ELEXES

NAVIGATING MDSAP FOR HARMONIZED REGULATORY COMPLIANCE

Case Study

Background of the Case Study

In the fast-paced landscape of medical device development, a visionary point-of-care COVID testing device company sought regulatory approval from Health Canada and the FDA. Recognizing the complexity of international markets, they partnered with Elexes, a specialized consulting firm, to streamline their quality management system.

Challenge

The company faced dual challenges of meeting Health Canada's stringent requirements and aligning with the FDA's quality system regulations. Their existing system lacked the harmonization required for both regions, and a comprehensive overhaul was essential.

Consulting Intervention

How Elexes Helped The Client?

Elexes initiated a meticulous gap analysis, identifying discrepancies between the existing system and MDSAP requirements. As listed below, Elexes developed about 33 Standard Operating Procedures (SOPs) for the client. For each of these procedures, the scope was very well defined and the process was such that it would mimic the actual operations of the company.

Things We Helped With

SOP for Labeling and Packaging

SOP for Control of Monitoring and Measuring Devices

SOP for Quality Audit

SOP for Work Environment and Infrastructure Management

SOP for Complaint and Feedback Handling

SOP for Record Control

Quality Manual

SOP for Biological Safety and Infection Control

SOP for Sales and Distribution

SOP for Management Review

SOP for DHF, DMR, and DHR

SOP for Design Control

SOP for Hiring and Training

SOP for Document Control

SOP for Data Analysis

SOP for Engineering changes

SOP for Risk Management

SOP for Supplier selection

SOP for Adverse Event Reporting

SOP for Purchasing

SOP for Clinical Performance Evaluation

SOP for Testing Activities

SOP for Nonconforming Product

SOP for Production Planning and Control

SOP for Emergency Handling

SOP for Regulatory Compliance

SOP for Post-Market Activities

SOP for Handling, Storage, and Transportation

SOP for Corrective Action and Preventive Action

SOP for Process Validation

SOP for Incoming Inspection and Final Inspection

SOP for Identification and Traceability

List of all the Procedures and Documents we suggested & why?

1

Quality Manual

This Quality Manual describes the structure of QMS and encompasses an overview of all activities, functions, and processes within the organization that contribute to the design, development, manufacturing, distribution, and support of the product.

2

SOP for Document Control

This SOP defines the responsibilities and authorities, and describes the methods for controlling documents within the organization that are necessary for the development, manufacture, distribution, and support. This includes but is not limited to procedures, work instructions, and forms.

3

SOP for Record Control

This SOP defines the responsibilities and authorities, and describes the methods for controlling records generated or maintained by the organization that are necessary for the development, manufacture, distribution, and support. This encompasses but is not limited to product design records, production records, device history records, and other quality management system records.

4 SOP for Hiring and Training

This SOP describes the responsibilities and authorities and the methods used to ensure that personnel who must work by "Manufacturer's" QMS requirements are qualified, trained, and competent to perform their assigned duties.

5 SOP for Management Review

This SOP is,

a. to describe general controls to conduct the Management Review Meeting (MRM) in the organization as per QMS Requirements
b. to describe responsibilities and authorities, and describe the system for appointment of Management Representative (MR)

6 SOP for Quality Audit

This SOP defines the responsibilities and authorities, and the methods for performing and handling Quality Audits including external audits and unannounced audits.

7 SOP for Process Risk

This SOP describes the methods to identify, analyze, evaluate, and treat the risks associated with the QMS processes and to assign the responsible authorities to perform and review the activities.

8 SOP for Data Analysis

This SOP outlines the methods to collect the data from various processes of QMS, analyze the data using statistical techniques, and utilize the results for improving and maintaining an effective QMS.

9 SOP for Process Validation

This SOP describes the process of validating and re-validating the software and equipment used in the QMS process - Design, Development, and Manufacturing and assigns the responsible authorities to perform and review the validation activities.

10

SOP for Design Control

This SOP is to describe responsibilities and authorities, and define the methods of all design and development activities related to the product. It encompasses the entire product lifecycle, from initial concept to post-market surveillance.

11

SOP for Risk Management

This SOP describes the methods to continually identify hazards associated with the subject devices, estimate and evaluate the risks associated with those hazards, control those risks, and monitor the effectiveness of that control.

12

SOP for Engineering changes

This SOP is to describe responsibilities and authorities, and define the methods for all engineering changes made to devices, components, or related processes within the organization. It encompasses the entire lifecycle of engineering changes, from identification and assessment to implementation and verification of such changes.

13

SOP for DHF, DMR, and DHR

This SOP describes the method for establishing, maintaining, and reviewing Device History Records, and Design History Files. Further, it outlines the information needed to prepare and maintain the Device Master Record.

14

SOP for Production Planning and Control

This SOP is to describe responsibilities and authorities, and define the methods for all production planning and control activities. It encompasses processes related to scheduling, resource allocation, monitoring, and reporting.

15

SOP for Control of Monitoring and Measuring Devices

This SOP is to describe responsibilities and authorities, and define the methods for all monitoring and measuring devices used at the organization, including devices used in product verification, process monitoring, and other activities that impact product quality.

16

SOP for Testing Activities

This SOP is to describe responsibilities and authorities, and define the methods for all testing activities, encompassing design verification, design validation, process validation, and any other testing related to product development.

17

SOP for Nonconforming Product

This SOP is to describe responsibilities and authorities, and define the methods used to identify, segregate, document, review, communicate, and disposition non-conforming products.

18

SOP for Supplier selection

This SOP is to describe responsibilities and authorities and the methods for evaluation and re-evaluation of suppliers.

19

SOP for Purchasing

This SOP is to describe responsibilities and authorities and the process for the purchase of goods and services.

20

SOP for Sales and Distribution

This SOP is to describe responsibilities and authorities, and the methods used to distribute products for sales, subcontracted processing, non-clinical, or clinical use.

21

SOP for Handling, Storage, and Transportation

This SOP is to describe responsibilities and authorities and the methods in handling, storage, and transportation of the product at the manufacturer facility. It encompasses activities related to the receipt, inspection, storage, retrieval, packaging, labeling, and transportation.

22

SOP for Complaint and Feedback Handling

This SOP is to describe responsibilities and authorities and the methods used to investigate the process and product-related complaints including returned products.

23

SOP for Corrective Action and Preventive Action

This SOP is to describe responsibilities and authorities, and the system for corrective and preventive actions to correct actual nonconformities, prevent future occurrences of nonconformity, or make improvements to the quality system.

24

SOP for Regulatory Compliance

This SOP describes the activities to be followed to be in/stay in compliance with the regulatory requirements of the US FDA, HC, TGA, ANVISA, and PMDA/MHLW.

25

SOP for Adverse Event Reporting

This SOP is to describe responsibilities and authorities and to define the process of post-marketing surveillance/monitoring the post-distribution experience gained from products to implement appropriate actions.

26

SOP for Incoming Inspection and Final Inspection

This SOP is to describe responsibilities and authorities and to define the process for all activities related to the inspection of incoming materials, components, and final products. It encompasses the entire inspection process, from receipt of materials to the release of finished products.

27

SOP for Identification and Traceability

This SOP is to describe responsibilities and authorities and to define the process for all identification and traceability activities conducted by the organization. It encompasses processes related to product labeling, documentation, and records.

28

SOP for Labeling and Packaging

This SOP is to describe responsibilities and authorities and to define the process for all labeling and packaging activities conducted at/by the organization for medical devices. It encompasses the design, printing, inspection, and application of labels, as well as the packaging and handling.

29

SOP for Biological Safety and Infection Control

This SOP is to describe responsibilitiesand authorities and to define the process for ensuring biological safety and control of infections.

30

SOP for Work Environment and Infrastructure Management

This SOP is to describe responsibilities and authorities and to define the process of all areas, facilities, and infrastructure that directly or indirectly impact the quality and safety of the product. It encompasses workspaces, utilities, equipment, storage areas, and any other elements of the work environment.

31

SOP for Clinical Performance Evaluation

This SOP is to describe responsibilities and authorities and to define the process for all clinical performance evaluation activities conducted at/by the organization throughout the product lifecycle. It encompasses the planning, execution, and documentation of clinical performance evaluations.

32

SOP for Post-Market Activities

This SOP is to describe responsibilities and authorities and to define the process for all post-market surveillance activities conducted at/by the organization. It encompasses the monitoring of product performance, feedback mechanisms, complaint handling, and reporting obligations.

33

SOP for Emergency Handling

This SOP describes the emergency response plan for internal/external disaster management to stabilize the business and the QMS in such cases.

Elexes also introduced tailored procedures, including

RISK MANAGEMENT PROTOCOL

To address MDSAP requirements for comprehensive risk assessments.

CAPA (CORRECTIVE AND PREVENTIVE ACTION) FRAMEWORK

Ensuring systematic problem-solving and preventive measures.

COMPLAINT HANDLING MECHANISM

Establishing a robust system with real-world examples and simulations for staff training.

IMPLEMENTATION SHOWCASE

Elexes guided the company in establishing a proactive complaint-handling procedure. Real-world examples and simulations were integrated to enhance staff understanding. This proactive approach aimed to preemptively address potential issues, aligning with the MDSAP framework.

MDSAP CERTIFICATION

Leveraging Elexes' expertise and experience, the team streamlined the MDSAP certification process. The team facilitated communication with auditors, ensuring seamless compliance. Elexes' involvement significantly reduced the certification timeline, allowing the company to proceed swiftly.

Key Takeaways

Proactive Procedures

Tailoring procedures to regulatory nuances is crucial. The complaint handling procedure, when implemented proactively, acts as a preemptive regulatory shield.

MDSAP as a Catalyst

MDSAP certification not only ensures compliance with multiple jurisdictions but can expedite overall regulatory approval processes.

Expert Guidance Matters

Engaging Elexes who is well versed in MDSAP intricacies ensured a smoother journey; real-world examples and targeted interventions save both time and resources.

Success Statement

In this success story, the confluence of regulatory expertise and proactive quality management resulted in swift MDSAP certification, opening doors to both Health Canada and the FDA. The case exemplifies the paramount importance of strategic partnerships in the dynamic landscape of global medical device compliance.