Table of Contents

1 Purpose 3
2 Scope of the Quality Management System 3
3 Justification for Exclusions and Non-Application of Requirements 3
3.1 Exclusions 3
3.2 Non-Applicability 3
4 Normative References 4
5 Guidance documents 4
6 Roles of the Organization 4
7 Processes and Relationships 5
7.1 Management Processes 6
7.2 Resource Management Processes 7
7.3 Product Realization Processes 8
7.4 Monitoring and Measurement Processes 9
8 Structure of the Quality Management System 10
9 Security Policies and Controls 11
9.1 Physical Security 11
9.2 Access to Systems 11
9.3 HIPAA Compliance 11
9.4 Business Associates Agreements 11
9.5 Data Breach Procedure 11
10 Business Continuity and Disaster Recovery 12
10.1 Scope and Objectives 12
10.2 Risk Assessment 12
Threat 13
Impact Level 13
Probability 13
Mitigation 13
Microsoft Azure Interruption 13
Sway's software is fully functional off-line by including temporary encrypted local storage of profile data. If an outage to Microsoft Azure occurs, Sway will continue to operate locally on the device. 13
App Store Interruption 13
Service Down Requiring Sway Software Team 13
Sway Customer Support Team 13

10.3 Critical Business Functions 13
10.4 Plan Activation 14
10.5 Internal Communications 14
10.6 Facilities 14
10.7 Succession and Delegation of Authority 14
Executive Management 14
Software Development 14
Customer Support 14
Chase Curtiss 14
(Tulsa, OK) 14
Jordan Beacham 14
(Fort Worth, TX) 14
Alex Pettigrew 14
(Dallas, TX) 14
Kelsey Scott 14
(Tulsa, OK) 14
Michael Naizer 14
(Austin, TX) 14
Jordan Beacham 14
(Fort Worth, TX) 14
Alex Pettigrew 14
(Dallas, TX) 14
Alexis Garner 14
(Fort Worth, TX) 14
10.8 Deactivation 14
10.9 Contact List 15
Appendix A – Application of Requirements and Essential Documentation of the QMS 16
Appendix B – Organizational Chart 18

1 Purpose

This quality manual describes the scope of the Sway Medical quality management system, including details of and justification for any exclusion or non-application, the documented procedures for the quality management system, and the interaction between the processes of the quality management system. This quality manual provides an outline of the structure used in the quality management system.

The primary uses of the quality manual are:

(a) To communicate Management's expectations for quality to the organization.
(b) To demonstrate the company's compliance with requirements.
(c) To serve as a measure for compliance to management's expectations for:
    i. Internal audits
    ii. Government inspections and notified body audits
    iii. Customer audits

2 Scope of the Quality Management System

Sway Medical develops and distributes software as medical devices (SaMD) for use in mobile applications at 32 S. Lewis Ave., Tulsa, OK 74101.

3 Justification for Exclusions and Non-Application of Requirements

3.1 Exclusions

No clauses of ISO 13485 are excluded from the Sway Medical Quality Management System.

3.2 Non-Applicability

The following clauses of ISO 13485 are not applicable to products developed and distributed by Sway Medical.

Clause	Justification for Non-Application
6.4 Work environment and contamination control	The conditions for the work environment have no adverse effect on product quality and environmental controls are not necessary to ensure conformity to product requirements.
7.5.2 Cleanliness of product	Sway Medical devices are comprised of software only. There are no requirements for cleanliness of product or contamination control.
7.5.5 Particular requirements for sterile medical devices	Sway Medical devices are not sterile.
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems	Sway Medical devices are not sterile.

7.5.9.2 Particular requirements for implantable medical devices	Sway Medical devices are not implantable.
7.6 Control of monitoring and measuring devices.	There is no monitoring or measurement to be undertaken, and no monitoring and measuring equipment is needed to provide evidence of conformity of Sway Medical devices.

4 Normative References

Document Number	Document Description
ISO 13485:2016	Medical devices, Quality management systems: Requirements for regulatory purposes
U.S. Food and Drug Administration, 21 CFR Part 820	Quality System Regulation
93/42/EEC and 2007/47/EC Amendment	Official Journal of the European Communities, Council Directive, Medical Device Directive
SOR/98-282	Canadian Medical Device Regulation
Australia Statutory Rules No. 236, 2002	Therapeutic Goods (Medical Devices) Regulations of 2002
ISO 14971:2007	Medical devices, Application of risk management to medical devices
EN ISO 14971:2012	Medical Devices, Application of risk management to medical devices

5 Guidance documents

Document Number	Document Description
GHTF SG3/N15R8/2005e	Implementation of Risk Management Principles and Activities Within a Quality Management System
Guidance for Industry. Part 11, Electronic Records	Electronic Signatures – Scope and Application
GHTF/SG3/N18:2010	Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes
2017-01-06 MDSAP AU P0002.004	Medical Device Single Audit Program, Audit Model, and Companion Document

6 Roles of the Organization

Sway Medical is a specification developer, manufacturer, and distributor of mobile application software devices for vestibular analysis and cognitive functions for use with the Apple iOS and Google Android mobile operating systems. The Sway Medical organizational structure is comprised of five functional areas, including Top Management, Research and Development, Business Development, Quality Assurance / Regulatory Affairs, and Finance and Administration. These functional areas are responsible for the implementation and management of the quality management system processes. The organizational structure is illustrated in Appendix B.

7 Processes and Relationships

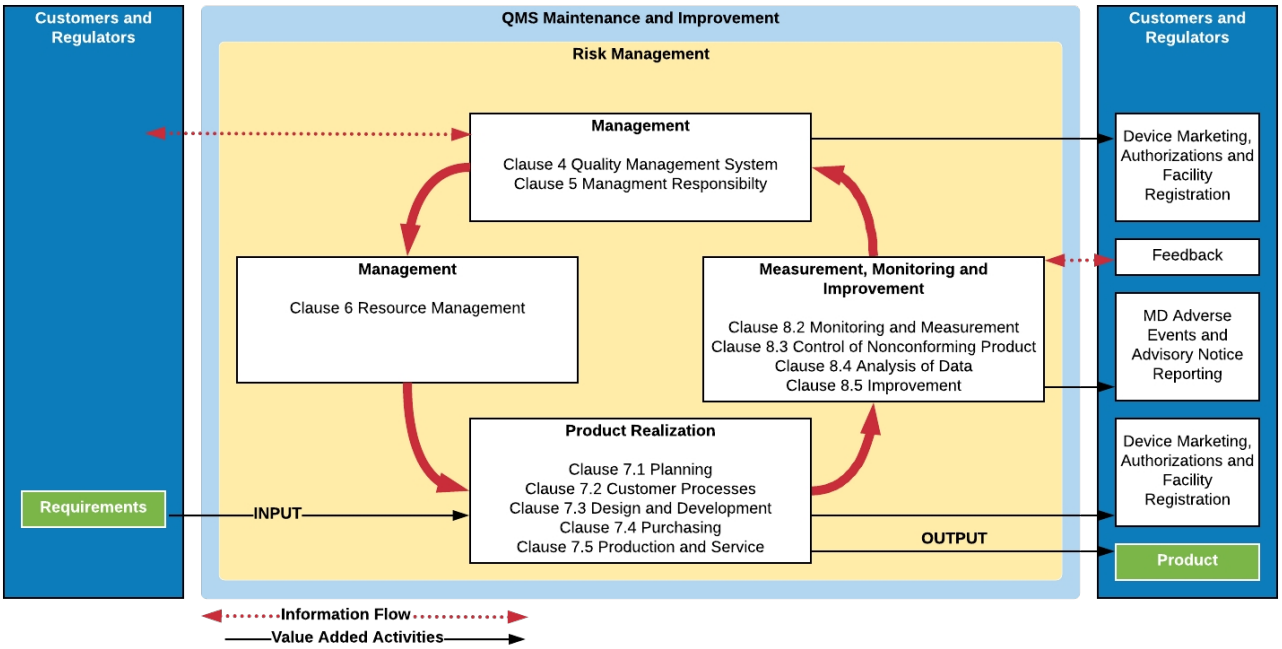


Figure 1 – Sway Medical Quality Management System (Clause references to ISO 13485:2016)

Sway Medical applies appropriate risk management methods and techniques to all quality management processes including outsourced processes, and has established, implemented, and maintains a documented quality management system. The processes of the quality management system and their interaction are illustrated in Figure 1. The list of documentation defining the key processes comprised in the quality management system is illustrated in Appendix A. This system is based on a risk-based process approach to develop, implement, and improve the effectiveness of the quality management system, with the objective of meeting customer and regulatory requirements, and providing medical devices that meet customer and regulatory requirements.

If any process that affects product conformity to requirements is outsourced, the outsourced processes are monitored to ensure control over such processes. Sway Medical retains responsibility of conformity to the requirements listed in Appendix A, including its customers. The controls for all outsourced process suppliers include written quality agreements and are proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with Sway Medical Purchasing requirements.

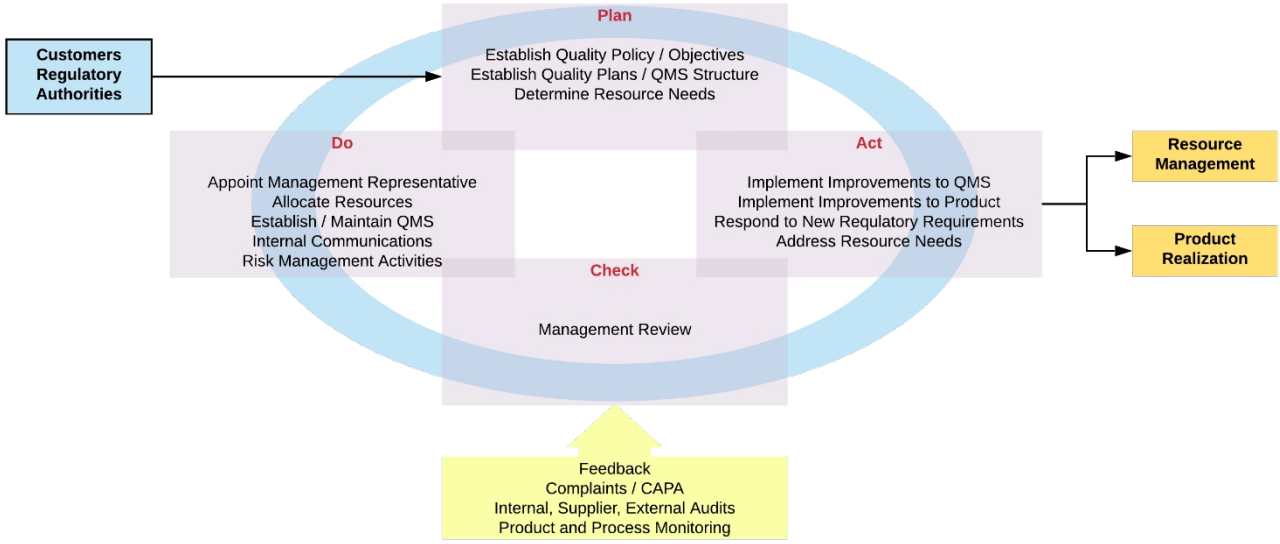


Figure 2: Management Processes

7.1 Management Processes

7.1.1 The intent of the management process is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities

(a) to assure the quality management system is functioning properly and effectively, and

(b) to monitor the quality management system and make necessary adjustments.

7.1.2 The Management Process and its relationship with the Resource Management and Product Realization processes is illustrated in Figure 2.

7.1.3 Top management is responsible for the development, implementation, and maintenance of the Quality Management System, and shall ensure that customer requirements and applicable regulatory requirements are determined, met, and any risks associated with the related processes are reduced to an acceptable level.

7.1.4 Top management establishes the Quality Policy and ensures that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization.

7.1.5 Top Management is responsible for maintaining the integrity of the quality management system when changes to the quality management system are planned and implemented.

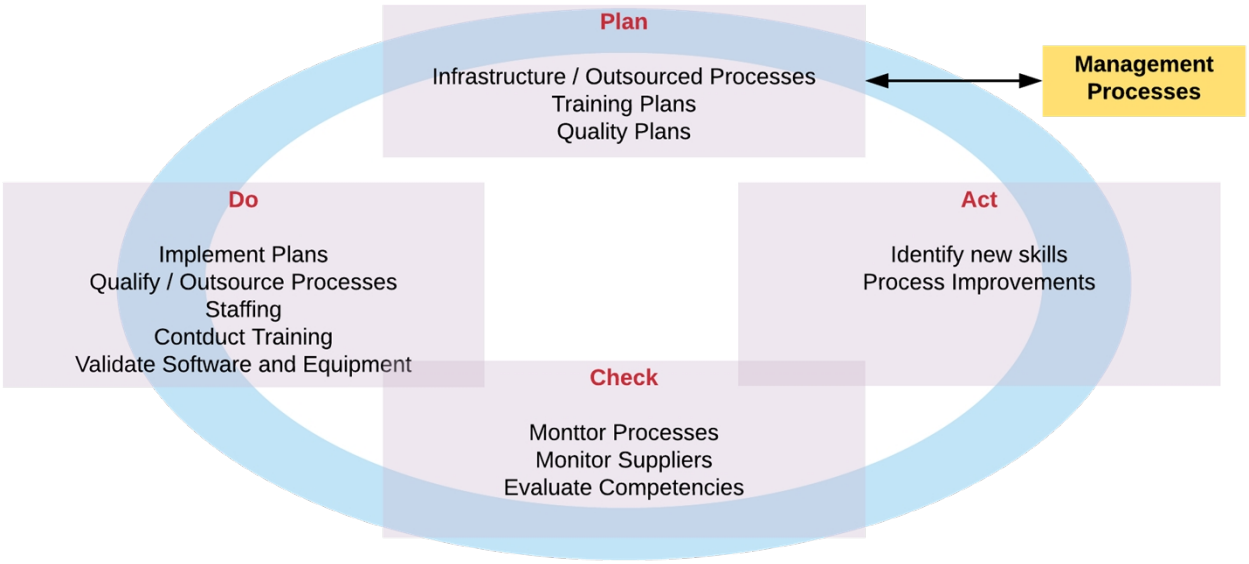


Figure 3: Resource Management Processes

7.2 Resource Management Processes

7.2.1 The Resource Management processes determine and provide the resources needed to implement the quality management system, maintain its effectiveness, and meet applicable regulatory and customer requirements.

7.2.2 Resource Management processes include requirements for personnel and the infrastructure. Top Management determines personnel competence and training, as well as the requirements, including maintenance requirements, for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product.

7.2.3 The Resource Management process and its relationship to the management process is illustrated in Figure 3.

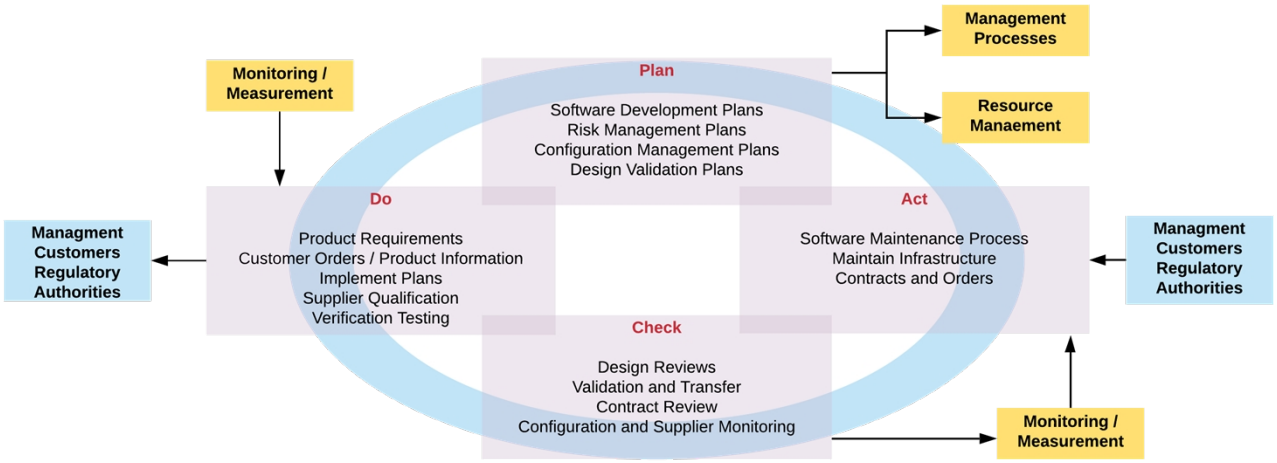


Figure 4: Product Realization Processes

7.3 Product Realization Processes

7.3.1 The Product Realization Processes ensure that the basic design and realization of Sway Medical product provided to customers is measurable by quality controls and that the requirements specified by the customer can be met, including:

(a) requirements for delivery and post-delivery activities,

(b) requirements not stated by the customer but are necessary for the specified or intended use (where known), as well as

(c) any statutory and regulatory requirements, and

(d) any additional requirements determined by Sway Medical.

7.3.2 The product realization processes provide clear, certifiable standards for the process of bringing Sway Medical devices to market and ensures product usability and safety requirements are met.

7.3.3 These processes include documented procedures to ensure that purchased product conforms to specified purchasing information, and that suppliers are evaluated and selected based on criteria proportionate to the risk associated with the medical device.

7.3.4 The Product Realization process and its relationship to the Management, Resource Management and Monitoring and Measurement processes is illustrated in Figure 4.

7.3.5 Control of production is incorporated in the design transfer process for Sway Medical and the deployment of the Sway application to the appropriate application store (Apple or Google).

7.3.6 The service provisions of the Sway application are documented in QP-16-01 Customer Feedback and Complaints. Since there is no direct service of the application, this is done through complaint and feedback handling and software updates to the application if necessary.

7.3.7 Installation activities are documented through the design transfer process. Update software revisions are deployed to the Apple or Google App stores and made available for download by users.

7.3.8 Servicing of the product is performed through an update of the software through a new software version. There is no service provision other than a software update.

7.3.9 Customer property is limited to electronic information, including the potential for Electronic Protected Health Information (ePHI) and is managed by adherence to QP-04-02 HIPAA Compliance.

7.3.10 There is no rework to the software for the Sway application. A new software version is made available to implement changes to the software.

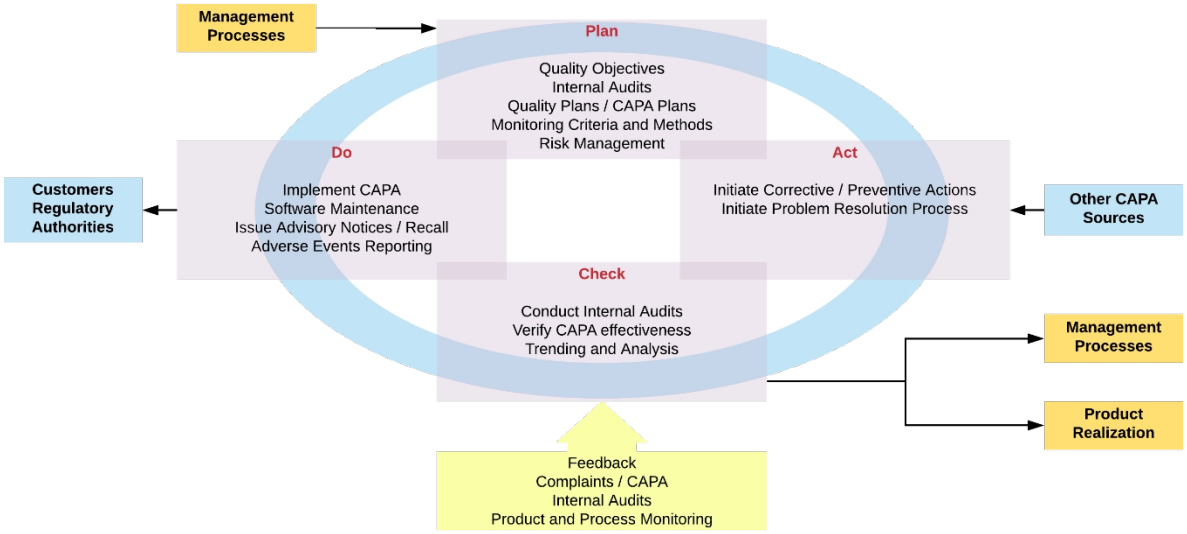


Figure 5: Monitoring and Measurement Processes

7.4 Monitoring and Measurement Processes

7.4.1 The monitoring and measurement processes include the Sway Medical feedback system, complaint handling, requirements for reporting to regulatory authorities, internal audit, inspection and release of product, control of nonconforming product, analysis of data, process monitoring requirements, and the CAPA system.

7.4.2 Top Management plans and implements the Monitoring and Measurement processes (see QP-18-01 Monitoring and Measurement) needed to demonstrate conformity of product, ensure conformity of the quality management system, and maintain the effectiveness of the quality management system. This includes determination of appropriate methods, including statistical techniques, and the extent of their use.

7.4.3 The information gathered in the feedback process serves as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

7.4.4 Top Management is responsible for establishing methods for monitoring and measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is undertaken, as appropriate.

7.4.5 The Monitoring and Measurement process is illustrated in Figure 5 and shows its relationship to other processes and Product Realization.

8 Structure of the Quality Management System

The documentation structure at Sway Medical is comprised of four levels of increasing specificity and detail as illustrated in Figure 6. The structure and authority of documentation is further defined in standard operating procedures.

Figure 6: Structure of the Quality Management System

Sway Medical has determined the necessary documentation for the effective operation of the Quality Management System processes. The extent of the quality management system documentation is based on:

(a) the size of the organization and type of activities,

(b) the complexity of processes and their interactions, and

(c) the competence, experience and knowledge of personnel.

Top Management has established, implemented and maintains all requirements, procedures, activities and arrangements required to be documented by ISO 13485 and applicable regulatory requirements.

Procedures determined to be necessary for the effective operation of the Sway Medical Quality Management System are listed in Appendix A.

9 Security Policies and Controls

Sway Medical has enacted security policies and control to ensure the protection of customer accounts and protected health information. These policies and controls include company requirements, physical security of office space, devices, and systems, and the appropriate security and privacy training for Sway team members.

9.1 Physical Security

Although Sway is a remote first company, the security of office space and devices with access to Sway systems is critical. All office locations used by Sway employees must have locked access that is only accessible with a key, pin code or access card. Every employee is required to have password or pin code enabled security on any devices with access to Sway systems.

9.2 Access to Systems

Access to Sway systems is provided on an as-needed basis to limit the exposure of customer and protected health information. Sway employees are shielded from viewing identifiable information when possible, by shielding patient names with unique identification codes.

9.3 HIPAA Compliance

All employees are required to complete annual Health Insurance Portability and Accountability Act (HIPAA) training and maintain compliance with HIPAA, the Health Information Technology for Economic and Clinical Health Act (HITECH) and the Family Education Rights and Privacy Act (FERPA) standards.

9.4 Business Associates Agreements

Sway Medical includes language in our standard terms of service to act as a business associate for covered entities under HIPAA and HITECH.

9.5 Data Breach Procedure

In the event of an unauthorized release, disclosure or acquisition of personal health information, Sway Medical will provide notification to affected customers with 72 hours after becoming aware of the incident unless notification within this time limit would disrupt the investigation of the incident by law enforcement. In such an event, notifications shall be made within a reasonable time after the incident.

9.5.1 Security Breach Notification

The security breach notification sent to customers will include the following information to the extent know and as it becomes available:

(a) The name and contact information of the reporting entity unless prohibited by confidentiality.

(b) The type of protected health information that were or are reasonably believed to have been the subject of a breach.

(c) The date of the breach or the best estimate of the timeframe the breach likely occurred.

(d) Any justification for notification delay beyond 72 hours unless bound by confidentiality.

(e) A description of the breach incident based on what is known at the time of notification.

9.5.2 Incident Response Plan

Sway Medical will compose a written incident response plan that reflects industry best practices following an initial investigation into the breach event. The incident report plan will be provided to customers within 14 days from becoming aware of the breach.

9.5.3 Federal and State Requirements

Sway Medical will adhere to all federal and state requirements with respect to a data breach and response plan related to Protected Health Information, including, when appropriate or required, the required responsibilities and procedures for notification and mitigation of any such data breach in a given geography.

10 Business Continuity and Disaster Recovery

The Sway Medical Business Continuity Plan (BCP) objective is to facilitate the resumption of critical operations, functions and technology in a timely and organized manner in response to natural, technological, and man-made incidents. The continuation and resumption of critical operations and technological services is critical to Sway's viability as a medical device provider. The Sway software and critical support services have been designed to maintain the function of the product, even with interruption in service of essential providers or key Sway team members. With a remote software business based on third party services such as Microsoft Azure, Apple App Store and Google Play Store, Sway is highly reliant on these three services providers to maintain access to the Sway software.

10.1 Scope and Objectives

The Sway Medical Business Continuity Plan addresses continuity of service that could be affected by technological service interruption or incapacitation of key employees that may impact service. Since Sway is a remote work environment with multiple offices and no critical infrastructure relying on continuity of operation of a specific work facility, the impact of disasters in this plan is focused on the potential interruption in service caused by the permanent or temporary loss of key employees and services providers.

The primary objectives of this plan are:

a) Maintain Critical Business Functions

b) Ensure Redundancy in Critical Roles

c) Maintain Access to Sway Products, Services and Customer Support

10.2 Risk Assessment

The risk assessment for Sway Medical's Business Continuity Plan is limited to the types of interruptions that are likely to occur that could affect service. Since Sway Medical does not depend upon a specific facility or location to maintain operations, the typical risk assessment of natural disasters does not

apply. The impact of natural disasters on individual key employees could be felt, but would be captured as a temporary or permanent loss of the employee in the risk assessment below:

Threat	Impact Level	Probability	Mitigation
Microsoft Azure Interruption	High	○ Highly Likely ○ Likely ○ **Possible** ○ Unlikely	Sway's software is fully functional off-line by including temporary encrypted local storage of profile data. If an outage to Microsoft Azure occurs, Sway will continue to operate locally on the device.
App Store Interruption	Low	○ Highly Likely ○ Likely ○ Possible ○ **Unlikely**	Sway distributes software through the Apple App Store and Google Play Store. In the unlikely scenario that either store is down, new downloads would not be able to occur causing testing on new devices to be unavailable.
Service Down Requiring Sway Software Team	Medium	○ Highly Likely ○ **Likely** ○ Possible ○ Unlikely	A succession plan is outlined in section 9.7 that addresses the unlikely scenario that a disruption in services occurs while a member of the software team is incapacitated.
Sway Customer Support Team	Low	○ Highly Likely ○ **Likely** ○ Possible ○ Unlikely	Sway customer support is a critical business function to support customers when issues arise. A succession plan for customer support is outlined in section 10.7.

10.3 Critical Business Functions

Critical business functions are those functions and critical activities that an organization must maintain when there has been a disruption to normal operations in order to sustain support and services to customers. The critical business functions are essential to the business and its customers and must be continued in order for the organization to meet its mission.

Sway has two critical activities that must be maintained as a part of business continuity to ensure customer access to our products:

a) Access to the Sway Software

   i. Access is highly dependent upon third party service providers including Microsoft, Google and Apple. Annual audits of the service contract with each these entities occurs in Q4.

b) Customer and Support Services

i. Customer and support services are critical to support users who may be experiencing issues. Maintaining staff and access to systems is critical to maintain customer support.

10.4 Plan Activation

Plan activation would occur if service to Microsoft Azure Services, Apple App Store, or Google Play Store is interrupted or if key Sway team members are incapacitated. Key Sway team members for the purposes of business continuity are the Sway Software Development team, Sway Customer Support and Executive Management.

10.5 Internal Communications

If the business continuity plan is initiated, the entire Sway staff would be notified via email from executive management and direct communication from each employee's manager. This internal communication would provide notice to Sway employees of what existing Sway systems were down, which employees were unable to address potential outages should they occur and what communication should occur with customers to notify them of potential disruptions in services. For outages of less than 12 hours from identification, no customer-wide communication will occur. If an outage lasts longer than 12 hours, all Sway customers will be notified immediately by the CEO or next in line of succession for executive management.

10.6 Facilities

Sway does not maintain a central facility that is used for the services provided to customers. The Sway software is supported by geographically redundant servers on Microsoft Azure. Customer support is provided from both Sway office facilities and remotely for at-home employees, which makes the need for a business continuity plan relating to natural disasters unnecessary. If a natural disaster affects access to internet, or the tools needed to deploy Sway services, a geographically diverse team will allow for succession into software development and customer support roles.

10.7 Succession and Delegation of Authority

Executive Management	**Software Development**	**Customer Support**
Chase Curtiss (Tulsa, OK)	Jordan Beacham (Fort Worth, TX)	Alex Pettigrew (Dallas, TX)
Kelsey Scott (Tulsa, OK)	Michael Naizer (Austin, TX)	Jordan Beacham (Fort Worth, TX)
Alex Pettigrew (Dallas, TX)		Alexis Garner (Fort Worth, TX)

10.8 Deactivation

The deactivation of the business continuity plan will occur when services are restored, and all Sway team members return to full participation in daily activities outside of normal scheduled time off.

10.9 Contact List

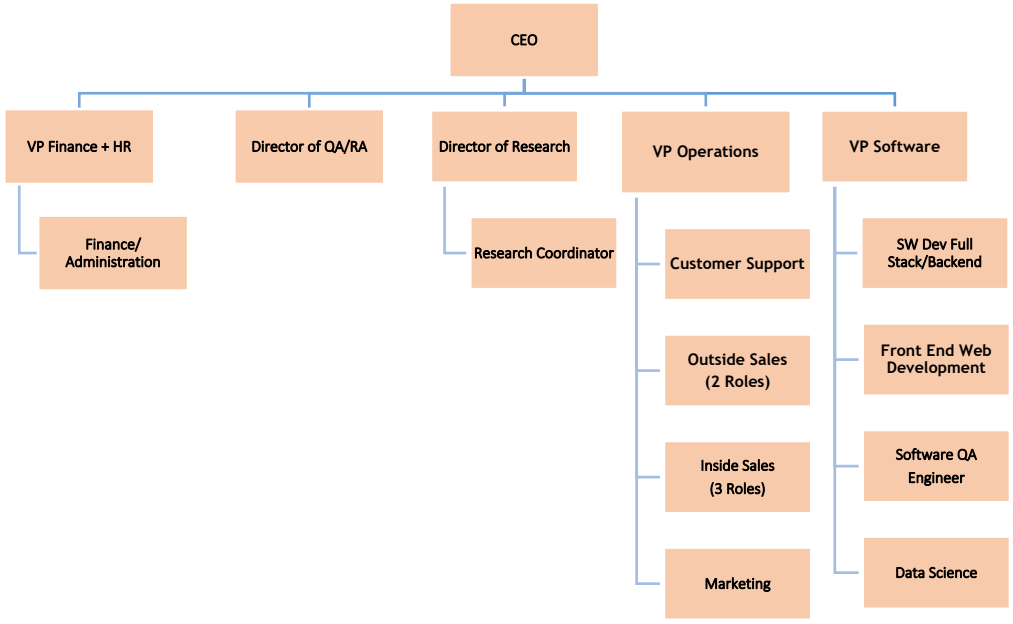
An internal contact list is provided to all Sway employees that includes personal cell phone numbers for all team members. Customer issues or complaint reports should be communicated through email at support@swaymedical.com or by calling 855-792-9633 option 2 for support.

Appendix A – Application of Requirements and Essential Documentation of the QMS

Doc No	Title	13485:2016	QSR	CMDR	TGA	MDD
QP-01-01	Sway Medical Quality Manual	4.2.2	21 CFR 820.20d.		Sch. 3, 1.4(4)	Annex II, 3.2
QP-01-02	Sway Medical Quality Policy	5.3	21 CFR 820.20(a)		Sch3, P1, 1.4(5)(a)	
QP-01-03	Sway Outsourcing Policy	4.1.5	21 CFR 820.50		Sch3, P1, 1.4(5)(b)(ii)	Annex II, 3.2(b)
QP-01-04	Sway Software Validation Policy	4.1.6; 6.3b	21 CFR 820.70(i); 21 CFR 820.75(c)			
QP-02-01	Control of Documents and Records	4.1.2; 4.2.3; 4.2.4	21 CFR 820.20(e); 21 CFR 820.40; 21 CFR 820.180	55; 56	Sch3, P1, 1.4(4)	Annex II, 3.2
QP-02-02	Information Systems	4.1.6; 4.2.5; 6.3b	21 CFR 820.70(i); 21 CFR 820.180			
QP-03-01	Management Review	4.1.2; 5.6	21 CFR 820.20(c)		Sch3, P1, 1.4(5)(b)(iii)	Annex II, 3.2(b)
QP-03-02	Canadian Licensing and Obligations to Inform	7.2.3		26		
QP-03-03	Planning Quality Objectives	4.1.2; 5.4.1	21 CFR 820.20(a)			Annex II, 3.2a.
QP-03-05	Internal Communications	5.5.3	21 CFR 820.25			
QP-04-01	Competence, Awareness and Training	4.1.2; 6.2	21 CFR 820.25			
QP-04-02	HIPAA Compliance	6.2				
QP-04-03	Training, QMS Documentation Review and Approval	6.2	21 CFR 820.25			
QP-04-04	Training, Sway Medical Quality Management System Overview	6.2	21 CFR 820.25			
QP-04-05	Training, Introduction to ZenQMS at Sway Medical	6.2	21 CFR 820.25			
QP-06-01	Sales Order Process	7.2.2	21 CFR 820.160	52		
QP-07-01	Product Development Process	7.3.1	21 CFR 820.30	32	Sch3, P1, 1.4(5)(c)(i)	Annex II, 3.2(c)
QP-07-02	Design Change Control	4.1.2; 7.3.9	21 CFR 820.30(i)	1; 34; 43(1)(b)	Sch3, P1, 1.5	Annex II, 3.2(c)
QP-08-01	Product Rick Management Process	4.1.2; 7.1	21 CFR 820.30(b)	10	Sch3, P1, 1.4(5)(c)(i)	Annex II, 3.2(b)
QP-09-01	Usability Engineering	4.1.2; 7.3.3	21 CFR 820.30(c)	11; 13; 16	Sch3, P1, 1.4(4)	Annex II, 3.2(c)
QP-11-01	Supplier Management	4.1.2; 7.4.1	21 CFR 820.50		Sch3, P1, 1.4(5)((d)(ii)	Annex II(3.2(d))
QP-11-02	Quality Agreements	4.1.5	21 CFR 820.198			
QP-13-02	Process and Method Validation	4.1.2; 7.5.6	21 CFR 820.75(a)			Annex II, 3.2(c)
QP-16-01	Customer Feedback and Complaints	4.1.2; 8.2.1; 8.2.2	21 CFR 820.198	57 (1)(a)	Sch3, P1, 1.4(3)(a)	Annex II(3.2(d))
QP-16-02	Medical Device Reporting	4.1.2; 8.2.3	21 CFR 803	59-61.1		
QP-16-03	Mandatory Problem Reporting - Canada	4.1.2; 8.2.3		59-61.1		
QP-16-04	Vigilance Reporting System – EU	4.1.2; 8.2.3				Article 95

Doc No	Title	13485:2016	QSR	CMDR	TGA	MDD
QP-16-05	Vigilance Reporting System – AUS	4.1.2; 8.2.3			Sch3, P4, 4.2(a)	Article 10, 9 (k)
QP-17-01	Quality Audit	4.1.2; 7.4.1; 8.2.4	21 CFR 820.50; 21 CFR 820.22		Sch3, P1, 1.4(5)((d)(ii)	Annex II(3.2(d))
QP-18-01	Monitoring and Measurement	8.2.5	21 CFR 820.70			
QP-19-01	Analysis of Data	8.4	21 CFR 820.250			
QP-20-01	Corrective and Preventive Action	8.5.2; 8.5.3	21 CFR 820.100			
QP-20-02	Recalls – Canada			58 (b)		
QP-20-03	Field Notices – EU					Article 95
QP-20-04	Recall Procedure – AUS				3A (b)	
QP-20-05	Corrections and Removals – US		21 CFR Part 806			

Appendix B – Organizational Chart



REVISION HISTORY

Version 01 Effective on 12-Sep-2020
Update organization chart to add Sales Operations Manager

Version 02 Effective on 23-Oct-2020
Update company address in 2 Scope

Version 03 Effective on 26-Aug-2022
Updated for formatting and grammar errors

Version 04 Effective on 29-Aug-2022
Update for emergency response plan and data breach notification

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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Signed 3:40:23 PM UTC 29-Aug-2022

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