OMNICA CORPORATION
Product Development
Engaging Views and OMNInews
DESIGN AND ENGINEERING NEWSLETTER

Should you hire an "ISO Registered" Contractor to develop your medical device?

The International Organization for Standardization (ISO) is located in Switzerland. The ISO 9000 guidelines were originally published in 1987 and the requirements of a quality management system were added in 2008. The standards can apply to any type of organization, and are oriented toward companies who do business internationally. Certification or Registration (in North America) is performed by an independent registrar, not by ISO. It is a *process standard* that many countries have adopted in an effort to control quality by *standardizing management*.

For firms who choose to implement the ISO Quality Management System, the designation insures that the processes within the company follow specific guidelines. Quality management by way of the ISO standard dictates how records are stored, the way information is transferred, rules for design and engineering changes, customer communications process, record keeping procedures, etc. These companies operate under a strict regulatory structure and shoulder the added burden associated with fixed costs and overhead.

The ISO guidelines will introduce a strict regulatory structure.

For a *design firm*, rigid rules that add an extra layer of bureaucracy can easily become a complicated hindrance. For example, when the documentation process itself needs to be documented, it can slow the product development cycle, disrupt the momentum of creativity, and extend the overall schedule.

All medical device developers must follow the FDA Quality Systems Regulations.

Regardless of whether ISO guidelines are followed, the FDA mandates their own set of rules in the Quality Systems Regulations (QSR). They are required by law when developing medical devices in the U.S. to establish consistency with quality systems worldwide. The FDA defines the elements of Design Control as the foundation for development of medical devices to make certain that producers address potential problems early in the product design process when they can be more easily corrected. Every medical device manufacturer is responsible for maintaining records to demonstrate compliance with the QSR.

Our clients have unique design control systems.

With the exception of some small start-up firms (who are in their initial planning stages), all of our clients have unique design control systems in place. At Omnica, we have developed a quality system that follows the model of the ISO guidelines and the FDA Quality Systems Requirements (QSR). It describes the general process of activity within the company during the project development cycle. Our design and regulatory team will adapt to the client's design control system to support their compliance with FDA regulations. Since we are not ISO Certified and we control our own management policies, this method gives us the flexibility to accommodate almost everyone.

What is the difference between ISO 9000, ISO 9001, and the 13485 standards?

ISO 9000 refers to three quality management system standards in the series - ISO 9000, 9001, and 9004:2009. ISO 9000 includes definitions and terminology that clarify concepts in the ISO 9001 requirements *process* standards (not product standards) used for certification. ISO 9004:2009 goes beyond ISO 9001 and has to do with sustaining a quality management approach and maintaining objectives for the long term. The ISO 9001 Quality Management Systems are reviewed every 5 years and an updated version is expected in 2015.

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ISO 13485 harmonizes *medical device* regulatory requirements with quality management systems.

ISO 13485 is an International Standard that requires the quality management system within an organization to ably and consistently meet customer and regulatory guidelines relevant to the development of *medical devices* and related services. The primary objective of this International Standard is to facilitate a harmonized medical device regulatory framework for quality management systems. It generally corresponds to the ISO 9001 guidelines, but it is not equivalent. ISO 13485 adds extra medical device-related requirements that are not included in ISO 9001, and removes others that are not applicable to their development.

Omnica will satisfy our customer's management and quality needs.

Omnica is a close-knit horizontal organization focused on medical device development. The foundations and principles we have in place are similar to those advocated by the ISO 9001 requirements with one significant difference: Omnica's work methods allow us to meet all of our customers' management and quality needs (ISO and others), and easily adapt to their processes. This obviates the need to function in a rigid operational structure and saves our clients time and money.

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