derek Lamb	Derek Lamb, Helen Lamb,
1474893367	Non Conformance Issues	26/09/16	Derek Lamb	Derek Lamb, Helen Lamb, John Lamb,
1474382034	Non Conformance Issues	20/09/16	Derek Lamb	Derek Lamb,

17. Changes to the Management system

Upgrading to 13485:2016 addition of the roles and titles ,rolling tasks and audits.

Changes to the ec certificates, and the 9001 Viamed certificate

18. Changes to CE marked products

Discussed the selling of now discontinued product lines, and the changes to the Viamed EC certificate, brining the Envitec sensors onto the main certificate, and Bluepoint becoming the main named manufacturer of bluepoint product range.

In Attendance

Derek Lamb
John Lamb
Steve Nixon
Helen Lamb
Jean Lamb