ISO 13485

Quality Management System Requirements
For Medical Devices

AN EXECUTIVE OVERVIEW

PERRY JOHNSON
CONSULTING, INC.

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ISO 13485:2016
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Medical Devices —
Quality Management Systems —
Requirements for Regulatory Purposes

An Executive Overview

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ISO 13485:2016

An Executive Overview

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FOREWORD _____

In 1996, the International Organization for Standardization (ISO) released ISO 13485, *Quality management systems- Medical Devices- Particular Requirements for the Application of ISO 9001* and ISO 13488, *Quality management systems- Medical Devices- Particular Requirements for the Application of ISO 9002*. These two international quality management systems standards, medical devices derivatives of ISO 9001, were developed by ISO Technical Committee (TC) 210, Quality Management and Corresponding General Aspects for Medical Devices. U.S. participation in ISO/TC 210 is organized and administered by the Association for the Advancement of Medical Instrumentation (AAMI).

ISO 13485:1996 and ISO 13488:1996 required accountability, compliance with regulations, such as the U.S. Food and Drug Administration (FDA)'s Current Good Manufacturing Practices (CGMP), maintenance of documentation and traceability of products, producing a world-class approach to the design, development, manufacture, distribution and servicing of medical devices. Such devices, coming in close contact with patients and ranging from minor support for conditions to life saving capability, demand high criteria.

ISO/TC 210, with the participation of the AAMI, revised ISO 13485 and ISO 13488 to align with the process-based ISO 9001:2000 and later revision ISO 9001:2008 in 2003.

The new version, ISO 13485:2016, *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, was released in 2016.

Registration to ISO 13485, which can aid in complying with regulations, offers a major competitive edge for medical device companies and is becoming a virtual requirement to do business in many marketplaces. Far-sighted firms are planning for registration by conducting a thorough investigation of the standard=s revised requirements.

This booklet was created to aid medical device manufacturers seeking to implement ISO 13485:2016, or upgrade from ISO 13485:2003. It outlines the general requirements of ISO 13485:2016.

Since registration to ISO 13485 is a lengthy and detailed process, it is strongly suggested that firms seeking registration retain the services of a reputable consulting firm.

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THE USERS OF THIS GUIDE _____

This guide will be useful to managers and other personnel in organizations that meet any of the following criteria:

- Medical device designers and manufacturers.

- Medical device servicing, repair or re-conditioning firms.

- Manufacturers of custom or implantable medical devices.

- Manufacturers of accessories used with medical devices.

- Testing laboratories that work with medical devices.

- Companies that fabricate medical devices under contract to another firm and subject to its specifications.

- Suppliers seeking to meet customer ISO 13485 registration mandates.

- Health care industry executives and employees.

- Agents of foreign medical device manufacturers selling products in the United States, Canada, the European Union and other countries.

- Medical device manufacturers seeking to meet regulatory ISO 13485 mandates or otherwise comply with government regulations.

- Government and other regulatory officials.

- Persons with quality assurance responsibility or interest in a medical device manufacturing setting.

- Firms wishing to do future business with medical device manufacturers.

- Consumers interested in production of safe high-quality medical devices.

- Suppliers seeking a competitive edge in the marketplace.

- Organizations desiring to make customer satisfaction a top priority.

- Companies already registered to ISO 13485:2003 seeking an upgrade to ISO 13485:2016.

- Any other parties with an interest in medical device quality management.

- Any other firms interested in becoming registered to ISO 13485:2016.

WHAT IS ISO 13485? _____

ISO 13485:2016, *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, is a quality management systems standard for the medical devices industry that is derived from ISO 9001:2008. This standard was developed by ISO Technical Committee (TC) 210, Quality Management and Corresponding General Aspects for Medical Devices.

ISO 13485, released in 2016, is structured similar to the ISO 9001:2008 but is written to harmonize with additional medical devices sector-specific requirements. Many of these sector-specific medical device requirements come directly from existing regulations.

The medical device field is extensive and rapidly evolving through technological advancements, and demands run high for medical devices to meet the highest quality levels for health and safety. ISO 13485 is a universal medical device standard that is applicable to any company in any nation. It provides a roadmap for quality management in medical device manufacturing facilities in order to produce top-caliber products and meet regulatory requirements, such as the U.S. Food and Drug Administration (FDA)'s Current Good Manufacturing Practices (CGMP).

Registration provides objective evidence of meeting quality management system requirements of both customers and major regulatory agencies. ISO 13485 registration is objective because a registrar, an independent certifying body, performs regular audits to verify whether a quality management system is meeting all requirements. This independent evaluation is important to customers and regulatory agencies because it is an unbiased guarantee that a company is performing at its highest level.

Because the ISO 9000 series is the foundation of this standard, one must have a basic knowledge of it in order to fully understand the fundamentals of ISO 13485. A brief description of this series of standards follows.

The Origin of ISO the 9000 Series

ISO 9000 is a series of quality management systems standards created by the International Organization for Standardization (ISO), a federation of 132 national standards bodies based in Geneva, Switzerland. The American National Standards Institute (ANSI) is the member body representing the United States.

The ISO 9000 quality management standards are not specific to products or services, but apply to the processes that create them. The standards are generic in nature so that they can be used by manufacturing and service industries all over the world. First released in 1987 and revised in a limited manner in 1994, they underwent a major overhaul in 2000.

ISO 9000 is the descendant of a number of earlier quality standards, including the British BS 5750 and DEF/STAN 05-8, the NATO AQAP-1 and the U.S. Department of Defense MIL-Q-9858A. The purpose for developing ISO 9000 was to simplify the international exchange of goods and services by creating a common set of quality standards.

BS 5750 had the greatest influence on this international standard when it was first released by ISO in 1987. Most industrialized nations quickly adopted harmonized versions of ISO 9000. These national versions, which are identical to the international standard, include the American ANSI/ISO/ASQ Q9000, sponsored by ANSI and the American Society for Quality (ASQ), and the European Union's EN 29000.

ISO 9001:2008 was intended to establish, document and maintain a system for ensuring the output quality of a process. When implemented correctly, it can offer a company several advantages. It offers a guide to build quality into products or services, and helps to avoid costly inspections, warranty costs and rework.

Today, the international standards are sanctioned by the 15 nations of the European Union (EU), making ISO 9001:2008 registration a virtual prerequisite for doing business there. Please note that while ISO 13485:2016 is a stand-alone standard, it is structured similar to ISO 9001:2008, which has been superseded by ISO 9001:2015. For the convenience of users, Annex B of the standard shows the correspondence to ISO 9001:2015.

Previously, there were more than 20 ISO 9000 standards and documents, and this proliferation raised concerns among ISO 9000 users and consumers. In response, ISO/Technical Committee (TC) 176, Quality Management and Quality Assurance, agreed that the revisions originally issued in the year 2000 would consist of four primary standards, supported by several technical reports. These four primary standards and current revision levels are:

- **ISO 9000:2015**, *Quality Management Systems – Fundamentals and Vocabulary*. This document simplifies the quality concepts, terms and definitions that accompany the standard. In addition to a revised vocabulary, this standard includes an introduction to quality-management-principle concepts.

- **For ISO 13485:2016 purposes, ISO 9001:2008**, *Quality Management Systems – Requirements* specifies requirements for quality management systems for use where an organization needs to demonstrate its capability to provide products that meet customer and applicable regulatory requirements and to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system. If an organization can demonstrate conformity to ISO 9001:2008 requirements, it may be registered to this standard.

- **ISO 9004:2009**, *Quality Management Systems – Managing for the sustained success of an organization – A quality management approach.* a companion to ISO 9001:2008, provides guidance on quality management systems, including processes for continual improvement that contribute to the satisfaction of an organization's customers and other interested parties and processes for self-assessment. Organizations do not and cannot become certified or registered to ISO 9004:2009.

- **ISO 19011:2011**, *Guidelines for auditing management systems.* is an important standard because it addresses three key areas of concern: internal auditor qualifications, the conduct of internal audits, and internal-audit program management.

Current Good Manufacturing Practices (CGMP)

Quality management systems for products regulated by the U.S. Food and Drug Administration (FDA), such as medical devices, are known as Current Good Manufacturing Practices (CGMP). Companies selling medical devices in the United States must meet the applicable CGMP regulation, which is contained in 21 Code of Federal Regulations (CFR) Parts 808, 812 and 820. Part 820 contains the CGMP quality management system regulation. Part 808 covers exemptions from federal preemption of state and local medical device requirements. Part 812 covers investigational device exemptions.

CGMP requirements for medical devices were first authorized by Section 520 (f) of the Federal Food, Drug and Cosmetic Act, 21 United States Code 360j (f), which was enacted into law as part of the Medical Device Amendments of 1976. The FDA issued its first CGMP regulation for the manufacture, packaging, storing and installation of medical devices in 1978.

A 1990 FDA evaluation of medical device recalls from 1983 to 1989 found that approximately 44 percent were due to faulty product design. As a result, the Safe Medical Devices Act (SMDA) of 1990 amended Section 520 (f) to give the FDA authority to add pre-production design controls to the CGMP regulation, and added a new Section 803 that encourages the FDA to work with foreign countries for mutual recognition of CGMP requirements.

Under the SMDA, Section 520 (f) requires manufacturers to have a quality management system addressing design, manufacture, packaging, labeling, storage, installation and servicing of medical devices for commercial distribution.

Section 520 (f) further mandates that specifications and controls be established for each device; devices are designed under the quality management system so they meet these specifications; devices are manufactured under the quality management system; devices are correctly installed, checked and serviced; quality data are analyzed to identify and correct quality problems; and complaints are addressed and resolved.

The FDA requires producers of finished devices to ensure their parts are acceptable and meet specifications. Medical device manufacturers covered by CGMP include:

- Remanufacturers – Firms that renovate or otherwise process a finished device to significantly change its performance or safety specifications, or intended use.

- Custom device manufacturers.

- Contract manufacturers – Companies that fabricate finished devices under contracts with other manufacturers.

- Contract testing laboratories – Facilities that design or test components for a manufacturer against its specifications is considered an extension of the quality management system. In-house facilities are subject to CGMP inspections, but not independent laboratories, some of which handle non-medical products.

- Repackagers, relabelers and specification developers – Firms that alter packaging, distribute domestic or imported devices, or create specifications for devices made by a second party are subject to CGMP requirements. Packaging, labeling and specifications are considered steps in the manufacturing process.

- Accessory manufacturers – Extra components that are used with main devices, whether supplied to a company by a contractor or produced in-house, are considered manufacturing steps and are subject to CGMP requirements.

- Initial distributors of imported devices – Firms or persons that are a foreign company's point of contact with the FDA must maintain complaint files and meet general record keeping requirements.

Section 520 (f) also organizes medical devices into classes, based upon their degree of sustaining human life, complexity and invasiveness.

- A Class I device is not intended to be sold or represented as capable of supporting or sustaining life, or preventing an impairment to health, and does not present a risk for illness or injury. It is regulated by FDA general controls that provide assurance that a product is safe and effective.

- Class II devices may provide life-sustaining abilities. These devices must be produced under performance standards that ensure they will be safe and effective during operation, with the FDA inspecting and approving the control methods the manufacturer chooses to make certain the devices are safe and effective. Special controls, such as performance and design standards, post-market monitoring and patient registries, are also recommended.

- A Class III device is often life sustaining or may help prevent impairment to human health. General or special controls are insufficient to ensure their safety and effectiveness. Some Class III devices must receive a pre-market approval (PMA) or undergo a product development protocol (PDP) by the FDA before being sold.

Following SMDA approval, the FDA began the CGMP revision process to add design controls and make the regulations consistent with international quality management system requirements. In 1993, the FDA published a CGMP revision proposal. FDA representatives worked with ISO/TC 210 and the Global Harmonization Task Force (GHTF), which consists of government and medical device industry representatives from the U.S., Canada, the European Union (EU), Japan and Australia, to harmonize proposed CGMP revisions with ISO 9001:1994, ISO 13485:1996, the European medical device quality standard EN 46001:1996, and the EU Medical Devices Directive.

The FDA issued a Working Draft of the revised CGMP in 1995 and published the revised CGMP regulation in 1996. This regulation took effect in 1997, except for the design control requirements, which became effective in 1998.

CGMP requirements now cover a full quality management system, including designing, manufacturing, packaging, labeling, storing, installing, purchasing and servicing medical devices intended for human use. Medical device producers located or doing business in the U.S. must meet CGMP requirements as part of their commitment to comply with all regulations under ISO 13485 and assure that their medical devices are safe and effective for the intended use.

Component manufacturers are exempt from the CGMP regulation. A component is defined by Section 820.3 (c) as "any raw material, substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the finished, packaged and labeled device."

Manufacturers must establish quality management systems appropriate to the devices designed and manufactured, and the manufacturing processes employed. They must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement CGMP requirements.

CGMP requirements in Part 820 were drafted to harmonize with ISO 9001:1994 and ISO 13485:1996, and use a similar structure.

These requirements provide a general blueprint for any medical device manufacturer, whether they make simple surgical hand tools or massive magnetic resonance imaging (MRI) machines. General objectives are listed, such as properly trained employees, design reviews and validation, calibrated equipment and process controls, instead of specific methods. CGMP requirements are flexible, allowing manufacturers to select their own methods for compliance.

CGMP is organized into the following subparts. Section titles appear in the comparison chart on the next two pages.

Subpart A   General Provisions (Sections 820.1, 820.3 and 820.5)

Subpart B   Quality management system Requirements (Sections 820.20, 820.22 and 820.25)

Subpart C   Design Controls (Section 820.30)

Subpart D   Document Controls (Section 820.40)

Subpart E   Purchasing Controls (Section 820.50)

Subpart F   Identification and Traceability (Sections 820.60 and 820.65)

Subpart G   Production and Process Controls (Sections 820.70, 820.72 and 820.75)

Subpart H   Acceptance Activities (Sections 820.80 and 820.86)

Subpart I   Nonconforming Product (Section 820.90)

Subpart J   Corrective and Preventive Action (Section 820.100)

Subpart K   Labeling and Packaging Control (Sections 820.120 and 820.130)

Subpart L   Handling, Storage, Distribution and Installation (Sections 820.140, 820.150, 820.160 and 820.170)

Subpart M   Records (Sections 820.180, 820.181, 820.184, 820.186 and 820.198)

Subpart N   Servicing (Section 820.200)

Subpart O   Statistical Techniques (Section 820.250)

CGMP and ISO 13485 Comparison Chart

CGMP		ISO 13485:2016	
820.1	Scope	1	Scope
820.3	Definitions	3	Terms and Definitions
820.5	Quality management system	4.1.1-4.1.6 4.2.1 4.2.2	General Requirements Documentation-General Quality Manual
820.20	Management Responsibility	5.1 5.3 5.4 5.5 5.6	Management Commitment Quality Policy Planning Responsibility, Authority and Communication Management Review
820.22	Quality Audit	8.2.4	Internal Audit
820.25	Personnel	6.2	Human Resources
820.30	Design Controls	7.3	Design and Development
820.40	Document Controls	4.2.4	Control of Documents
820.50	Purchasing Controls	7.4	Purchasing
820.60	Identification	7.5.8	Identification
820.65	Traceability	7.5.9	Traceability
820.70	Production and Process Controls	7.5.1	Control of Production and Service Provision
820.72	Inspection, Measuring and Test Equipment	7.6	Control of Monitoring and Measuring Devices
820.75	Process Validation	7.5.6	Validation of Processes for Production and Service Provision
820.80	Receiving, In-Process and Finished Device Acceptance	7.4.3 8.2.6	Verification of purchased product Monitoring and Measurement of Product
820.86	Acceptance Status	7.5.8	Status Identification
820.90	Nonconforming Product	8.3	Control of Nonconforming Product
820.100	Corrective and Preventive Action	8.5.2 8.5.3	Corrective Action Preventive Action
820.120	Device Labeling	7.5.1	Control of Production and Service Provision

CGMP		ISO 13485:2016	
820.130	Device Packaging	7.5.11	Preservation of Product
820.140	Handling	7.5.11	Preservation of Product
820.150	Storage	7.5.11	Preservation of Product
820.160	Distribution	7.5.11	Preservation of Product
820.170	Installation	7.5.3	Installation Activities
820.180	General Requirements (Records)	4.2.5	Control of Records
820.181	Device Master Record	4.2.3	Medical Device File
820.184	Device History Record	4.2.5	Control of Records
820.186	Quality management system Record	4.2.5	Control of Records
820.198	Complaint Files	8.5.1	Improvement-General
820.200	Servicing	7.5.4	Servicing Activities
820.250	Statistical Techniques	8.4	Analysis of Data

Back to ISO 13485

In highly industrialized countries, medical devices have long been subject to government regulation, with the U.S. market under the jurisdiction of the FDA. As these regulations evolved, many of them have incorporated quality management system requirements for medical device manufacturers, such as the FDA's CGMP and the Japanese Good Manufacturing Practices Regulation.

Following the development of the ISO 9000 Quality Management Systems (QMS) standards, issued in 1987, an international demand arose to apply ISO 9000 quality management systems to medical devices.

The Global Harmonization Task Force (GHTF), which consists of government and medical device industry representatives from the U.S., Canada, the European Union (EU), Japan and Australia, was established in 1992 with the goal of harmonizing medical device regulations. The GHTF seeks to produce globally harmonized guidance documents that address regulation of medical device safety, performance and effectiveness; promotion of technical innovation; and encouragement of global trade. Its Study Group 3 has worked to harmonize regulatory QMS requirements in the world's major markets.

Meanwhile, the EU developed its own medical device derivatives of the 1987 ISO 9000 standards, releasing in 1993 European Normative (EN) 46001:1993, a harmonized version of ISO 9001:1987, with specific requirements for suppliers of medical devices, along with EN 46002:1993, a medical devices derivative of ISO 9002:1987. EN 46002 differed from EN 46001 by excluding the design control element (4.4). Due to the importance of the European market, EN 46001 and EN 46002 were adopted and implemented by medical device manufacturers around the world.

At the same time, medical devices sold in the EU must meet health and safety product requirements in the New Approach Directives, thereby acquiring CE Marking, a necessity for their sale in Europe. The EN standards and their successors are applied to the conformity assessment requirements of these directives, with manufacturers required to register to these standards. The three directives that apply to medical devices are the Active Implantable Medical Devices Directive (AIMD), approved in 1993 and fully effective in 1994; the Medical Devices Directive (MDD), approved in 1995 and fully effective in 1998; and the In Vitro Diagnostic Medical Devices Directive, approved in 1999 and fully effective in 2003.

In 1993, the GHTF advocated harmonization of medical device regulations with ISO 9000. The ISO Technical Management Board (TMB) responded by recognizing that the medical device sector, due to its heavy worldwide regulation, requires sector-specific standards. As a result, in 1994 it approved the creation of Technical Committee (TC) 210, Quality Management and Corresponding General Aspects for Medical Devices, to manage development of quality management system and risk management standards in order to effectively address the needs of regulatory authorities and manufacturers, protect health and safety, eliminate trade barriers and promote global harmonization.

ISO/TC 210 established a Memorandum of Understanding (MOU) with the GHTF. The Association for the Advancement of Medical Instrumentation (AAMI) was chosen by ANSI to administer the Secretariat and U.S. Technical Advisory Group (TAG) of ISO/TC 210. AAMI, founded in 1967, is an alliance of nearly 6,000 users and manufacturers of medical instrumentation and technology, and the leading developer of national and international standards for the manufacture, use and maintenance of medical devices. It is the primary source of consensus and timely information on medical instrumentation and technology.

Following the release of revised ISO 9000 standards in 1994, ISO/TC 210 began the process of developing medical device derivatives. In 1996, it released ISO 13485:1996, *Quality management systems - Medical Devices - Particular requirements for the application of ISO 9001*, a harmonized version of ISO 9001:1994, with specific requirements for suppliers of medical devices, along with ISO 13488:1996, *Quality management systems - Medical Devices - Particular requirements for the application of ISO 9002*, the medical devices derivative of ISO 9002:1994. As with the EN standards, ISO 13488 differed from ISO 13485 by excluding the design control element (4.4).

The EU continued to go its own way with ISO 9000 medical device derivatives, revising the EN standards to align with the 1994 ISO 9000 standards. In the same year, it released EN 46001:1996, *Quality management systems - Medical devices – Particular requirements for the application of EN ISO 9001*, and EN 46002:1996, *Quality management systems - Medical devices – Particular requirements for the application of EN ISO 9002*. The revised EN standards had slightly different sector-specific requirements from those of ISO 13485 and ISO 13488.

Other documents developed by ISO/TC 210 have been ISO 14969:1999, *Quality management systems – Medical Devices – Guidance on the Application of ISO 13485 and ISO 13488*, and ISO 14971:2000, *Medical Devices – Application of Risk Management to Medical Devices*.

In 1998, Health Canada became the first regulatory body to require medical device manufacturers to achieve ISO 13485 or ISO 13488 registration in order to obtain device licenses to sell their products. Section 32 of Canada's Medical Device Regulations created the Canadian Medical Device Conformity Assessment System (CMDCAS) to administer the registration system, with registration required by 2003.

The importance of ISO 13485 in encouraging and supporting global harmonization of medical device requirements increased in 1999, when the GHTF held extensive discussion about completely phasing out the EN 46000 series in favor of ISO 13485 and ISO 13488. In 2000, ISO 13485 and ISO 13488 became European standards, replacing EN 46001 and EN 46002. Later that year, the ISO 9000 standards were again revised, with ISO 9001 the sole registration standard.

ISO/TC 210 then began the process of revising ISO 13485 and ISO 13488 to align with ISO 9001. Despite ISO 9001:2000 Section 1.2, Application, which allows the exclusion of design control requirements (now Element 7.3), thereby eliminating the need for ISO 13488, ISO/TC 210 initially decided to revise both standards, producing Committee Draft (CD) versions of these revisions in 2001.

ISO/CD 13488:200x, *Quality Management Systems – Medical Devices – System Requirements for Regulatory Purposes for Manufacturing, Inspection and Testing, and Distribution Organizations*, states in Section 1.2, "Clause 1.2 of ISO 9001:2000 does not apply to this International Standard". ISO 13485 is a quality management system incorporating design and development controls and is applicable for meeting regulatory requirements specific to medical device organizations. However, some regulations may not require such a quality management system and ISO 13488 provides requirements for systems which do not require design and development control (see 7.3)."

In 2002, ISO/TC 210 reversed its position on Section 1.2 and withdrew the ISO 13488 revision under the ISO/TC 176 applications approach to ISO 9001. ISO 13485 reached Draft International Standard (DIS) status that year with the publication of ISO/DIS 13485:200x, *Quality Management Systems – Medical Devices – System Requirements for Regulatory Purposes*. Section 1.2 of ISO/DIS 13485:200x allowed for the exclusion of design control requirements.

ISO 13485:2016, *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, was released in 2016. Section 1.2 states:

"All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of you."

"If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of you to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls (see 4.2.2a and 7.3)."

"If any requirement(s) in Clause 7 of this International Standard is (are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, you does not need to include such a requirement(s) in its quality management system (see 4.2.2a)."

"The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by you, are the responsibility of you and are accounted for in your quality management system (see 4.1a)."

"In this International Standard, the terms 'if appropriate' and 'where appropriate' are used several times. When a requirement is qualified by either of these phrases, it is deemed to be 'appropriate' unless you can document a justification otherwise. A requirement is considered 'appropriate' if it is necessary for:

• the product to meet specified requirements, and/or

• you to carry out corrective action."

Now that the revised ISO 13485 standard has been released, the ISO 14969 guidance document will be revised and published as ISO/TR 14969:200x, *Medical Devices – Quality Management Systems – Guidance on the Application of ISO 13485:2016.*
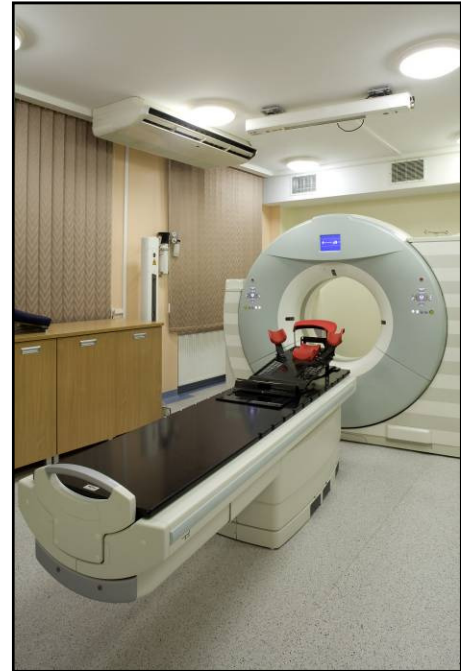
ISO 13485:2016 contains medical device sector-specific requirements, but not all of ISO 9001:2008. Section 1.1, General, states, "The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements." Most of the omitted ISO 9001:2008 requirements are in the areas of continual improvement and customer satisfaction.

Medical device sector-specific requirements include a file for each type or model of medical devices a company makes that includes or identifies documents defining product specifications and quality management system requirements for manufacturing, installation and servicing. Manufacturing specifications must be retained for at least the product's lifespan. Clinical evaluations during the design phase must be performed if required by regulations.

A company must establish documented requirements for environmental conditions, including the health, cleanliness and clothing of personnel affecting product quality. If appropriate, special arrangements must be established and documented to control contaminated or potentially contaminated products, in order to prevent contamination of other products, workers or the manufacturing environment.

Documented control procedures are required for products that have a limited shelf-life or require special storage conditions. If appropriate, the manufacturer must provide installation instructions for medical devices. On the whole, more extensive documentation is required to comply with regulations.

Once products have gone on the market, the company must monitor whether customer requirements have been met and establish a customer feedback system to provide early warning of quality problems. Customer complaints should be followed by corrective and/or preventive actions. If regulations require, procedures must be established for notifying regulatory agencies.

Traceability is mandatory under ISO 13485. Products must be uniquely identifiable, with written records of their manufacture and distribution. This documentation helps identify the product's status throughout its lifespan, ensuring that only product that has passed the required inspections and tests is distributed, used or installed.

REGISTERING TO ISO 13485 _____

Medical device manufacturers can register to ISO 13485:2016, but this does not mean that these companies are also registered to ISO 9001:2008. As noted in the previous section, ISO 13485 contains medical device sector-specific requirements, but not all of ISO 9001:2008.

ISO 13485:2016, Section 1.1, General, states, "The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001."

Medical device manufacturers therefore have the option of implementing and registering to ISO 13485 alone, or both ISO 13485 and ISO 9001. Registration to ISO 13485 or both standards is tangible expression of a firm's commitment to quality that is internationally understood and accepted. Registered organizations almost universally realize major increases in customer acceptance, as well as reductions in costs.

ISO 13485 and ISO 9001 registration is carried out by registrars, accredited organizations that review the quality manual and other documentation to ensure that they meet the standards, and audit the processes to ensure that the quality management system described in the documentation is in place and is effective. Once registration is obtained, the registrar conducts regular surveillance audits to determine if the quality management system continues to meet the standards' requirements.

As it typically takes 6 to 18 months to complete the ISO 13485 and ISO 9001 registration process, organizations are advised not to put off registration for too long.

Key Steps to Completing Registration

Before an organization can be considered for registration, several preliminary steps must be taken:

1) The first is to implement a quality management system that meets ISO 13485:2016 requirements.

2) To qualify for registration, it's not enough to just conform to the standard. A quality manual must be created which stipulates a facility's quality-related policies, procedures and practices. This document plays a vital role in the registration process. Because the manual is the principal document used during an audit, it must be a true reflection of the facility's quality management system. The manual must also address, point by point, all ISO 13485:2016 and regulatory requirements.

3) The facility's quality management system must be in operation for a minimum of three to six months so that employees are familiar with the system and an evidentiary trail of documents has been created for auditors to review.

After successfully completing the preliminary steps, a relationship must be established with a registrar. The registrar's job is to verify whether an organization's quality management system has been properly implemented and is in conformity with ISO 13485:2016 and regulatory requirements.

Once the services of an accredited registrar have been obtained, a formal application must be filed. When all of the paperwork has been submitted, the registrar audits the facility's quality manual. After the registrar has verified that the manual is a satisfactory reflection of the company's quality management system and meets all ISO 13485:2016 and regulatory requirements, an on-site audit of your facility is scheduled.

During the audit, the registrar interviews employees, reviews records, and performs a detailed inspection of the facility's quality management system and procedures. The purpose of the audit is to ensure that the facility's quality management system is functioning adequately, and conforms to all ISO 13485:2016 and regulatory requirements.

Afterward, the registrar reports its findings in an audit report. If any major or minor nonconformities were found, you (or auditee) must take corrective action to remedy the cause of the nonconformity. Nonconformities must be remedied within a set time frame, determined by the registrar. Once the registrar has closed out all outstanding nonconformities, ISO 13485:2016 certificate of registration is issued.

To ensure that medical device organizations are following ISO 13485:2016 requirements after registration is obtained, the registrar conducts on-site surveillance audits one to two times a year.

Remember: In order to achieve registration to ISO 13485:2016, you must completely embrace the standards, which focus on performance, documentation and objective/audit evidence.

What to Look For in a Registrar

In selecting a registrar, it is extremely important for every organization to be aware of the relevant qualifications.

A registrar must:

- Be accredited by a national accreditation body, such as the ANSI-ASQ National Accreditation Board (ANAB), the Raad voor Accreditatie (RvA) of the Netherlands or the United Kingdom Accreditation Service (UKAS);

- Maintain a listing of its ISO 13485 qualified auditors;

- Have personnel on its executive (registration) committee or governing board with medical device industry experience and expertise in the appropriate Standard Industrial Classification (SIC), North American Industry Classification System (NAICS), (NACE) Nomenclature of Economic Activities, or European Accreditation of Certification (EA) codes;

- Conform to the European standard EN 45012, *General Criteria for Certification Bodies Operating Quality management system Certification*; and

- Conform to ISO/IEC 17021-1:2015 *Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements*

What to Look For in an Auditor

Requirements have been established for the auditors working for accredited ISO 13485 registrars. Before an auditor can evaluate a facility to verify whether its quality management system conforms to ISO 13485:2016, the auditor must satisfy the following conditions:

1) Auditors must have satisfactorily completed ISO 13485 and ISO 9000 training courses, and demonstrated their knowledge of ISO 13485:2016 by passing exams. Certificates are awarded to those auditors who have successfully completed this training;

2) Auditors must comply with ISO 19011:2011, Guidelines on auditing management systems. It applies to the conduct of first and second party audits; auditor qualification; and audit program management;

3) They must be recognized and qualified as ISO 13485 auditors under the registrar's criteria; and

4) At least one member of an audit team must have relevant medical devices industry experience in the appropriate SIC, NAICS or EA codes, as determined by the registrar's qualification process, for each client.

Before hiring the services of a registrar, it's a good idea to make sure the registrar and its auditors have met these qualifications.

THE BENEFITS OF ISO 13485 _____

ISO 13485 is an ideal quality management system for medical device manufacturers that are serious about quality and complying with regulations, with ISO 13485 registration providing a competitive edge.

Medical device manufacturers that operate ISO 13485 quality management systems tend to exhibit a philosophy of prevention rather than detection; continual review of critical process points and regulatory requirements; corrective actions and outcomes; consistent communication within the process, and among facility, suppliers and customers; thorough record keeping and efficient control of critical documents; total quality awareness by all employees; and a high level of executive management confidence and support.

These attributes lead to dependable process input, control of quality costs, improved compliance with regulations, increased productivity and reduced waste. A well-designed and implemented ISO 13485 quality management system creates a process that tends to be lean, sensitive to customer and regulatory needs, highly reactive, efficient and positioned at the leading edge of the marketplace.

Expected benefits of ISO 13485 include:

- Increased safety and effectiveness in manufacturing and using medical devices

- Reduced liability and regulatory problems

- Enhanced relationships between you and its customers

- Standardization of quality management system requirements

- Efficient management of external audits and site visits

- Overall cost reduction and increased competitiveness

- Enhanced management and improvement of your performance

Another major benefit of becoming ISO 13485 registered is that it will set your company apart from your competitors. ISO 13485 is an ideal quality management system standard for competing in business because it aims to control quality and regulatory compliance costs, increase productivity and reduce waste. It's also customer driven. When implemented correctly, the elements of ISO 13485 work meticulously together to ensure that required quality levels are met, and that customer and regulatory needs are satisfied. This can be a powerful strategic tool.

Bottom line: A medical device manufacturer that chooses to conform to ISO 13485 will be operating a top-notch quality management system that focuses on informed and competent management decision making, control of quality and regulatory compliance costs, increased productivity and reduced waste.

ISO 13485 QUALITY MANAGEMENT SYSTEM REQUIREMENTS _____

3   Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

3.1 Advisory Notice *is notice issued by you , subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:*

- *use of a medical device,*
- *modification of a medical device,*
- *return of the medical device to you that supplied it, or*
- *destruction of a medical device*

    Note 1 to entry: Issuance of an advisory notice can be required to comply with applicable regulatory requirements.

3.2 Authorized Representative *is a natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.*

[SOURCE: GHTF/SG1/N055:2009, 5.2]

3.3 Clinical Evaluation *is an assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.*

[SOURCE: GHTF/SG5/N4:2010, Clause 4]

3.4 Complaint *is a written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from your control or related to a service that affects the performance of such medical devices.*

Note 1 to entry: This definition of "complaint" differs from the definition given in ISO 9000:2015.

3.5 Distributor *is a natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.*

Note 1 to entry: More than one distributor may be involved in the supply chain.
Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

[SOURCE: GHTF/SG1/N055:2009, 5.3]

3.6 Implantable medical device *is a medical device which can only be removed by medical or surgical intervention and which is intended to:*

– *be totally or partially introduced into the human body or a natural orifice, or*
– *replace an epithelial surface or the surface of the eye, and*
– *remain after the procedure for at least 30 days*

Note 1 to entry: This definition of implantable medical device includes active implantable medical device.

3.7 Importer *is a natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.*

[SOURCE: GHTF/SG1/N055:2009, 5.4]

3.8 Labelling *is a label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents.*

[SOURCE: GHTF/SG1/N70:2011, Clause 4]

3.9 Life-cycle *is all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.*

[SOURCE: ISO 14971:2007, 2.7]

3.10 Manufacturer *is a natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).*

Note 1 to entry: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture", as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: GHTF/SG1/N055:2009, 5.1]

3.11 **Medical Device** *is an instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:*

 − *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
 − *diagnosis, monitoring, treatment, alleviation of or compensation for an injury;*
 − *investigation, replacement, modification, or support of the anatomy or of a physiological process;*
 − *supporting or sustaining life;*
 − *control of conception;*
 − *disinfection of medical devices;*
 − *providing information by means of in vitro examination of specimens derived from the human body;*

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

 − *disinfection substances;*
 − *aids for persons with disabilities;*
 − *devices incorporating animal and/or human tissues;*
 − *devices for in vitro fertilization or assisted reproduction technologies.*

[SOURCE: GHTF/SG1/N071:2012, 5.1]

3.12 *Medical Device Family is a group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.*

3.13 *Performance Evaluation is an assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use.*

3.14 *Post-market Surveillance is a systematic process to collect and analyse experience gained from medical devices that have been placed on the market.*

3.15 *Product is a result of a process.*

Note 1 to entry: There are four generic product categories, as follows:

- *services (e.g. transport);*
- *software (e.g. computer program, dictionary);*
- *hardware (e.g. engine mechanical part);*
- *processed materials (e.g. lubricant).*

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product "automobile" consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

Note 2 to entry: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

- *an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);*
- *an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);*
- *the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);*
- *the creation of ambience for the customer (e.g. in hotels and restaurants).*

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

Note 3 to entry: This definition of "product" differs from the definition given in ISO 9000:2015.

[SOURCE: ISO 9000:20052), 3.4.2, modified]

3.16 *Purchased Product is product provided by a party outside your quality management system.*

Note 1 to entry: The provision of product does not necessarily infer a commercial or financial arrangement.

3.17 ***Risk*** *is a combination of the probability of occurrence of harm and the severity of that harm.*

Note 1 to entry: This definition of "risk" differs from the definition given in ISO 9000:2015.

[SOURCE: ISO 14971:2007, 2.16]

3.18 ***Risk Management*** *Is a systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.*

[SOURCE: ISO 14971:2007, 2.22]

3.19 ***Sterile Barrier System*** *is a minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.*

[SOURCE: ISO 11607﹣1:2006, 3.22]

3.20 **Sterile Medical Device** is a medical device intended to meet the requirements for sterility.

Note 1 to entry: The requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards.

Auditable requirements follow: It is <u>very important</u> to note that unlike ISO 13485:2003, there is no indication of the relationship between ISO 13485 and ISO 9001. This is a stand-alone document.

The following is a synopsis of the requirements in ISO 13485:2016

4 Quality Management System

4.1 General Requirements

4.1.1

How to document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements

What you must establish, implement and maintain as a requirement, procedure, activity or arrangement to meet requirements of this International Standard or applicable regulatory requirements.

What you must document as to your role(s) undertaken under the applicable regulatory requirements.

NOTE: These can include manufacturer, authorized representative, importer or distributor.

4.1.2

Determine the processes needed for the quality management system and the application of these processes throughout your organization taking into account all the roles;

Apply a risk based approach to the control of these processes;

Determine the sequence and interaction of these processes.

4.1.3

- Determine criteria and methods to effectively operate and control these processes;
- Ensure resources and information to support the operation and monitoring of these processes;
- Implement actions to achieve planned results and maintain process effectiveness;
- Monitor, measure as appropriate, and analyse the processes;
- Establish and maintain records needed to demonstrate conformance to ISO 13485:2016 and compliance with applicable regulatory requirements (see 4.2.5).

4.1.4

You must manage processes per requirements of ISO 13485:2016 and applicable regulatory requirements. Changes must be:

- Evaluated for their impact on your quality management system;
- Evaluated for their impact on your manufactured medical devices;
- Controlled per the requirements of ISO 13485:2016 and applicable regulatory requirements.

4.1.5

If you choose to outsource any process, you must monitor and ensure control over that process retaining responsibility of conformity to ISO 13485:2016 and to customer and applicable regulatory requirements for the outsourced process. These controls must be proportionate to any risk involved and the ability of the external party to meet the requirements per 7.4. The controls must include written quality agreements.

4.1.6

You must document procedures for the validation of the application of computer software used in your quality management system. The software applications must be validated prior to initial use and, as appropriate, after changes to the software or its application.

You must take a specific approach and perform activities associated with software validation and revalidation proportionate to the risk associated with the use of the software.

You must maintain records of the validation (see 4.2.5).

4.2 Documentation Requirements

4.2.1 General

Documentation (see 4.2.4) must include:

- Documented quality policy and quality objectives;
- A quality manual;
- Documented procedures and records required by ISO 13485:2016;
- Documents, including records, you have determined necessary to ensure the effective planning, operation, and control of your processes;
- Any other documentation specified by applicable regulatory requirements.

4.2.2 Quality Manual

Your quality manual must include:

- The scope of the quality management system, including details of and justification for any exclusion or non-application;
- Your documented procedures or reference to them;
- Your description of the interaction between the processes of the quality management system.

The quality manual must include an outline of the structure of the documentation used.

4.2.3 Medical Device File

You must establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of ISO 13485:2016 and compliance with applicable regulatory requirements - or each medical device type or medical device family.

The file(s) must include, but is not limited to:

- A general description of the medical device, its intended use/purpose, and labelling, including any instructions for use;
- Product specifications;
- Manufacturing, packaging, storage, handling and distribution specifications or procedures;
- Measuring and monitoring procedures;
- Applicable requirements for installation;
- Applicable procedures for servicing.

4.2.4 Control of Documents

If you need a document to operate a part of the quality management system, you must control it. Records are a special type of document and must be controlled according to the requirements given in 4.2.5. You must document a procedure that defines the controls needed to:

- Review and approve documents for adequacy prior to issuing them;
- Review, update as necessary and re-approve documents after you issue them;
- Ensure that you have the current revision status and changes to documents identified;
- Ensure that employees have relevant versions of applicable documents available to them;
- Ensure that documents remain readable and readily identified;
- Ensure that documents of external origin, that you have determined to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;
- Prevent any deterioration or loss of documents;
- Prevent the unintended use of obsolete documents and add suitable identification to them.

You must ensure that changes to documents are reviewed and approved either by the original approving function or another designated function that has access to important background information upon which to base your decisions.

You must define the period for which at least one copy of obsolete documents are retained. The period must ensure that documents used to manufacture and test medical devices are available for at least the lifetime of the medical device as you define it, but that period cannot be less than the retention period of any resulting record (see 4.2.5), or as specified by applicable regulatory requirements.

4.2.5 Control of Records

Records must be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

You must document procedures that define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

You must define and implement methods for protecting confidential health information contained in records per the applicable regulatory requirements.

Records must remain readable, readily identifiable and retrievable. Changes to a record must remain identifiable.

You must retain the records for at least the lifetime of the medical device as you define it, or as specified by applicable regulatory requirements, but not less than two years from the date you released the medical device.

5 Management Responsibility

5.1 Management Commitment

You must provide evidence of commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

- Communicating to your staff the importance of meeting customer regulatory requirements;
- Establishing a quality policy;
- Establishing quality objectives;
- Holding management reviews;
- Providing resources.

5.2 Customer Focus

You must determine and meet customer requirements and applicable regulatory requirements.

5.3 Quality Policy

You must issue a quality policy that:

- Is applicable to the purpose of your company;
- Contains a commitment to comply with requirements and maintain the effectiveness of the quality management system;
- Sets a platform for establishing and reviewing quality objectives;
- You communicate to your staff and ensure they understand it;
- You review periodically to determine it is still suitable.

5.4 Planning

5.4.1 Quality Objectives

You must establish quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, at relevant functions and levels within your company. These quality objectives must be measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Top management must ensure that:

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives;
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

You must establish, define, document, and communicate responsibilities and authorities within your company.

You must document the interrelation of all personnel who manage, perform and verify work affecting quality and those people must have the independence and authority necessary to perform these tasks.

5.5.2 Management Representative

You must appoint a member of your management who, in addition to that person's other responsibilities, has responsibility and authority for:

• Making certain that processes needed for the quality management system are documented;
• Communicating to top management how effective the quality management system is and if improvement is required;
• Making certain your company promotes the awareness of applicable regulatory requirements and quality management system requirements throughout your company.

5.5.3 Internal Communication

You must establish appropriate communication processes within your company and that ensures communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

You must document a procedure for management review. You also must review your quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. Your review must include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews must be maintained (see 4.2.5).

5.6.2 Review Input

Here are the minimum required inputs to management review, but you are not limited to them. You must review information from:

• Feedback;
• Complaints and how they are handled;
• Reporting to regulatory authorities;
• Audits;

- Process monitoring and measurement;
- Product monitoring and measurement;
- Corrective action;
- Preventive action;
- Open actions from previous management reviews;
- Changes that could impact the quality management system;
- Recommendations for improvement;
- Any new or revised regulatory requirements that apply to your company.

5.6.3 Review Output

You must record output from management review (see 4.2.5) and include the input reviewed and the decisions and actions applicable to:

- Improvement required to maintain the suitability, adequacy, and effectiveness of your quality management system and processes;
- Improvement of your product related to customer requirements;
- Changes required to respond to new or revised regulatory requirements that apply to you;
- Any resources required to support the changes and the quality management system in general.

6 Resource Management

6.1 Provision of Resources

You must determine and provide the resources for:

- Implementation of the quality management system and to maintenance of its effectiveness;
- Meeting the applicable regulatory and customer requirements.

6.2 Human Resources

Any member of your company performing work that affects product quality must be competent based on appropriate education, training, skills and experience.

You must document the process for establishing competence, providing needed training, and ensuring awareness of personnel.

You must:

- Decide what the required competence is for people performing work affecting product quality;
- Deliver training or take other actions to achieve or maintain the necessary competence;
- Evaluate the how effectiveness those actions taken actually are;
- Ensure your people are aware of the relevance and importance of their work and how they help you achieve the quality objectives;
- Keep appropriate records of education, training, skills and experience (see 4.2.5).

NOTE: The tools used to check effectiveness should be in balance with the risk associated with the work for which the training or other action is being provided.

6.3 Infrastructure

You must document the requirements for the infrastructure require so you can achieve conformity to product requirements, prevent mix-up of products, and make certain product is handled in an orderly manner.

Infrastructure can apply, as appropriate, to:

- Buildings your people occupy, workspace areas, and associated utilities required;
- Process equipment used to provide product (both hardware and software);
- Supporting services- like transport, communication, or information systems.

You must document your requirements for the maintenance activities, including the intervals between performing maintenance activities, when maintenance activities, or absence of it, can impact product quality. When applicable, these requirements must apply to equipment used in production, the control of the work environment and monitoring and measurement.

Maintenance records must be maintained (see 4.2.5).

6.4 Work Environment and Contamination Control

6.4.1 Work Environment

You must document the requirements for the work environment required to achieve conformity to product requirements.

If the conditions for the work environment could have an adverse effect on product quality, you must document the requirements for the work environment and the procedures to monitor and control the work environment.

You must:

- Document your requirements for health, cleanliness and clothing of personnel if contact between the personnel and the product or work environment could affect medical device safety or performance;
- Ensure that all persons who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

NOTE: You can refer to ISO 14644 and ISO 14698 for further information.

6.4.2 Contamination Control

When applicable, you must plan and document arrangements for the control of contaminated or potentially contaminated product so you can prevent the contamination of the work environment, personnel, or product.

For sterile medical devices, you must document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

7 Product Realization

7.1 Planning of Product Realization

You must plan and develop the processes needed for product realization. Planning of product realization must be consistent with the requirements of the other processes of the quality management system.

You must document one or more processes for risk management in product realization.

Records of risk management activities must be maintained (see 4.2.5).

When you plan for product realization, you must determine the following, as appropriate:

- Quality objectives and requirements for the product;
- The need for you to establish processes and documents (see 4.2.4) and provide resources specific to your product, including infrastructure and work environment;
- Needed verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to your product together with the criteria for product acceptance;
- Records required to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5).

The output of this planning must be documented in a form suitable for your method of operations.

NOTE: See ISO 14971 for further information

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to Product

You must determine:

- Requirements your customer specifies, including required delivery and post-delivery activities;
- Requirements your customer did not state but you determine necessary for specified or intended use, as known;
- Any Applicable regulatory requirements related to your product;
- Any user training required to ensure specified performance and safe use of the medical device;
- Any additional requirements you determine.

7.2.2 Review of Requirements Related to Product

You must review the requirements related to your product. This review must be conducted prior to your commitment to supply product to the customer (e.g. submission of quotations, acceptance of contracts or orders, acceptance of changes to contracts or orders) and you must make certain that:

- Requirements for product are defined and documented;
- Contract or order requirements that differ from previously expressed data are resolved;
- You meet any applicable regulatory requirements;
- Any user training you identify per 7.2.1 is available or planned to be available;
- You have the ability to meet the defined requirements.

You must maintain records of the results of the review and actions arising from the review (see 4.2.5).

When your customer provides no documented statement of requirement, then you must confirm the customer requirements before acceptance.

When product requirements change, then you must make certain that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Communication

You must plan and document arrangements for communicating with customers in as it relates to:

- Information about your product;
- Inquiries, contracts or order handling, including changes or amendments;
- Customer feedback, including customer complaints;
- Need for advisory notices.

You must communicate with regulatory authorities per applicable regulatory requirements.

7.3 Design and Development

7.3.1 General

You must document procedures for design and development.

7.3.2 Design and Development Planning

You must plan and control the design and development of product. As appropriate, design and development planning documents must be maintained and updated as the design and development evolves.

During design and development planning, you must document:

- The design and development stages;
- The review(s) required at each design and development stage;
- The verification, validation, and design transfer activities appropriate at each design and development stage;
- The responsibilities and authorities for design and development;
- The methods to ensure traceability of design and development outputs to design and development inputs;
- The resources required, including necessary competence of personnel.

7.3.3 Design and Development Inputs

You must determine the inputs relating to product requirements and maintain records (see 4.2.5). These inputs must include:

- Functional, performance, usability and safety requirements, according to the intended use;
- Applicable regulatory requirements and standards to your design;
- Applicable output(s) of risk management;
- As appropriate, information you learn from previous similar designs;
- Other requirements you determine essential for design and development of the product and processes.

You must review these inputs for adequacy and approval.

Requirements must be complete, unambiguous, able to be verified or validated, and not in conflict with each other.

NOTE: See IEC 62366–1 for further information.

7.3.4 Design and Development Outputs

Design and development outputs must:

- Meet input requirements for design and development;
- Provide appropriate information for purchasing, production and service needs;
- Contain or reference product acceptance criteria;
- Specify the characteristics of the product essential for the design's safe and proper use.

The outputs of design and development must be in a form suitable for verification against the design and development inputs and must be approved prior to release.

Records of the design and development outputs must be maintained (see 4.2.5).

7.3.5 Design and Development Review

At suitable stages, you must perform systematic reviews of design and development per planned and documented arrangements to:

- Evaluate the ability of the results of design and development to meet requirements;
- Identify and propose necessary actions.

Members participating in reviews must include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions must be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5).

7.3.6 Design and Development Verification

Design and development verification must be performed per planned and documented arrangements to make certain the design and development outputs meet the design and development input requirements.

You must document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification must include confirmation that the design outputs meet design inputs when so connected or interfaced.

Records of the results and conclusions of the verification and necessary actions must be maintained (see 4.2.4 and 4.2.5).

7.3.7 Design and Development Validation

Design and development validation must be performed per planned and documented arrangements to make certain the resulting product is capable of meeting the requirements for the specified application or intended use.

You must document validation plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

Design validation must be conducted on representative product samples. Representative product samples include initial production units, batches or their equivalents. The rationale for the choice of product used for validation must be recorded (see 4.2.5).

As part of design and development validation, you must perform clinical evaluations or performance evaluations of the medical device per applicable regulatory requirements.

A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer.

If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation must include confirmation that the requirements for the specified application or intended use have been met when connected or interfaced.

Validation must be completed prior to release for use of the product to the customer.

Records of the results and conclusion of validation and necessary actions must be maintained (see 4.2.4 and 4.2.5).

7.3.8 Design and Development Transfer

You must document procedures for transfer of design and development outputs to manufacturing. These procedures must make certain that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and production capability can meet product requirements.

Results and conclusions of the transfer must be recorded (see 4.2.5).

7.3.9 Control of Design and Development Changes

You must document procedures to control design and development changes. The organization must determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.

Design and development changes must be identified. Before implementation, the changes must be:

• Reviewed
• Verified
• Validated, as appropriate
• Approved

The review of design and development changes must include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.

Records of changes, their review and any necessary actions must be maintained (see 4.2.5).

7.3.10 Design and Development Files

You must maintain a design and development file for each medical device type or medical device family. This file must include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 Purchasing Process

You must document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information.

You must establish criteria for the evaluation and selection of suppliers. The criteria must be:

- Based on your supplier's ability to provide product that meets your requirements;
- Based on the performance of the supplier;
- Based on the effect of the purchased product on the quality of the medical device;
- Proportionate to the risk associated with the medical device.

You must plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product must be monitored. The results of the monitoring must provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements must be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities must be maintained (see 4.2.5).

7.4.2 Purchasing Information

Purchasing information must describe or reference the product to be purchased, including as appropriate:

- Product specifications;
- Requirements for product acceptance, procedures, processes and equipment;
- Requirements for qualification of supplier personnel;
- Quality management system requirements.

You must ensure the adequacy of specified purchasing requirements prior to your communication to the supplier.

Purchasing information must include, as applicable, a written agreement that the supplier notify you of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.9, you must maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).

7.4.3 Verification of Purchased Product

You must establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities must be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When you become aware of any changes to the purchased product, you must determine whether these changes affect the product realization process or the medical device.

When you or your customer intends to perform verification at the supplier's premises, you must state the intended verification activities and method of product release in the purchasing information.

Records of the verification must be maintained (see 4.2.5).

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Production and service provision must be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls must include but are not limited to:

- Documentation of procedures and methods for the control of production (see 4.2.4);
- Qualification of infrastructure;
- Implementation of monitoring and measurement of process parameters and product characteristics;
- Availability and use of monitoring and measuring equipment;
- Implementation of defined operations for labelling and packaging;
- Implementation of product release, delivery, and post-delivery activities.

You must establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record must be verified and approved.

7.5.2 Cleanliness of Product

You must document requirements for cleanliness of product or contamination control of product if:

- Product is cleaned by you prior to sterilization or use;
- Product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;
- Product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;
- Product is supplied to be used non-sterile, and its cleanliness is of significance in use;
- Process agents are to be removed from product during manufacture.

If product is cleaned per a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.

7.5.3 Installation Activities

You must document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate.

If the agreed customer requirements allow installation of the medical device to be performed by an external party other than you or your supplier, you must provide documented requirements for medical device installation and verification of installation.

Records of medical device installation and verification of installation performed by you or your supplier must be maintained (see 4.2.5).

7.5.4 Servicing Activities

If servicing of the medical device is a specified requirement, you must document servicing procedures, reference materials, and reference measurements, as necessary, for performing servicing activities and verifying that product requirements are met.

You must analyse records of servicing activities carried out by you or its supplier:

- To determine if the information is to be handled as a complaint;
- As appropriate, for input to the improvement process.

Records of servicing activities carried out by you or your supplier must be maintained (see 4.2.5).

7.5.5 Particular Requirements for Sterile Medical Devices

You must maintain records of the sterilization process parameters used for each sterilization batch (see 4.2.5). Sterilization records must be traceable to each production batch of medical devices.

7.5.6 Validation of Processes for Production and Service Provision

You must validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation must demonstrate the ability of these processes to achieve planned results consistently.

You must document procedures for validation of processes, including:

- Defined criteria for review and approval of the processes;
- Equipment qualification and qualification of personnel;
- Use of specific methods, procedures and acceptance criteria;
- As appropriate, statistical techniques with rationale for sample sizes;
- Requirements for records (see 4.2.5);
- Revalidation, including criteria for revalidation;
- Approval of changes to the processes.

You must document procedures for the validation of the application of computer software used in production and service provision. Such software applications must be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation must be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation must be maintained (see 4.2.4 and 4.2.5).

7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

You must document procedures (see 4.2.4) for the validation of processes for sterilization and sterile barrier systems.

Processes for sterilization and sterile barrier systems must be validated prior to implementation and following product or process changes, as appropriate.

Records of the results and, conclusion of validation and necessary actions from the validation must be maintained (see 4.2.4 and 4.2.5).

NOTE: See ISO 11607-1 and ISO 11607-2 for further information.

7.5.8 Identification

You must document procedures for product identification and identify product by suitable means throughout product realization.

You must identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status must be maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.

If required by applicable regulatory requirements, you must document a system to assign unique device identification to the medical device.

You must document procedures to ensure that medical devices returned to you are identified and distinguished from conforming product.

7.5.9 Traceability

7.5.9.1 General

You must document procedures for traceability. These procedures must define the extent of traceability per applicable regulatory requirements and the records to be maintained (see 4.2.5).

7.5.9.2 Particular Requirements for Implantable Medical Devices

The records required for traceability must include records of components, materials, and conditions for the work environment used, if these could cause the medical device not to satisfy its specified safety and performance requirements.

You must require that suppliers of distribution services or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection.

Records of the name and address of the shipping package consignee must be maintained (see 4.2.5).

7.5.10 Customer Property

You must identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under your control or being used by you . If any customer property is lost, damaged or otherwise found to be unsuitable for use, you must report this to the customer and maintain records (see 4.2.5).

7.5.11 Preservation of Product

You must document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation must apply to the constituent parts of a medical device.

You must protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

• Designing and constructing suitable packaging and shipping containers;
• Documenting requirements for special conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they must be controlled and recorded (see 4.2.5).

7.6 Control of Monitoring and Measuring Equipment

You must determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

You must document procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

As necessary to ensure valid results, measuring equipment must:

- Be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: when no such standards exist, the basis used for calibration or verification must be recorded (see 4.2.5);
- Be adjusted or re-adjusted as necessary: such adjustments or re-adjustments must be recorded (see 4.2.5);
- Have identification in order to determine its calibration status;
- Be safeguarded from adjustments that would invalidate the measurement result;
- Be protected from damage and deterioration during handling, maintenance and storage.

You must perform calibration or verification per documented procedures.

In addition, you must assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. You must take appropriate action in regard to the equipment and any product affected.

Records of the results of calibration and verification must be maintained (see 4.2.5).

You must document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications must be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation must be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation must be maintained (see 4.2.4 and 4.2.5).

NOTE: See ISO 10012 for further information.

8 Measurement, Analysis and Improvement

8.1 General

You must plan and implement the monitoring, measurement, analysis and improvement processes needed to:

- Demonstrate product conformity;
- Ensure quality management system conformity;
- Maintain quality management system effectiveness.

This must include determining appropriate methods, including statistical techniques, and the extent you use them.

8.2 Monitoring and Measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, you must gather and monitor information relating to whether you meet customer requirements. The methods for obtaining and using this information must be documented.

You must document procedures for the feedback process. This feedback process must include provisions to gather data from production and post-production actions.

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

If applicable regulatory requirements require you to gain specific experience from postproduction activities and you must include this review as part of the feedback process.

8.2.2 Complaint Handling

You must document procedures for timely complaint handling per applicable regulatory requirements. These procedures must include at a minimum rules and assignments for:

- Receiving and recording information;
- Evaluating information to decide if the feedback is a complaint;
- Initiating investigations of complaints;
- Determining if you need to report the information to the appropriate regulatory authorities;
- Handling of complaint-related product;
- Determining if you need to initiate corrections or corrective actions.

You must document a justification if you do not investigate. Any correction or corrective action resulting from the complaint handling process must be documented.

If an investigation determines activities outside you contributed to the complaint, applicable information must be exchanged between you and the external party involved.

Complaint handling records must be maintained (see 4.2.5).

8.2.3 Reporting to Regulatory Authorities

If applicable regulatory requirements require that you give notice of the complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, you must document procedures for providing notification to the appropriate regulatory authorities.

Records of reporting to regulatory authorities must be maintained (see 4.2.5).

8.2.4 Internal Audit

You must conduct internal audits at planned intervals to determine whether the quality management system:

- Conforms to planned and documented activity, requirements of this International Standard, quality management system requirements established by you, and applicable regulatory requirements;
- Is effectively implemented and maintained.

You must document a procedure to describe the roles and rules for planning and conducting audits and recording and reporting audit results.

An audit program must be scheduled, considering the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods must be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process. Auditors cannot audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, must be maintained (see 4.2.5).

The management for the audited area must make certain that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities must include the verification of the actions taken and the reporting of verification results.

NOTE: See ISO 19011for further information.

8.2.5 Monitoring and Measurement of Processes

You must apply value added methods for monitoring and, as appropriate, measurement of the quality management system processes. These methods must demonstrate the processes have achieved expected results. When expected results are not achieved, correction and corrective action must be taken, as appropriate.

8.2.6 Monitoring and Measurement of Product

You must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at suitable stages of the product realization process per the planned and documented arrangements and documented procedures.

Evidence of conformity to the acceptance criteria must be maintained. The identity of the person authorizing release of product must be recorded (see 4.2.5). As appropriate, records must identify the test equipment used to perform measurement activities.

Product release and service delivery must not proceed until the planned and documented arrangements have been satisfactorily completed.

For implantable medical devices, you must record the identity of personnel performing any inspection or testing.

8.3 Control of Nonconforming Product

8.3.1 General

You must make certain that product that is not in conformance with product requirements is identified and controlled to prevent its unintended use or delivery. You must document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.

The evaluation of nonconformity must include a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nonconformities and any ensuing action taken, including the evaluation, any investigation and the rationale for decisions must be maintained (see 4.2.5).

8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery

You must deal with nonconforming product by one or more of the following ways:

- Taking action to eliminate the detected nonconformity;
- Taking action to preclude its original intended use or application;
- Authorizing its use, release or acceptance under concession.

You must ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession must be maintained (see 4.2.5).

8.3.3 Actions in Response to Nonconforming Product Detected After Delivery

When nonconforming product is identified after delivery or use has started, you must take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken must be maintained (see 4.2.5).

You must document procedures for issuing advisory notices per applicable regulatory requirements. These procedures must be capable of being put into effect at once. Records of actions relating to the issuance of advisory notices must be maintained (see 4.2.5).

8.3.4 Rework

You must perform rework per documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures must undergo the same review and approval as the original procedure.

After the completion of rework, product must be verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records of rework must be maintained (see 4.2.5).

8.4 Analysis of Data

You must document procedures to determine, collect and analyze appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures must include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data must include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

• Feedback;
• Product conformity to requirements;
• Characteristics and trends of processes and product, including opportunities for improvement;
• Suppliers;
• Audits;
• Service reports, as appropriate.

If the analysis of data shows that the quality management system is not suitable, adequate or effective, you must use this analysis as input for improvement as required in 8.5.

Records of the results of analyses must be maintained (see 4.2.5).

8.5 Improvement

8.5.1 General

You must identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.

8.5.2 Corrective Action

You must take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions must be taken without undue delay. Corrective actions must be proportionate to the effects of the nonconformities encountered.

You must document a procedure to define requirements for:

• Reviewing nonconformities (including complaints);
• Determining the causes of nonconformities;
• Evaluating the need for action to ensure that nonconformities do not recur;
• Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
• Verifying that the corrective action does not adversely affect the ability to meet applicable;
• Regulatory requirements or the safety and performance of the medical device;
• Reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken must be maintained (see 4.2.5).

8.5.3 Preventive Action

You must determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions must be proportionate to the effects of the potential problems.

You must document a procedure to describe requirements for:

• Determining potential nonconformities and their causes;
• Evaluating the need for action to prevent occurrence of nonconformities;
• Planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
• Verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
• Reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken must be maintained (see 4.2.5).

CONCLUSION _____

ISO 13485:2016 represents progress, harmony and perseverance, for it is the end product of more than a decade's worth of international efforts to harmonize medical device quality management. This standard combines the most effective quality practices found in the ISO 9000 series and national medical device regulations, such as the FDA's CGMP.   It promotes medical device safety, performance and effectiveness; regulatory compliance; technical innovation; and global trade.

In the heavily regulated medical device field, ISO 13485 is the international solution for better quality and regulatory compliance. It is having an enormous impact on thousands of medical device manufacturers around the world, and is pointing them to ISO 13485 registration.

Organizations that are already ISO 13485:2003 registered will need to update their quality management systems to conform to ISO 13485:2016 and maintain this standard's requirements.

As registration typically takes 6 to 18 months to complete, medical device manufacturers are advised to start moving now. Registration should not be put on the back burner. Companies shouldn't delay registration, but should take full advantage of the competitive edge and entry into many major markets such status carries.

There are many benefits to be derived from implementing a well-structured quality management system such as ISO 13485, and the registration process is rigorous and timely. For this reason, not to mention the high rate of failure that afflicts companies seeking registration for the first time, it's a good idea to seek the services of an outside professional consulting firm.

A competent quality consultant can walk your company through the ISO 13485 requirements and identify any problems that may halt the registration process.