31st August 2022

The Importance of Renewing ISO 13485

Medical Device Quality Management System

We are thrilled to announce Extel has received approval to maintain its ISO 13485 accreditation.

An international standard, ISO 13485, has been developed by the International Organization for Standardization (ISO) to provide guidelines and guidelines for the design, production, installation, and distribution of medical devices. To provide medical devices that comply with regulatory requirements and customer requirements, ISO 13485 specifies how to establish a Quality Management System (QMS). Therefore, it is often referred to as a medical device quality management system.

Medical device manufacturing is highly regulated since safety and quality are of utmost importance. To ensure that medical devices distributed in the market are safe for consumers and meet their purposes, organizations are required to meet certain standards, comply with legal requirements, and meet the requirements of the governing bodies.

Many manufacturers (including most design agencies) create their own QMS, as ISO 13485 isn't mandatory for medical devices, which puts them at risk of not complying with legal requirements. In turn, this puts their customers at even greater risk.

The need to review a QMS standard by a certified third party is vital for determining aspects that may need to be revised, omitted, or improved. An ISO 13485 review incorporates market updates, technological advances, and regulations revisions. A major change that has been introduced by the ISO is that it has placed "greater emphasis on risk management and risk-based decision making" as well as "increased regulations for organizations in the supply chain."

Following is an overview of ISO 13485:

Scope
In addition to addressing the purpose and possible users of the standard, other clauses are also addressed in the standard

References
Describes how ISO 9001:2015 is referenced in the standard and introduces the details (click here to read more on ISO 9001)

Terms and Definitions
Provides a definition of the terminology used throughout the standard

Quality Management System
Ensures that medical devices are manufactured in compliance with the organization's QMS, including:

- Adherence to the standard
- Recordkeeping and documentation processes
- Associated policies and guidelines
- Maintaining files that detail the general descriptions, purposes, and other critical device information

Management Responsibility
Management's involvement in ensuring standards are implemented successfully

Resource Management
Ensures that the processes can be performed with adequate and available personnel, infrastructure, and equipment

Product Realization
From concept to implementation, the overall medical device product journey must follow quality protocols at every stage.

Measurement, Analysis, and Improvement
Utilizes processes such as data analysis, complaint handling, reporting of events to authorities, continuous improvement, and product evaluation to incorporate customer feedback

Our accreditation enables us to continue providing organizations across the globe with quality, safe and compliant medical device design and manufacturing services.

As an ISO 13485 accredited company, Extel offers the following benefits:

Evidence-based decision making
We believe that keeping focused and working toward quality goals is easier when the ISO 13485 certification is in place. Our management team constantly receives data from our departments. As a result of these facts and data, decisions are made that can be aligned with our customers, and our own, strategic goals and objectives. Our management team is involved and accountable in taking appropriate action if it perceives any lack of progress towards the set goals.

Streamlined processes and continuous improvement
Our ISO quality management system bases continuous improvement as a core principle. When our QMS was first adopted, it truly embedded continuous improvement into our culture. Quality, safety and customer satisfaction merged with the nature of evolving technology to not only comply with our QMS but to constantly evolve our services and deliverables for our customers.

Improved employee engagement and training
It is imperative that all our employees receive training in order to keep up with the rapidly evolving technologies used in the medical industry and elsewhere.

A properly documented process enables employees to understand their role in ISO 13485. The more our employees understand their roles, the more they become engaged. This results in higher operational efficiency and productivity. Our employees thrive on thinking of ways to improve processes and are willing to give the best insight that can help our customers succeed.

Design and development
There has been a renewed emphasis on design and development guidelines in some categories of products in the ISO 13485 standard. Unique to Extel is our ISO 13485 accreditation for not just medical device manufacturing, but also the design and development stage.

Customer Satisfaction

Customer satisfaction is one of the core principles of ISO 13485 implementation and has been a core value of ours for over 30 years. Rather than focusing on individual departmental or company goals, ISO 13485 implementation focuses on customer needs. In addition to the fact that the customers strongly believe Extel has a good quality management system in place, ISO 13485-certified companies are considered more reliable by the customers than those without.

Have you reviewed your current supplier of design, development and manufacturing to check on the QMS for your medical devices?

Extel has a proud and extensive history of enabling our customer to deliver life-changing medical devices throughout the world. See some of our case studies here:

- Sommetrics Case Study
- Blamey Saunders Case Study

If you're looking to introduce a new or upgraded medical device to your market, you want to ensure product quality, safety and compliance.

You can download our ISO13485 accreditation here (new certificate approved for download in October 2022).

Contact us today

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