MDSAP Audit Checklist (FDA)

Medical Techlabs Inc. / 2 Feb 2023 / Mark Smith

Complete

Score	**97.9%**	Flagged items	**0**	Actions	**2**

Site

Medical Techlabs Inc.

Conducted on	02.02.2023 10:00 PST
Prepared by	Mark Smith
Location	Stowe Rd, Winchester, CA, USA (33.7219616, -117.0638976)

Actions

2 actions

MDSAP Audit Checklist (FDA) / 2.2 Leadership - Customer Focus

2.2.2 Are customers and stakeholders kept informed?

No

While we have semi-annual customer updates currently rolled out, we have found that taking that effort up a notch can help us improve our customer relations. This fiscal year, we must keep our customers and stakeholders informed more regularly.

To Do | Assignee SafetyCulture Staff | Priority Low | Due 09.02.2023 23:48 PST | Created by SafetyCulture Staff

Coordinate with our Chief Experience Officer, Michelle Wellington, to align with FY2023-2024 plans.

MDSAP Audit Checklist (FDA) / 4.1 Support – Resources, Competence and Awareness

4.1.5 Are personnel who have been assigned QMS responsibilities qualified and deemed competent based on skills, experience, and education & training requirements?

No

To Do | Assignee SafetyCulture Staff | Priority Low | Due 09.02.2023 23:58 PST | Created by SafetyCulture Staff

Aside from the Chief Experience Officer and quality managers, we need to create a specific team in charge of handling QMS responsibilities.

1.1 Quality Management System – Scope

100%

MDSAP Quality Manual -Section 1

1.1.1 Is objective evidence available to demonstrate that each site has defined, planned, and implemented MDSAP QMS quality management system?	Yes
1.1.2 Has each site improved the effectiveness of its QMS through the use of quality objectives, audit results, analysis of data, corrective and preventive actions, and management review?	Yes
1.1.3 Has each site identified the processes needed to implement MDSAP throughout the organization?	Yes
1.1.4 Have criteria and methods been established to ensure that the operation and control of these processes are effective?	Yes
1.1.5 Has a quality manager been appointed with defined responsibility and authority for ensuring that the management system related to quality is implemented?	Yes
1.1.6 Are processes measured, monitored, and analyzed with appropriate actions taken to achieve planned results and continual improvement?	Yes

1.2 Quality Management System Documented information

100%

PROCEDURE MDSAP QMS P0002 – Document Control and Approval Procedure
PROCEDURE MDSAP QMS P0007 – Control of Quality Records Procedure
PROCEDURE MDSAP QMS P0015 – Naming Convention of Electronic Record Policy
MDSAP Quality Manual – Section 7.5 Documented information

1.2.1 Are documents required for the quality management system properly controlled and managed?	Yes

1.2.2 Has each site implemented the MDSAP QMS P0002 in the following aspects:

a. Developing, reviewing and approving documents for adequacy before they are issued?	Yes
b. Reviewing, updating as necessary?	Yes
c. Re-approving changed documents to ensure adequacy prior to use?	Yes
d. Identifying and maintaining the current revision of	Yes

documents?	
e. Ensuring current documents remain legible, readily identifiable and retrievable?	Yes
f. Identifying and controlling documents of external origin?	Yes
g. Notifying staff of new, revised or cancelled documents?	Yes
h. Archiving superseded or obsolete documents?	Yes
i. Preventing unintended use of obsolete documents retained for any purpose?	Yes

1.2.3 Has the established MDSAP Quality Manual been implemented, including:

a. Scope of quality system, details and exclusion justifications?	Yes
b. MDSAP QMS Procedures?	Yes
c. Sequence and interaction of processes or reference to them?	Yes
1.2.4 Are records properly managed and controlled?	Yes

1.2.5 Has each site implemented the MDSAP QMS P0007 in the following aspects:

a. Identification?	Yes
b. Recording and error correction?	Yes
c. Electronic record identification and back up?	Yes
d. Access?	Yes
e. Retention?	Yes
f. Disposal?	Yes
g. Archiving?	Yes
1.2.6 Do the record control procedures cover reports, correspondence, and technical records, i.e. collection reports, analytical worksheets, equipment data recordings, etc.?	Yes
1.2.7 Do record control procedures cover quality records such as procedures, audit reports, corrective action reports, and management reviews?	Yes

This fiscal year, we must put more emphasis on our records on management reviews as we revamp our continuous improvement efforts on that aspect.

2.1 –Leadership and Commitment

100%

MDSAP Quality Manual – Section 5.1 Leadership and Commitment

2.1.1 Has the RAC demonstrated commitment to the QMS development and improvement by:

a. Communicating to the staff the importance of meeting customer as well as regulatory & legal requirements?	Yes
b. Communicating the established quality policy and quality objectives?	Yes
c. Conducting management reviews?	Yes
d. Ensuring availability of necessary resources?	Yes

2.2 Leadership - Customer Focus

1 action, 50%

MDSAP Quality Manual – Leadership - Section 5.1.2 Customer Focus

2.2.1 Does top management ensure that customer requirements are determined and met with the goal to achieve customer satisfaction?	Yes
2.2.2 Are customers and stakeholders kept informed?	No

While we have semi-annual customer updates currently rolled out, we have found that taking that effort up a notch can help us improve our customer relations. This fiscal year, we must keep our customers and stakeholders informed more regularly.

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2.3 Leadership - Policy

100%

MDSAP Quality Manual – Leadership- Section 5.2 Policy
MDSAP QMS F0001.1 QMS Policy and Objectives

2.3.1 Is there an established quality policy?	Yes

Quality Policy [2023].pdf

2.3.2 Has top management ensured that the quality policy is communicated and understood within each site?	Yes
2.3.3 Is the quality policy included in the document control process?	Yes

2.4 Leadership - Responsibility and Authority

100%

MDSAP Quality Manual – Leadership - Section 5.3 Organizational roles, responsibilities and authorities

2.4.1 Are functions and their interrelations within each site defined and communicated?	Yes
2.4.2 Are responsibilities and authorities defined?	Yes
2.4.3 Is an individual appointed who has the responsibility and authority for ensuring QMS establishment, implementation, and maintenance?	Yes

3.1 Planning - Strategic and Quality Planning

100%

MDSAP Quality Manual – Section 6. Planning
MDSAP QMS F0001.1 QMS Policy and Objectives

3.1.1 Are there established quality objectives?	Yes
3.1.2 Is quality management system planning carried out to meet the requirements of the quality management system and the quality objectives?	Yes
3.1.3 If applicable, is there evidence that the integrity of the quality management system is maintained during changes?	Yes

4.1 Support – Resources, Competence and Awareness

1 action, 80%

PROCEDURE MDSAP QMS P0014 – Training
MDSAP Quality Manual – Support – Section 7.1 Resources, Section 7.2 Competence and Section 7.3 Awareness

4.1.1 Is objective evidence available to demonstrate that the MDSAP site has adequate infrastructure needed to implement the quality management system and to maintain its effectiveness?	Yes
4.1.2 Has the MDSAP site available resources to enhance customer satisfaction by meeting customer requirements?	Yes
4.1.3 Are personnel performing work affecting quality competent on the basis of appropriate education, training, skills, and experience?	Yes
4.1.4 Has the MDSAP site determined the necessary competence for personnel performing activities affecting	Yes

product quality?

4.1.5 Are personnel who have been assigned QMS responsibilities qualified and deemed competent based on skills, experience, and education & training requirements?

No

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Aside from the Chief Experience Officer and quality managers, we need to create a specific team in charge of handling QMS responsibilities.

4.2 Support – Internal Communication

100%

MDSAP Quality Manual – Support - Section7.4 Communication

4.2.1 Is there communication between various levels and functions with respect to the processes of the management system?

Yes

5.1 Operation – Operational planning and control

100%

MDSAP Quality Manual – Operation, Section 8.1 Operational planning and control
MDSAP Audit Procedures and Forms
MDSAP Assessment Procedures and Forms
MDSAP products and services: Assessment documentation, audit reports and manufacturer certificates

Yes

5.1.1 Has the MDSAP site planned and developed the processes needed for their products and services?

Yes

5.1.2 Is objective evidence available to demonstrate that the MDSAP site's management ensures that the MDSAP staff uses defined procedures for performing work, for assuring work is reproducible, and for maintaining information integrity?

Yes

5.2 Operation – Release of Product and Services

100%

MDSAP Quality Manual – Operation, Section 8.6 Release of products and services
MDSAP Audit Procedures and Forms
MDSAP Assessment Procedures and Forms
MDSAP products and services: Assessment documentation, audit reports and manufacturer certificates

5.2.1 Does MDSAP measures and monitors product and services characteristics to verify that product and services requirements have been met?

Yes

5.2.2 Is there objective evidence that product and services

Yes

acceptance criteria have been met?

5.2.3 Do records identify the person authorizing release of the products and services?	Yes
5.2.4 Are all specified activities performed before product release and service delivery?	Yes
5.2.5 If there are instances in which all specified activities have not been performed before product release or service delivery, has a relevant authority, or as appropriate the customer, been informed and approval gained?	Yes

5.3 Operation – Control of Non-conforming outputs

100%

PROCEDURE MDSAP QMS P0009 – Nonconformity and Corrective Action
MDSAP Quality Manual – Operation, Section 8.7 Control of nonconforming outputs

5.3.1 Does each MDSAP site- ensure that a non-conforming output is identified and controlled to prevent unintended use or delivery?	Yes

5.3.2 Has each MDSAP site implemented the MDSAP QMS P0009 in the following aspects:

a. Assignment of responsibility for halting work where appropriate and ensuring work resumption upon resolution of non-conformity;	Yes
b. Making appropriate disposition on a non-conforming output;	Yes
c. When necessary, notifying the customer of the non-conformance.	N/A
5.3.3 Is non-conforming output corrected and subjected to re-verification after correction to demonstrate conformity?	N/A
5.3.4 When non-conforming output is detected after delivery or use has started, is appropriate action taken regarding the consequences of the non-conformity?	Yes

6.1 Performance Evaluation and Improvement – General

100%

MDSAP Quality Manual – Performance Evaluation, Section 9.1.1 General
PROCEDURE MDSAP QMS P0004 – Risk Management
PROCEDURE MDSAP QMS P0013 – Continual Improvement

6.1.1 Is objective evidence available to demonstrate that MDSAP has defined, planned, and implemented the monitoring and measurement activities needed to assure	Yes

conformity and to achieve improvement?	
6.1.2 Are suitable methods used to measure and monitor these key processes?	Yes
6.1.3 Are the intended purposes of the key processes quantified by process parameter specifications, by specifications for the product output of the process or by some other means?	Yes

6.2 Performance Evaluation and Improvement – Monitoring, measurement, analysis and evaluation - Customer Satisfaction - Complaints & Feedback

100%

PROCEDURE MDSAP QMS P0011 – Complaints and/or Customer Feedback
PROCEDURE MDSAP QMS P0004 – Risk Management
MDSAP Quality Manual –Performance evaluation – Section 9.1.2 Customer satisfaction

6.2.1 Are complaints properly documented, investigated and resolved?	Yes
6.2.2 Is feedback other than complaints properly documented and reviewed for opportunities to improve processes, services and work products?	Yes
6.2.3 Has each MDSAP site implemented the MDSAP QMS P0011 in the following aspects:	
a. Receiving, documenting and categorizing complaints and feedback about any process, internal or external, that impacts MDSAP components' processes, services or work products?	Yes
b. Processing the complaint?	Yes
c. Determination and investigation of adverse impact?	N/A
d. For complaints with adverse impact, initiation of corrective action process to resolve the complaint or elevate the issue to the appropriate level for resolution?	Yes
e. Including complaints/feedback in audits and internal management reviews to ensure that follow-ups were effective in correcting the root causes?	Yes
f. Review to determine if actions taken in response to complaints or feedback were sufficient and appropriate?	Yes
g. Closing complaints after corrective action has been completed?	Yes
6.2.4 Is complaint data tracked and trended in the CAPA system?	Yes

Are trending results parts of management review?	Yes
6.2.5 Is customer satisfaction information recorded and monitored?	Yes
6.2.6 Is customer feedback analyzed for trends and improvements?	Yes

6.3 Performance Evaluation and Improvement – Analysis and Evaluation

100%

MDSAP Quality Manual – Performance Evaluation, Section 9.1.3 Analysis and Evaluation
PROCEDURE MDSAP QMS P0013 – Continual Improvement

6.3.1 Does MDSAP analyze data to determine the suitability and effectiveness of the quality management system?	Yes
6.3.2 Does MDSAP analyze data to identify improvements that can be made?	Yes
6.3.3 Does MDSAP analyze data to provide information on customer satisfaction?	Yes
6.3.4 Does MDSAP analyze data to provide information on conformance to product and services requirements?	Yes
6.3.5 Does MDSAP analyze data to provide information on trends?	Yes

6.4 Performance Evaluation and Improvement - Monitoring, measurement, analysis and evaluation - Internal Assessment/Audit and Continual Improvement

100%

PROCEDURE MDSAP QMS P0008 – Internal Assessment
PROCEDURE MDSAP QMS P0013 – Continual Improvement
PROCEDURE MDSAP QMS P0004 – Risk Management
MDSAP Quality Manual – Performance Evaluation - Section 9.2 Internal Audit

6.4.1 Are internal audits systematically conducted to monitor and determine compliance with the requirements of the MDSAP quality management system?	Yes

6.4.2 Has each MDSAP site implemented the MDSAP QMS P0008 in the following aspects:

a. Implementation of responsibilities for management?	Yes
b. Implementation of responsibilities by the quality system manager?	Yes

c. Implementation of responsibilities for auditor?	Yes
6.4.3 Are audits carried out by trained and qualified personnel?	Yes
a. Are audits conducted by people other than those who performed activities being audited?	Yes
b. Are records of auditor training and/or qualifications maintained and available?	Yes
6.4.4 Are audits conducted in accordance with planned scope and schedules, taking into account the results of previous audits?	Yes
6.4.5 Are audit findings documented on the appropriate forms and reports, according to documented procedures?	Yes
6.4.6 Does management take timely corrective action on deficiencies found during audits?	Yes
In the event the audit discloses a problem with incorrect procedures or invalid processes, is immediate corrective action taken?	Yes
6.4.7 Do follow-ups verify and document corrective action implementation and effectiveness?	Yes
6.4.8 Is the final audit report, with resolutions, submitted to management for final approval?	Yes
6.4.9 Is the audit closed after final approval of the audit report from management?	Yes

6.5 Performance Evaluation and Improvement - Management Review

100%

PROCEDURE MDSAP QMS P0005 – Management Responsibility and Management Review
PROCEDURE MDSAP QMS P0013 – Continual Improvement
PROCEDURE MDSAP QMS P0004 – Risk Management
MDSAP Quality Manual –Performance Evaluation - Section 9.3 Management Review

6.5.1 Does top management review the quality management system at planned intervals (at least annually), to determine the fitness and effectiveness of the quality system in achieving the stated quality objectives?	Yes
a. Does management review include management as well as the quality system manager?	Yes

6.5.2 Do management reviews include at a minimum:

a. Suitability of policies and procedures?	Yes
b. Changes that could affect the quality management system?	Yes
c. Outcome of recent audits?	Yes
d. Status of corrective and preventive actions and follow-up from prior management reviews?	Yes
e. Customer complaints/feedback?	Yes
f. Process performance?	Yes
g. Product conformity, including product related customer requirements?	Yes
h. Recommendations and opportunities for improvement?	Yes
i. Resources and staff training?	Yes
6.5.3 Do reviews evaluate the need to change the quality management system, including quality policy and quality objectives?	Yes

6.5.4 Are management reviews recorded to include:

a. Summary of findings;	Yes
b. Decisions and actions related to improvement of the effectiveness and efficiency of the quality management system and its processes;	Yes
c. Improvements related to customer requirements;	Yes
d. Determination of resource needs.	Yes
6.5.5 Are management reviews maintained and subsequent actions assigned, planned and monitored to completion?	Yes

6.6 Performance Evaluation and Improvement - Improvement – Nonconformity and Corrective Action

100%

PROCEDURE MDSAP QMS P0009 – Nonconformity and Corrective Action
PROCEDURE MDSAP QMS P0013 – Continual Improvement
PROCEDURE MDSAP QMS P0004 – Risk Management
MDSAP Quality Manual – Improvement - Section 10.2 Nonconformity and corrective action

6.6.1 Does each MDSAP site identify, document, investigate, track and correct the causes of non-conformances?	Yes

6.6.2 Has each MDSAP site implemented the MDSAP QMS P0009 in the following aspects:

100%

a. Identifying non-conformities, including those contained in customer complaints?	Yes
b. Investigation to examine the extent?	Yes
c. Determining the root cause of non-conformity to prevent recurrence?	Yes
d. Determining and implementing corrective actions needed?	Yes
e. Implementing corrective actions appropriate to the magnitude of the problem?	Yes
f. Recording results of corrective actions?	Yes
g. Reviewing corrective actions taken to determine their effectiveness?	Yes
h. Stopping work if necessary until the non-conformance is addressed?	Yes
i. Approval of by the initiator's immediate manager of the correction action?	Yes
j. Closing the corrective action when there is objective evidence that the action is completed and effective?	Yes
6.6.3 Do procedures require that processes/services/work products will not be used until the problem is resolved and verified by the appropriate manager and quality system manager?	Yes
6.6.4 For corrective actions initiated due to complaints, are customers contacted to confirm their concerns have been met prior to closing corrective actions?	Yes
6.6.5 Do procedures ensure relevant information on corrective actions is reviewed during audits and submitted for management review?	Yes

6.7 Performance Evaluation and Improvement - Improvement - Continual Improvement

93.75%

PROCEDURE MDSAP QMS P0013 – Continual Improvement MDSAP Quality Manual – Improvement, Section 10.3 Continual	Yes

Improvement

6.7.1 Is the site engaged in continual improvement of its work products, processes and services according to an established procedure?	Yes
6.7.2 Analysis of Data: Are appropriate data collected and analyzed to determine quality management system suitability and effectiveness, and to identify possible improvements?	Yes
Do data include measuring and monitoring activities?	Yes

6.7.3 How are data analyzed to provide information and identify opportunities for improvement on:

a. Customer satisfaction and/or dissatisfaction?	Yes
b. Conformance to customer requirements?	Yes
c. Characteristics of processes, products, and trends of quality characteristics?	Yes
d. Contractors' performance?	Yes
6.7.4 Is there objective evidence available to demonstrate that the site's management has created an environment that empowers and encourages staff to actively seek opportunities for improvement of performance in processes, services and products?	Yes
6.7.5 Are processes to achieve continual improvement of the quality management system planned and managed?	

6.7.6 How is continual improvement of the quality management system facilitated through use of:

a. Quality policy?	Yes
b. Quality objectives?	Yes
c. Internal Audit results?	Yes
d. Analysis of data?	Yes
e. Corrective actions?	Yes
f. Management reviews to include reviews of corrective action reports, audit reports, and customer feedback?	Yes

Completion

Comments/Recommendations

As a summary of the needed actions upon completing this report, here are the main recommendations:
- Coordinate with our Chief Experience Officer, Michelle Wellington, to align with FY2023-2024 plans.
- Aside from the Chief Experience Officer and quality managers, we need to create a specific team in charge of handling QMS responsibilities.

Name and signature

Mark Smith
03.02.2023 00:03 PST

Appendix

Quality Policy [2023].pdf