

## VIAMED Board Directors Meeting

**Derek Lamb, Helen Lamb, Jean Lamb, Steve Nixon, 03/08/2021 10:08:24**

<p style="text-align: center;"><b>ISO Issues (5) Issues to address</b> Last reviewed 17/09/2020 (0 Days Between Review)</p> <div style="display: flex; justify-content: space-between; margin-bottom: 10px;"> <span>Agreed To Current Status</span> <span>Not Discussed Skip Section</span> </div> <p>Click <b>ONLY</b> if Section Discussed    Click <b>ONLY</b> if Section <b>NOT</b> Discussed</p> <hr/> <p><b>Objective: Review Notifications, Recalls (I)</b></p> <div style="display: flex; margin-top: 20px;"> <div style="flex: 1;"> <p>Subject</p> <input style="width: 90%;" type="text"/> <p>New Action/Notes</p> <div style="border: 1px solid #ccc; height: 150px; margin-top: 5px;"></div> </div> <div style="flex: 0.5; padding-left: 10px;"> <p><input type="radio"/> Further Action Required</p> <p><input type="radio"/> For Information Only</p> <p><input checked="" type="radio"/> File To history</p> <p><b>DeadLine</b> <input style="width: 50px;" type="text"/> / <input style="width: 50px;" type="text"/></p> <p><input style="width: 50px;" type="text"/> / <input style="width: 50px;" type="text"/></p> <p>General <input style="width: 50px;" type="text"/></p> <p>Add Item</p> </div> </div> <p style="margin-top: 20px;">Click <a href="#">here to add issue</a> another section</p>	<p><b>Sections Remaining (23)</b></p> <ul style="list-style-type: none"> <li>(16.0) ISO Issues</li> <li>(16.2) Documentation and records</li> <li>(16.3) Quality planning</li> <li>(16.4) Achievement of Quality Policy and Objectives. Confirm still suitable</li> <li>(16.5) Changes to the Management system</li> <li>(16.6) Changes to CE marked products</li> <li>(16.7) External Parties risks and opportunitys review</li> <li>(16.8) New products</li> <li>(16.9) Advisory notices &amp; recalls</li> <li>(16.10) Possible system changes</li> <li>(16.11) Recommendations or improvement</li> <li>(16.12) Results of internal audits / Mini Audits</li> <li>(16.13) Audits Meeting Closure</li> <li>(17.0) Company Issues</li> <li>(17.1) GDPR</li> <li>(17.2) Review of responsibilities</li> <li>(17.3) Resources required</li> <li>(18.0) Building fabric Issues</li> <li>(19.0) Responsibilities, Staff , Training Issues</li> <li>(20.0) Distributor Issues</li> <li>(21.0) Supplier Issues and review</li> <li>(21.1) Supplier / subcontractor performance</li> <li>(22.0) Any other Business</li> </ul>
---	---

## Open Issues

691 Days since Last update		
# <a href="#">152525</a> Created By: Helen Lamb Viewed on 18/Sep/2019 Created: 28 Aug 2019 Investigate By <b>Derek Lamb</b>	<b>13485 section 6.3 I am unsure if we have fully documented the infrastructure</b> Added by Helen Lamb sent to Derek Lamb 13485 section 6.3 I am unsure if we have fully documented the infrastructure. Possibly check 6.4.1 too I think we may need more documentation re what what infrastructure we need and why we need it. building, workspace and utilities, equipment, information systems. Think we have some of this but think we missing building and utilities.	New Controls Add Notes <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div> <div style="text-align: right; margin-top: -5px;">//</div> <div style="margin-top: 10px;"> <input type="button" value="Add Notes"/> </div> <div style="margin-top: 20px;"> <input type="button" value="Complete Issue"/> </div> <div style="margin-top: 20px; text-align: center;"> <div style="border: 1px solid #ccc; padding: 5px; background-color: #f0f0f0;">             HIDE ISSUE 152525           </div> </div>
<b>Actioned Notes</b>		

274 Days since Last update		
# <a href="#">200938</a> Created By: Derek Lamb Viewed on 02/Nov/2020 Created: 15 Oct 2020 Investigate By <b>Derek Lamb</b> FILE Added by Derek Lamb on 15/Oct/2020 <a href="#">MDR Guide for Distributors</a>	<b>Distributers and the MDR</b> Added by Derek Lamb sent to Derek Lamb See attached, Think bunzel in for a shock  <b>15 Oct 2020 Derek Lamb</b> Going to use this issue as a scratch / thought pad. first thoughts, Manufacturers, have to ensure under the MDR distributors of their product are compliant. this leads us, to before we can sell anything against a distributor price, we NEED a contract in place to ensure they comply with ISO13485, and if they loose it they need to inform us, then all the rules of iso13485 apply, they need full traceability, and feedback reporting etc..	New Controls Add Notes <div style="border: 1px solid #ccc; height: 40px; margin-top: 5px;"></div> <div style="text-align: right; margin-top: -5px;">//</div> <div style="margin-top: 10px;"> <input type="button" value="Add Notes"/> </div> <div style="margin-top: 20px;"> <input type="button" value="Complete Issue"/> </div> <div style="margin-top: 20px; text-align: center;"> <div style="border: 1px solid #ccc; padding: 5px; background-color: #f0f0f0;">             HIDE ISSUE 200938           </div> </div>
<b>Actioned Notes</b>		

291 Days since Last update		
----------------------------	--	--

291 Days since Last update		
# <a href="#">200939</a> Created By: Derek Lamb Viewed on 13/May/2021 Created:15 Oct 2020 Investigate By <b>Helen Lamb</b>	<b>Distributers and the MDR Copy Issue Main Issue #200938</b> Added by Derek Lamb sent to Derek Lamb See attached, Think bunzel in for a shock <hr/> <b>16 Oct 2020 Helen Lamb</b> Priority Changed From 5 To 1 <hr/> <b>Actioned Notes</b>	New Controls Add Notes <div></div> Add Notes Complete Issue <div>HIDE ISSUE 200939</div>

291 Days since Last update		
# <a href="#">200940</a> Created By: Derek Lamb Viewed on 20/Jul/2021 Created:15 Oct 2020 Investigate By <b>Steve Nixon</b>	<b>Distributers and the MDR Copy Issue Main Issue #200938</b> Added by Derek Lamb sent to Derek Lamb See attached, Think bunzel in for a shock <hr/> <b>16 Oct 2020 Steve Nixon</b> I know, but apparently they can have their own QMS systems if they can afford the time for the auditors to learn to use it. It is going to be an issue for some of our distributors, some will not make the grade. We need to make up info packs for them to include all the basic documents. For some QMS and storage facilities, records... will be a problem. <hr/> <b>Actioned Notes</b>	New Controls Add Notes <div></div> Add Notes Complete Issue <div>HIDE ISSUE 200940</div>

291 Days since Last update		
# <a href="#">206385</a> Created By: Auto_Meeting Viewed on 07/Dec/2020 Created:01 Dec 2020 DeadLine:01 Dec 2020 Investigate By <b>Derek Lamb</b>	<b>Audit 21 Audit Of Audit Viamed (173)</b> System Generated Audit 21 Review the Audit Calendar Screen ISO -> Audit Calendar Complete Audit 21 Confirm if Audit calendar needs changing. BEFORE starting Audit you need to update the Processes attached to the Audit. Find the doc in the Document	New Controls Add Notes <div></div> Add Notes Complete Issue

Index Admin Document -  
Copy and Paste List  
Processes Per Title replacing  
them in the current audit.  
Review Last years Audit see  
if its still suitable Carry out  
the Audit, reviewing and  
commenting on the ISO  
route map first. If there are  
any non Conformances from  
the Audit, create a follow up  
/ related Issue including all  
of the following - With a  
time for Completion  
Immediate Action Plan  
Corrective Action Plan  
Corrective Action  
Confirmation of Resolution  
if its a major / critical non  
conformance complete form  
QC 18 Review Last years  
Audit see if its still suitable  
Before Proceeding you need  
to update the Processes  
attached to the Audit Search  
the Document in the Index,  
View the Admin Page Copy  
and Paste the Attached  
Processes, replacing them in  
the current audit Any non  
Conformances from the  
Audit: Create a follow up /  
related Issue, With a time for  
Completion Immediate  
Action Plan Corrective  
Action Plan Corrective  
Action Confirmation of  
Resolution If its a major /  
critical non conformance  
complete form QC 18

HIDE  
ISSUE 206385

**Actioned Notes**

**Previous Review 17 Sep 2020**

## **ISSUES Since Last Review in meeting attached to Section**

198466 Complete Auto\_calender Issues Management Review (290)

System Generated Meetings -> Completed Auto Calendar Check the list Chase up any problems found and close any finished issues.

**25 Sep 2020 Derek Lamb**

done Auto Close Auto Issues

199153 Complete Auto\_calender Issues Management Review (290)

System Generated Meetings -> Completed Auto Calendar Check the list Chase up any problems found and

close any finished issues.

**01 Oct 2020 Derek Lamb**

done last night Auto Close Auto Issues

---

199923 Complete Auto\_calender Issues Management Review (290)

System Generated Meetings -> Completed Auto Calendar Check the list Chase up any problems found and close any finished issues.

**09 Oct 2020 Derek Lamb**

was done Auto Close Auto Issues

---

200805 Complete Auto\_calender Issues Management Review (290)

System Generated Meetings -> Completed Auto Calendar Check the list Chase up any problems found and close any finished issues.

**15 Oct 2020 Derek Lamb**

done Auto Close Auto Issues

---

200938 Distributers and the MDR

Added by Derek Lamb sent to Derek Lamb

See attached, Think bunzel in for a shock

**15 Oct 2020 Derek Lamb**

Going to use this issue as a scratch / thought pad. first thoughts, Manufacturers, have to ensure under the MDR distributors of their product are compliant. this leads us, to before we can sell anything against a distributor price, we NEED a contract in place to ensure they comply with ISO13485, and if they loose it they need to inform us, then all the rules of iso13485 apply, they need full traceability, and feedback reporting etc..

---

200939 Distributers and the MDR

**Copy Issue Main Issue #200938**

Added by Derek Lamb sent to Derek Lamb

See attached, Think bunzel in for a shock

**16 Oct 2020 Helen Lamb**

---

Priority Changed From 5 To 1

---

200940 Distributers and the MDR

**Copy Issue Main Issue #200938**

Added by Derek Lamb sent to Derek Lamb

See attached, Think bunzel in for a shock

**16 Oct 2020 Steve Nixon**

I know, but apparently they can have their own QMS systems if they can afford the time for the auditors to learn to use it. It is going to be an issue for some of our distributors, some will not make the grade. We need to make up info packs for them to include all the basic documents. For some QMS and storage facilities, records... will be a problem.

---

201530 Complete Auto\_calender Issues Management Review (290)

System Generated Meetings -> Completed Auto Calendar Check the list Chase up any problems found and close any finished issues.

**22 Oct 2020 Derek Lamb**

DONe Auto Close Auto Issues

---

202906 Complete Auto\_calender Issues Management Review (290)

System Generated Meetings -> Completed Auto Calendar Check the list Chase up any problems found and close any finished issues.

**02 Nov 2020 Derek Lamb**

Auto Close Auto Issues

---

203702 Complete Auto\_calender Issues Management Review (290)

System Generated Meetings -> Completed Auto Calendar Check the list Chase up any problems found and

close any finished issues.  
**05 Nov 2020 Derek Lamb**  
done Auto Close Auto Issues

Show VIAMED Board Directors Meeting History