

# Implementing ISO 13485:2003

## Selecting the Most Efficient Strategy and Implementation Plan Requires Thorough Analysis and Assessment

### Part 2 of 2



In part one of this article, ISO 13485:2003, a process-based system, is contrasted to the procedure-based system of QSR and ISO 9001:1994. The analogy is that while procedure-based systems view discrete functions such as CAPA, design control and others functions as rocks that rise above the water in a stream, ISO 13485:2003 views the stream itself as the quality system.

The numbers, however, do not totally bear this out. Table 1 identifies the approximate number of established procedures called for in each of the five standards.

The confines of an article such as this do not allow for a section-by-section review of ISO 13485:2003, but the following describes changes that are of particular concern to medical device manufacturers with special attention to areas where ISO 13485:2003 is more detailed or prescriptive than the FDA QSR.

One change in the new ISO standards that is more consistent with QSR allows functions that are not performed by an organization to be excluded. However, if a manufacturer performs design and development activities in the development of a medical device, it is no longer possible to exclude design control from a registration audit. There are no longer narrower, less comprehensive versions of the standard. Under ISO 13485:2003, if you perform the function, the process will be audited.

The first difference encountered between ISO 13485:2003 and ISO 9001:2000 is in the quality management system. The former standard deletes the words “continually improve” from the requirement to

establish and maintain a quality management system. In this same section, ISO 13485:2003 lists a number of the responsibilities of the organization in relation to the operation of the quality management system. It specifies that the organization shall identify the processes necessary for the system, determine the sequence and interaction of these processes, determine the criteria and methods for ensuring the effectiveness of the processes, ensure the availability of needed resources, monitor, measure and analyze the processes and implement actions necessary to achieve the planned results. This section also places on the organization the responsibility of ensuring that all outsourced activities comply with the standard.

In the section on customer focus,

STANDARD	NO. OF PROCEDURES
ISO 9001:1994	18
ISO 13485:1996	18
ISO 9001:2000	6
ISO 13485:2003	17
21 CFR, Part 820, QSR	36

Table 1



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ISO 13485:2003 deletes from its requirements that the product “aim at enhancing customer satisfaction,” and speaks only of meeting customer requirements. In line with the concept of recognizing customer requirements, ISO 13485:2003 includes “ensuring the promotion of awareness of regulatory and customer requirements throughout the organization” as a function of the management representative.

The QSR does not address the concept of customer focus or customer satisfaction. The agency’s concern is that the manufacturer meets the regulatory requirements and design and manufacture medical devices that are safe and effective.

Both ISO 13485:2003 and ISO 9001:2000 have expanded their coverage of management reviews. A list of specific topics to be considered during the review has been provided. This list includes audit reports, customer feedback, process effectiveness, the status of CAPA activities, recommendations for improvements and the impact on the system of new or revised regulations. Outputs from management reviews are also covered. These include improvements needed to maintain the effectiveness of the system, improvements to products in relation to customer requirements and resource needs. Although not specifically delineated in the QSR, these topics and outputs from management reviews are what the FDA expects to be covered. This is an instance in which ISO 13485:2003 helps in complying with the QSR.

The section entitled “Product Realization” in ISO 13485:2003 is the first encounter with the process orientation of the new standards. Here, we see a smooth flow of regulations, one subject seamlessly and logically transitioning into the next. Beginning with product planning, this section moves through product requirements as viewed by the customer, design and

development, purchasing (including vendor qualification), the purchasing process and receipt of material, control of production (including process validation, identification and traceability of materials and products), handling and storage and the control and calibration of test equipment and measuring instruments.

The QSR deals with most of these considerations as independent, almost isolated, functions. It should be pointed out, however, that the QSR is far more prescriptive in what is expected in the way of documentation that demonstrate compliance.

The final section of ISO 13485:2003 is entitled, “Measurement, Analysis and Improvement.” This section is totally new and deals with the methods used to evaluate the operation of the quality system and to

improve its effectiveness.

In reality, ISO 13485:2003 is not a radical departure from the QSR. Previously, ISO 13485:1996 was totally circumscribed by the QSR, whereby compliance with the latter meant more than adequate compliance with the former. And although the new ISO 13485:2003 has some requirements not found in the QSR, neither document contradicts the other.

### **Implementation Approach**

The medical device industry throughout the world will move toward adopting the new ISO 13485:2003 as the preferred quality system standard. Not everyone is there yet. At this time, it is important to know your target markets and determine the present quality standard requirements. For example, the Health Ministry of

Canada is in the process but has not completed the steps needed to accept ISO 13485:2003 from its recognized registrars. Thus, if you plan to distribute products in Canada soon, you will need a certification to either CAN/CSA ISO 13485:1998 (identical to ISO13485:1996) or CAN/CSA ISO 13488:1998. Once certified, you will have until March 15, 2006 to transition to the new standard (13485:2003).

If you already have a quality system in place, you might naturally ask: "Where do I start?"

- Step 1: Conduct a gap analysis. This should assess your current quality system and compare it with the new ISO13485:2003 requirements. You might consider hiring a knowledgeable consultant to perform the gap analysis to benefit from his objectivity and familiarity with standards,

independence and timeliness. The end result will be a matrix that provides you with a road map on how to reorganize your current quality system elements and the identification of gaps that require new procedures or additions to existing procedures.

- Step 2: Select a consultant. When selecting a consultant consider the following:

- Experience with implementing quality systems

- Experience in working with the same size organizations

- Good communication skills

- General availability to perform assignments and follow-up

- Step 3: Develop a plan. The gap analysis will enable you to develop a plan for implementing the necessary changes to the quality system. If you have chosen to use a consultant to

perform the gap analysis, you may want to use his expertise to assist you with developing this plan. The plan should include specific tasks that need to be completed; for example, reformatting and editing the quality manual to coincide with the new standard. Here are a few points to consider in establishing this plan:

- Reformatting and editing the quality manual

- Identifying specific tasks to address the gaps highlighted in the gap analysis

- Creating specific procedures that require changes

- Assigning responsibility for the tasks and the expected completion date

- Step 4: Implement the plan. Implementation of the new quality system includes:

- Approve and release the new procedures
- Conduct employee training
- Establish effective date of new procedures
- Schedule assessment dates to upgrade the quality system certification
- Conduct internal quality audits

To assist the implementation of one quality system that will meet multiple quality system standards (for example, the QSR, ISO 13485:2003 and ISO 9001:2000), table 2 is provided. The chart is constructed to help concentrate quality system modification efforts by tailoring individual company procedures to one standard and regulation and then making adjustments to comply with specific aspects of the other standards. The “X” denotes the standard

**Table 2**

ELEMENT	ISO 13485:2003	FDA QSR	ISO 13485:1996	ISO 9001:2000
Quality Manual	Z		X	X
Quality Policy	Y	X	Y	Y
Procedures	Z	X	Y	Y
Quality Planning	Z	X	Y	Y
Quality Records		X		
Competence, Awareness & Training	Y	X		Y
Infrastructure		X		
Work Environment	Y	X		
Risk Management	Y	X		Y
Customer Communications	Z	X		Z
Design Control Process	Y	X		
Purchasing Controls	Y	X		
Production	Y	X		
Servicing	Y	X		
Feedback (Customer & Regulatory)	Y	X		
Internal Audits	Y	X		
Process Control	Y	X		
Analysis of Data	Y	X		
Corrective Actions		X		
Preventative Actions		X		

Table 3

<b>ABC COMPANY</b>	<b>XYZ COMPANY</b>
<ul style="list-style-type: none"> <li>• Medical device manufacturer</li> <li>• Markets: Canada, USA, Europe &amp; Australia</li> <li>• FDA classification: Class II; Canadian classification: Class II; European classification: Class IIa; approved or cleared to market their products in all of its markets.</li> <li>• Current certification: ISO 9001:1994 &amp; ISO 13485:1996; also complies with 21 CFR 820, 803, 806 &amp; Part 11; The registrar is a notified body for Europe but is not recognized by Canada.</li> </ul>	<ul style="list-style-type: none"> <li>• Contract manufacturer of commercial non-medical products and medical devices</li> <li>• Markets: Canada, USA, Europe &amp; Australia</li> <li>• Medical device classifications: FDA classification: Class II; Canadian classification: Class II; European classification: Class IIa; client's devices are approved or cleared for marketing in all of its markets.</li> <li>• Commercial non-medical products: internal research shows that the non-medical market requires ISO 9001:2000 certification.</li> <li>• Current certification: ISO 9001:1994 &amp; ISO 13488:1996 for MDD; quality system also complies with 21 CFR 820, 803, 806 &amp; Part 11; the registrar is a notified body for Europe and recognized by Canada to meet the Canadian Medical Device Regulations (CMDR) requirements.</li> </ul>
<b>FIRST STEPS</b>	<b>FIRST STEPS</b>
<p>First Steps (Ensure continued marketing in Canada)</p> <ul style="list-style-type: none"> <li>—Make the necessary changes to the quality system to meet the Canadian Medical Device Regulations (CMDR)</li> <li>—Change the registrar to a notified body that is recognized for by Canada and Europe</li> <li>—Schedule an assessment for certification for CMDR</li> <li>—Ensure that the current quality system certification includes both Canada and Europe</li> </ul>	<p>First Steps (Ensure continued marketing in Canada and commercial product certification)</p> <ul style="list-style-type: none"> <li>—Maintain registrar for both Canada and Europe</li> <li>—Schedule an assessment for ISO 9001:2000 certification and CAN/CSA ISO 13488:1998 for CMDR certification; ISO 9001:2000 for commercial products; CAN/CSA ISO 13488 CMDR for medical products</li> <li>—Ensure that current quality system certification includes both Europe and Canada for both the commercial products and medical products</li> </ul>
<b>SECOND STEPS</b>	<b>SECOND STEPS</b>
<p>Second Steps (Ensure quality system certification into the future)</p> <ul style="list-style-type: none"> <li>—Make the necessary changes to the quality system to meet the new ISO 13485:2003</li> <li>—Implement risk management into your quality system per EN ISO 14971 (while watching for the GHTF's guidance on implementing risk management into a quality system)</li> <li>—Ensure the notified body is approved to certify to ISO 13485:2003 in Canada &amp; Europe</li> <li>—Schedule assessment for the change in certification during the normally scheduled 2004 audit; certification should be: ISO 13485:2003, MDD &amp; CMDR</li> <li>—Maintain certification</li> </ul>	<p>Second Steps (Ensure quality system certification into the future)</p> <ul style="list-style-type: none"> <li>—Make the necessary changes to the quality system to meet the new ISO 13485:2003</li> <li>—Implement risk management into quality system per EN ISO 14971 (while watching for the GHTF's guidance on implementing risk management into a quality system)</li> <li>—Ensure the notified body is approved to certify to ISO 13485:2003 in Canada &amp; Europe</li> <li>—Schedule assessment for the change in certification during the normally scheduled 2004 audit: medical product certification should be updated to ISO 13485:2003, MDD &amp; CMDR</li> <li>—Maintain the following certifications; ISO 9001:2000 for commercial products; ISO 13485:2003 – MDD &amp; CMDR for medical products</li> </ul>

to use when writing or editing specific procedures or the quality manual. The “Y” denotes the standard to use to add additional requirements that were not defined in the “X” denoted standard and regulation. The “Z” denotes an update that is required based on the new standard; therefore, the “X” edited element is updated using the requirements in the new standard.

Implementing a quality system that meets the needs of various global markets can be tricky and requires strategic planning. Tables 3 presents scenarios intended to help you construct the necessary content of your strategic plan. Understand that the scenarios represent only one approach and other possibilities exist.

The two scenarios present two dif-

ferent companies. One is a medical device manufacturer that designs, manufactures, installs and services the products. The second is a contract manufacturer that manufactures and services the products.

The two scenarios are offered to illustrate how a company's situation and objectives can impact the selection and implementation of a particular quality strategy, including the implementation of ISO 13485:2003. Understanding the right questions to ask is often the only way to find the best regulatory path. In addition, knowing where you are trying to go (i.e., market) is critical in determining the best compliance route. Selecting the most efficient strategy and implementation plan requires thorough analysis and assessment.

A company's quality system affects every aspect of its operations on a daily basis and is something that must be constantly maintained to ensure compliance. Using trained and knowledgeable employees or consultants will ideally provide not only the quickest path but also the most effective one to quality system compliance. ISO 13485:2003 brings the concept of global harmonization nearer to realization but not completely.

With most companies, compliance with a variety of quality systems simultaneously, including QSR and ISO 13485:2003, is very achievable and highly desirable. ISO 13485:2003 is similar in many aspects to QSR but not identical. These differences need to be considered when compliance to both quality systems is desired.

One major change from ISO 13485:1996 is transitioning from a procedural quality system to a process one. Another important aspect of ISO 13485:2003 is the inclusion of risk management throughout the quality system process, thus providing for a risk-based approach for determining a level of rigor when implementing the standards. For these reasons ISO 13485:2003 is a friend and not a foe!

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