The Arrival of ISO 13485:2003

New standard shifts quality system

From procedure-based to process-based

Part 1 of 2

ISO 13485:2003 is now upon us and in approximately two and a half years, compliance with this standard will be mandatory in numerous countries where many U.S. medical device manufacturers presently market their products. How we approach implementing this new standard will determine whether it is a friend or foe. We have been taught that change is good, but it is only through experience that we have learned that change often entails a great deal of work.

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ISO 13485 represents a major change—a change in concept, being a stand-alone quality system standard for medical devices, and a change in application, pushing the tendrils of quality systems and quality assurance into new areas with a quality process versus procedure orientation.

This article provides a compass but not a map to help medical device manufacturers decide how they can adapt their current quality systems, which comply with both FDA regulations and the demands of the European Union, to meet the new challenges and opportunities presented by ISO 13485:2003.

Before we begin preparing for the future, lets look back briefly at the past and the history of ISO Quality Management System standards. An overview of the standard and a discussion of the process approach to quality systems will be presented. We will then look at specific areas and functions that are differentiated under the new ISO standard and that is more prescriptive than the FDA's Quality System Regulation (QSR). Finally, some implementation and transition strategies and techniques are provided to help you organize you plans to revise, not devise, your current system into one that is compliant with all applicable standards and regulations governing the quality systems for medical device manufacturers.

History and Impact

In the mid-1980s, the International Organization for Standardization (ISO) began work on its first version of a non-industry-specific quality system standard. This became embodied in ISO 9001:1987. This standard was a radical departure from the old Quality Control image, exceeding even the FDA's Good Manufacturing Practices (GMPs) in scope. But by the early 1990s, an international consensus realized that this standard was not comprehensive enough. When finally approved, ISO 9001:1994 (with the organizationally narrower ISO 9002:1994, ISO 9003:1994 and the implementation guidance ISO 9004:1994), became the gold standard for quality systems the world

Table 1

The procedural approach focuses on 20 elements implemented with the concept, "say what you do, and do what you say." Quality records provide the objective evidence. The process approach, in contrast, focuses on four key elements: management responsibilities; resource management; product realization; and measurement, analysis and improvement.

Procedural Approach	Process Approach
"Say What You Do" via procedures, forms, templates, instructions, methods, etc.	Learn the processes that make up: Management Responsibilities, Resource Management, Product Realization, and Measurement, Analysis and Improvement
"Do What You Say" via techniques, practices, skills, routines, etc.	Learn the PROCESS FLOW via inter-relationships, risk management, participation, team work
"Quality Records" provides the evidence.	Dependent on the processes exposing opportunities for improvement in the systems and products

over. Within two years, industry specific standards, based on ISO 9001:1994, began to appear. EN 46001, application of EN ISO 9001 to the manufacture of medical devices, became the preferred route to achieve CE marking of medical device products destined for sale in the European Union.

In the U.S., the FDA revised the old GMPs into its present form in 21 CFR, Part 820, Quality System Regulation (QSR). Also, taking its cue from the European Union, ISO issued 13485:1996, Quality Systems—Medical devices—Particular requirements for the application of ISO 9001. For four years the international medical device community operated quite smoothly using one or more of these standards, which, while not identical, overlapped enough for companies to develop single quality systems that could address the requirements of each standard.

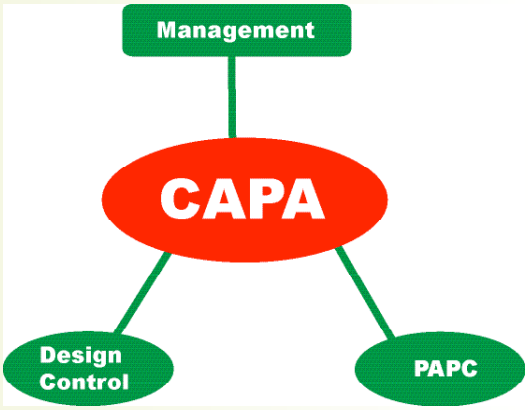
Then in 2000, ISO 9001 was revised. Just as ISO 9001:1994 had opened areas not historically a part of the quality system, such as design control and servicing, ISO 9001:2000 opened a Pandora's Box from which continuous improvement, customer satisfaction and training effectiveness issues emerged. This new standard was still industry nonspecific and was therefore not acceptable to many regulatory agencies. To correct this deficiency, the organization began work on a new standard to replace ISO 13485:1996, but this time it would be a stand-alone standard like the FDA's QSR. The new ISO 13485 standard was approved in 2003 and will become mandatory on July 1, 2006.

Just as ISO 13485:1996 was patterned after ISO 9001:1994, ISO 13485:2003 is structured like ISO 9001:2000 but steers a course between the process-based international standard on which it is patterned and the procedure-based QSR. It recognizes that some of the conceptual goals of ISO 9001 such as continuous improvement and customer satisfaction, are not appropriate to the heavily regulated medical device industry.

The evolution of quality system standards has taken yet another step forward. The original quality system standards led the industry from a quality control model to a quality assurance model. Instead of relying on inspectors to examine each and every device to ensure quality, it became everyone's responsibility to ensure quality through all phases of production. The quality assurance model relied on the procedural approach, taking the important elements of a quality system and organizing them by major function. This approach resulted in a quality system with standard operating procedures that address each of the 20 key elements of a quality system. This was complimented by instructions, tests, methods, techniques, skills, etc. that workers used to perform their duties.

ISO 13485:2003 and ISO 9001:2000 introduce yet another concept: the process approach. The evolution stems from the development of

Chart 1



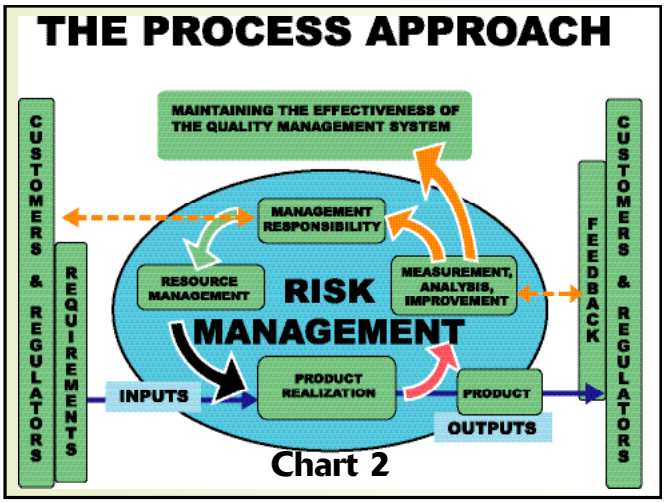


Chart 2

inspectional techniques to standardize the audit process and link the 20 elements to key subsystems. The core of the quality system involves four key elements that link to the other elements. The process approach focuses more on grouping the elements into key categories and organizing them to define the expected process flow. For example, design and development precedes purchasing controls, which precedes production controls. Another important factor is that within the procedural approach, each procedure operates on its own. This self-contained approach works, but it is not always clear which procedural element applies to a particular situation. For example, if applying environmental controls to a production process, when would nonconforming product procedures be selected over corrective and preventive action? (*See Table 1*). The new ISO 13485:2003 quality system standard also integrates risk management into the processes. The Global Harmonization Task Force is in the process of developing a guidance document for integrating risk management into a quality system. Risk-based decisions need to be integral to an effective quality system. Also, the FDA introduced the Quality System Inspection Technique (QSIT) with management serving as the hub and design control, corrective & preventive action (CAPA) and production and process control (PAPC) as the spokes. FDA has now structured QSIT with CAPA at the hub and management, design controls and PAPC as the spokes. This approach is an audit technique and not the structure of a quality system. (*See Chart 1*).

The ISO 13485:2003 process approach has a different organization than QSIT. Management responsibilities are similar in content to the management subsystem in QSIT. Resource management does not correlate directly to any of the elements of QSIT but rather correlates through linkages to other quality system elements. Product realization correlates to design controls and PAPC as well as other elements such as purchasing controls, identification and traceability and control of measuring equipment. Finally the measurement, analysis and improvement element contains CAPA as well as internal audits, monitoring and analysis requirements, control of nonconforming products and customer complaints. If there were a single process element at the hub of quality systems, it would be risk management. Chart 2 depicts the process approach including risk management.

How can risk management be tied ~~procedurally to process elements?~~ Examine the following processes as examples:

- Design controls
- Software development and problem reporting
- Purchasing processes and vendor selection criteria
- Receiving inspection, in-process and final acceptance processes and criteria
- Process validations
- Rework processes and decisions
- Failure investigation
- CAPAs
- Quality audits
- Recall procedure
- Nonconforming product dispositions

Risk should be examined from two points of view, including safety risk and business risk. The safety risk

Level of Concern	Table 2 Description of Risk
(3)	• The non-conformity requires full analysis and immediate action to determine scope and limit impact. • Requires further analysis to determine the cause. • Represents a minor or major regulatory compliance issue • Correction of the out-of-compliance condition may result in significant impact to the business such as temporary termination of production or the availability of the product to the customer. • Temporary action will add costs to the product or possibly will result in regulatory action.
(4)	• The non-conformity requires full analysis and immediate action to determine scope and limit impact. • Requires further analysis to determine the cause. • Represents a major or critical regulatory compliance issue. • Correction of the out of compliance condition may result in significant impact to the business such as voluntary recall of the product and/or will certainly result in regulatory action.

may be high, moderate or low depending on the product and its inherent risk. The risk level is the so-called "ceiling" for the safety risk component and can be characterized as "likeliness of resulting in serious injury or death" or "causing harm."

On the other hand, the business risk component should focus on the risk to the business. Rationale for quality system decisions should be documented based on risk. Table 2 illustrates what two different risk levels might contain (from a scale of 0-5, 5 is highest risk).

The EN ISO 14971 Medical Devices—Application of Risk Management to Medical Devices standard provides guidance for implementing risk management into your quality system. Additionally, keep your eyes and ears open for the release of additional guidance from the GHTF.

The ISO 13485:2003 standard is organized in a different manner than the previous standard and thus will require some adjustments to the quality system. The good news is that most of the effort will be moving toward the process approach (reorganizing rather than re-creating). The second adjustment is to implement risk-based decision processes throughout the quality system.

In review, ISO 13485:2003 and ISO 9001:2000 are described as process-based standards, whereas the QSR and ISO 9001:1994 were procedure-based. Process-based standards can be viewed as a continuum of activities, inputs and outputs that become the inputs of the next activity. The procedure-based system views the quality system as discrete functions—design control, production and process control and CAPA. The older standard views the quality system as rocks rising above the surface of a stream, whereas the new standards view the quality system as the stream itself.

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