ISO 9001:2015

and

ISO 13485:2016

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QMD-003

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

Instructions:

This manual is used as a template in developing your Quality Management System covering both the ISO 9001:2015 and ISO 13485:2016 international standards.

The specific additions for ISO 13485:2016, Medical Devices – QMS for regulatory purposes are highlighted in yellow.
To provide the correlation between the requirements of ISO 13485:2016 and those of ISO 9001:2015, each procedure and instruction contains the paragraph 3.1.2 (also highlighted in yellow) that reflects the corresponding clause numbers.

- Methods and systems used in the development and operation of the QMS vary widely from company to company.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your quality system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the QM-001 manual template are included in a separate file “QMS-Template-Instructions”.

Additional documentation review.

- Similarly, the blue text and suggestions displayed in the QMS documentation (that will follow) for the procedures, instructions, attachments, forms, and flow diagrams are intended to offer some options and to highlight the areas that require update or replacement.

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Introduction

Your Company developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

To fully understand the organization and its context, Your Company determined the external and internal issues that are relevant and that affect its ability to achieve the intended results of the quality management system.

The Quality Management System of Your Company meets the requirements of both the ISO 9001:2015 and ISO 13485:2016 international standards. The system addresses the design, development, production, installation, and servicing of the company's products and it incorporates the process approach where consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes.

This process approach provides for the management of the quality system and its processes through the application of a "Plan-Do-Check-Act" methodology and a focus on "Risk-Based-Thinking" leading to the prevention of undesirable outcomes.

The manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides the documented information with procedures or references for all activities comprising the Quality Management System that ensures the compliance to the necessary requirements of the standards.

This manual is used internally to guide the company's employees through the various requirements of the ISO standards that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or interested parties. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

A top management representative approves the manual.

President: _____ Date: _____

Section A Scope or the Quality Management System

General

To determine and establish the scope of the QMS, Your Company determined the boundaries and applicability of the QMS and considered the external and internal issues, the requirements of relevant interested parties, and the products and services of the company.
The scope is available and maintained as documented information stating the products and services covered by the QMS.
Your Company applies all the requirements of ISO 9001:2015 when they are applicable within the determined scope of the QMS.
As developed with procedure P-400 for Organizational context, include the scope of your QMS here:

_____

_____

Conformity to ISO 9001:2015 may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.
In the event that any requirement is not applicable at Your Company, justification for any instance where a requirement cannot be applied is documented.
Your Company has determined that the following requirement(s) is/are not applicable to the operations at this site:

_____.

As determined with procedure P-400, identify the requirement(s) that do not apply and document the justification here:

_____

_____

Section B References

a. Reference.

- ISO 9001:2015 Quality management systems requirements
- ISO13485:2016 Medical devices – Quality management systems - Requirements for regulatory purposes

b. Normative reference.

- ISO 9000:2015 Quality Management Systems – Fundamentals and vocabulary.

c. Definitions.

- Applicable definitions are included in documented procedures and instructions at par 3.0 to enhance the understanding of the process.