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ISO 13485 Quality Manual & Procedures Package

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Abstracts

GENERAL INFORMATION ABOUT ISO 13485

ISO 13485 (and variations such as DIN EN ISO 13485) is an internationally recognized quality standard which states the requirements of the Quality Management System (QMS) for the design and manufacture of Medical Devices. While it remains a stand-alone document, ISO 13485 is based on ISO 9001 with some additional clauses as well as the removal of some requirements.

ISO 13485:2016 specifies requirements for a Quality Management System where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

ISO 13485 is recognized by the Global Harmonization Task Force (GHTF) and has become the model QMS standard for the medical industry. ISO 13485 certification provides:

Global Recognition – ISO 13485 Standard is recognized in major markets around the world

United States of America

Europe

Canada

Japan

Australia

BENEFITS OF ISO 13485

A solid QMS provides:

Improved product safety

Increased Efficiency

Cost Savings

More Effective Risk Management

Increased likelihood of meeting Customer Requirements

Meet legal, regulatory, contractual and marketing requirements

Factors to take into consideration when implementing ISO 13485

Does this meet the regulations?

Is this as simple as possible?

How does this impact the business?

A roadmap for constructing QMS should be based on what to do and when to do it based on the stage of the product lifecycle.

Product Development

Transfer to Manufacturing

Go to Market

Post-Market

FIRST PHASE OF QMS

In the first phase of QMS, QMS procedures must be established for:

Design Controls

Risk Management

Document Control & Records Management

Supplier Management

In the second phase, QMS procedures must be established for the following:

Training

Purchasing

Device Master Record

Production & Process Controls

Labeling & Packaging

Receiving, Incoming, In-Process, Final Inspection

Identification & Traceability/Device History Record

Change Management

Nonconforming Material

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CAPA

Management Responsibility

ESTABLISHING THE LAST PART OF A QMS

Before going to market, the following need to be established into the QMS procedure:

Process Validation

Software Validation

Calibration

Preventive Maintenance

Handling, Storage, Distribution, & Installation

Servicing

Complaint Handling

Adverse Event Reporting/MDR

Corrections & Removals

Customer Feedback

Analysis of Data

Quality Manual

Establishing post market QMS

Define the internal auditing procedures

Set the schedule and frequency for internal audits

Make sure that personnel conducting internal audits have been appropriately trained to conduct audits

Although not fully harmonized, an ISO 13485 Quality Management System (QMS) is very close to the Food and Drug Administration's (FDA) QSR standards in this area, namely 21 CFR 820.

COMPARISON BETWEEN ISO 13485 AND FDA-QSR-21CFR-820

What is 21 CFR 820?

Title 21 of the Code of Federal Regulations (CFR) covers the broad area of food and drugs

Part 820 outlines

Quality Systems for medical device manufacturers.

Current Good Manufacturing Practice (CGMP) regulations that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.

These requirements are meant to ensure that medical devices are safe, effective, and in compliance with the Federal Food, Drug, and Cosmetic Act.

Where do they each apply?

ISO 13485 is a global standard that is voluntary in the US but required in some countries. Third party registrars (CB's) conduct audits to ensure conformance.

The Food and Drug Administration enforces 21 CFR 820.

21 CFR 820 is applicable to manufacturers of finished medical devices sold in

the United States, including imported products. Only parts of the requirement may apply, depending on the class.

RELATIONSHIP BETWEEN FDA-QSR 21 CFR 820 AND ISO 13485

They have several differences, which is what have kept them from harmonizing. ISO 13485:2003 is a standard based on ISO 9001 that is specific to medical devices. This standard is not adopted by the Food and Drug Administration (FDA) but the FDA participated in writing ISO 13485:2003 to make sure their requirements and ISO 13485:2003 are aligned. The FDA QSR has more stringent complaint handling & reporting requirements

However, if a company meets the requirements of ISO 13485:2003, they should easily be able to meet the FDA Quality System Requirements (QSR).

US FDA Medical Device Regulations & Guidelines

Design Control Guidance for Medical Device Manufacturers Text related to FDA 21 CFR 820.30 and sub clause 4.4 of ISO 9001.

Labeling for Medical Devices Guidance on medical device labeling from the FDA

Quality Systems Regulations (QSR) US FDA QSR regulation and Good Manufacturing Practices (GMP).

Post Market Surveillance Guidance on criteria and approaches for medical device post-market surveillance.

Human Factors in Medical Device Design Discusses the CDRH push to have manufacturers apply Human Factors to device design.

WHY WAS ISO 13485 REVISED?

All ISO standards are reviewed and revised regularly to make sure they remain relevant to the marketplace. ISO 13485:2016 responds to the latest QMS practices, reflecting the evolution in medical device technology and changes in regulatory requirements and expectations. This ensures that the standard remains compatible with other

management system standards, including the new edition of ISO 9001.

ISO 13485:2016 Quality Manual and Procedures saves time, save money, and simplify certification. The ISO 13485:2016 Quality Manual and Procedures comes with the following features:

Quality Manual in MS Word format for ease of editing

Procedures are written in MS Word and are ready for your customization

Related Forms are written in MS Word or Excel

Text to address each requirement of the ISO 13485:2016 Standard

Very clear instructions in obvious Blue Text to show you where to customize your Manual and Procedures

Required references to the recommended procedures and forms for your quality management system

Intuitive architecture for easy Document Control

This is a downloadable product.

You will also have the option of purchasing the files on a Jump-Drive during checkout but it is not necessary.

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