

Regulatory Update:

ISO 13485:2003

- **How can you reduce costs while satisfying ISO 13485:2003 and MDD requirements?**
- **What do you need to bridge the “Quality System Gap” between 13485:1996 and 13485:2003?**
- **Will complications with MDD harmonization affect your transition strategy?**
- **Is your ISO Registrar prepared to meet the challenge?**
- **What is the single most-important tactic for lower consultant fees?**

Valuable Guidance for Complex Regulatory Questions

Right now, medical technology companies in the U.S. are attempting to untangle the relationship between three separate quality system standards: ISO 13485, ISO 9001:2000, and 21 CFR part 820. How are these requirements similar? Where do they differ? Can one quality system be designed that satisfies all three? How does the proposed 2003 revision of ISO 13485 affect the equation? Thanks to his experiences on the ISO/TC 210 Working Group, as a QA consultant, and as a 35-year industry veteran, Ed Kimmelman believes he has the answers. Recently, Kimmelman used his insights and experience to develop a comprehensive, 80-page QS Matrix that definitively maps out the correspondences (and differences) between ISO 13485:2003, ISO 9001:2000, and 21 CFR part 820 (QS Matrix is available for free download at www.medical-language.com. A password is required. Please send your email request to mmiller@crimsonlanguage.com and include “QS Matrix” in the subject line).

While the QS Matrix provides a blueprint for a quality system to satisfy all three standards, two important charts, contained in Annex A of ISO 13485:2003, illustrate the differences between the 1996 and the 2003 versions of the standards. Armed with this valuable information, you will be ready to create your own 13485 “Gap Analysis” and begin the required transition effort

Three Important Standards, One Big Difference

According to Kimmelman, ISO 13485:2003, the new quality standard for medical devices that is scheduled for publication next year, shares many similarities with ISO 9001:2000. In fact, he notes that as much as 80% of the requirements text of 13485:2003 is quoted directly from 9001:2000. In particular, Kimmelman points out that 13485:2003 and 9001:2000 share the key “process model” approach to quality system structure. As it happens, the “process model” is also the biggest single difference between 13485:1996 and the new 2003 version of the standard.

What Three Elements Do You Need to Bridge the Standards Gap?

Effectively addressing the changeover from 13485:1996 to the new 2003 standard involves:

- A comprehensive “gap analysis” of your existing quality system and how it maps to the newly mandated process approach.
- Evaluation of your registrar: can they adequately support your transition to the new standard?
- A transition strategy that accounts for MDD harmonization – especially if you are selling (or expect to) in Europe.

Audit Your Registrar? Three Important Reasons Why

The second key element for effective transition to the new standard is a registrar that is equipped with the necessary resources and capabilities. A process audit differs substantially from a traditional “checklist” audit – your registrar’s experience (or lack of it) will directly impact their ability to assist you through the 13485 transition.

Interviews and information from:

Edward R. Kimmelman, JD

Regulatory consultant, past President of National Committee for Clinical Laboratory Standards, former Chairman of HIMA (now AdvaMed) Standards Section and Science and Technology Section, convener of the ISO/TC 210 Working Group 1 on Quality Systems.

Marc H. Miller, MBA

CEO of Crimson Medical Translation (ISO 9001:2000 certified language translation, graphic design, layout, and formatting for medical technology companies), former Sr. Research Fellow with S.I.A.R. (international strategy consultant / medical technology industries)

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Transition to 13485:2003 Opportunities for Cost-Saving And Increased Effectiveness

Some consultants recommend auditing your registrar in order to assess their familiarity with the new process approach. “Registrars are an important supplier”, noted Kimmelman in a recent interview, “and, like other suppliers, they are subject to audit to determine their capabilities. You should also remember that since they are a supplier, you have an obligation to help bring them up to speed, if they require it and you are able”. With over 50 U.S. registrars listed in the RAB database, there *is* the potential for variance in resources and experience.

Bottom line: if your registrar is not current on the process audit style mandated by the 13485:2003 standard, you have three choices: educate them yourself, run the risk of being out of compliance if they do not possess the required resources and training, or find a new registrar.

MDD Harmonization: Will it Affect Your Transition Strategy?

A key consideration for companies that sell into Europe is the relationship between the new 13485 standard and the MDD. The 1996 standard took five years to harmonize and, even though the 2003 standard is *supposed* to move more quickly, at least three EU countries (Switzerland, France, and Germany) have initially voted against adoption of the DIS version. For this reason, Kimmelman suggests that you immediately certify (or re-certify) to the 1996 standard – this effectively provides you with a three-year transition window. Next, prepare a Gap Analysis “to-do” list (using his free QS Matrix) and begin working with your registrar to transition to the new 2003 standard.

In addition to the MDD and the EU market, important Asian markets are also taking notice of 13485:2003. In Japan, adoption of the

13485:2003 quality system approach (vs. GMP) is currently under discussion. China has also expressed significant interest – going so far as to host a TC 210 working session.

Convert Your “Requirements” into “Opportunities”

No matter what other quality system changes you do (or do not) implement, you will be required to rewrite your quality system documentation in “process approach” terms. And, since you are already going through the exercise of rewriting your documentation, you should make the most of this excellent opportunity to examine your processes for potential cost-savings (it’s also a good time to do any QS “housecleaning” and implement outstanding CAPAs).

At this point, you may want to give yourself the best chance at maximum cost-savings by bringing in a consultant for a fresh perspective on your processes. Often, cost savings from targeted improvements can more than cover the required consulting investment.

Senior-level consultants like Kimmelman are clearly most effective for high-level strategy or other project management work. However, not every task (or company) requires a 35-year veteran. Assuming that they can demonstrate a strong familiarity with the process model, a consultant like Nicolle Caserma of Critical Path (Quality Engineer and ISO Management Rep, www.criticalpathconsultants.com) can successfully execute many of your 13485 transition requirements.

Focus on Contract Terms for Lower Consulting Fees

When negotiating consulting contracts for your 13485 transition assignments, you should consider a single item that can dramatically lower your consulting fees – so

says Critical Path’s Caserma. She suggests “fixed price” consultant contracts whenever possible. By writing contracts in fixed-price terms, you can avoid the pricing risk that is inherent in open-ended “time and materials” professional services contracts.

Other Opportunities for Cost-Saving and Increased Effectiveness

When re-evaluating your quality system processes, auditors recommend starting with your vendor audit program and list of approved vendors.

Since the time and expense required to audit outsourced vendors can be substantial, these costs can often be reduced or eliminated by working with vendors that have been certified to an existing quality standard such as ISO 9001:2000. By insisting on ISO certification as a precondition of supply, you can reduce costs while ensuring yourself of high-quality products and services.

In fact, many companies that cater to the medtech industries have already certified to the new ISO quality standard, 9001:2000. These tend to be companies with a specialized medical focus. In one unique case, Crimson Medical Translation – a language translation company – utilized a medical QA consultant and specialized medical auditor to design and certify its quality system. Although industry commitment like this is rare, it still pays to closely examine your vendor list for opportunities to reduce audit costs through ISO certification requirements.

How Can You Satisfy ISO 13485, MDD Requirements And Reduce Costs?

As previously noted, transition to 13485:2003 is a good time to implement outstanding CAPAs and examine your processes for efficiency and cost-saving opportunities.

For instance, language translation services are one area where small process changes and clearly-defined vendor qualifications can add up to big savings.

Free Legal Guidance for Language Requirements

Before implementing cost-saving changes, take the time to familiarize yourself with the relevant regulatory requirements. ISO 13485:2003 requires you to maintain strict control over your important outsourced services such as translation. Additionally, guidance on the MDD requires “procedures for ensuring accurate translation of e.g. labeling, instructions for use and product claims in marketing material. These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation” (NB-MED/2.5.2/Rec3). Additional information can be found in a legal memorandum that was commissioned by Crimson Medical Translation. Drafted by the law firm of McKenna & Cuneo, Crimson’s memo provides specific guidance on MDD language requirements (available for free download from Crimson’s website: www.medical-language.com).

Certification Requirements for Translation Vendors

Next, your vendor selection process should specify ISO certification. Auditors agree that the easiest path to demonstrate necessary control of your outsourced processes is to work with vendors that have been certified to the new ISO 9001:2000 standard. This, in turn, can reduce the amount of audit overhead that you incur. In effect, the certification saves

you money by ensuring consistent quality without having to validate each and every incoming translation.



Crimson has received ISO 9001:2000 certification for a specialized medical translation quality system

While ISO certification in general is helpful, certification to the new 9001:2000 standard is best. ISO 9001:2000 is closest in scope to 13485:2003 (in fact, 80% of 13485:2003 is quoted directly from 9001:2000). This ensures that your translation provider will be familiar with your quality system requirements.

Ideally, you should also work with a firm whose quality system has been specifically designed for medical translation. This guarantees that their processes are sufficient to handle complex 12-language projects, including layout and formatting, if necessary.

Finally, you should ask your provider for reference letters or recommendations from other medical technology companies. This will

provide you with important “proof of performance”.

Three Requirements for Quality and Cost-saving

Besides ISO certification and medical specialization, there are three key requirements that can substantially lower translation costs and improve quality.

1. *Language Capital Database* – translation memory tools enable you to capture and re-use previously translated material. This has the twin benefit of reducing translation costs while improving consistency and quality.
2. *Linguistic QA* – the standard translation/edit steps are insufficient when translating complex medical material. Crimson invented a third, proprietary QA step (Back-editing) in order to provide 100% translation verification.
3. *Integrated Formatting Services* – make certain that your vendor has in-house desktop publishing resources and is familiar with the formatting issues typically associated with multilingual documents. To maximize cost savings, be certain that your vendor is familiar with the interaction between formatting and translation memory.



Marc H. Miller is CEO of Crimson Medical Translation. The company’s San Francisco office recently received ISO 9001:2000 certification for a specialized medical translation Quality System

Valuable MDD, IVD, ISO, and Other Regulatory Resources Available at www.medical-language.com

Sometimes the toughest part of your job as a Regulatory Affairs professional is finding the right information.

Fortunately, there is now a website that can help – free of charge. Valuable, hard-to-find items located at www.medical-language.com include an IFU Labeling Symbols Library, IVD Danger Phrase

Translations, EU Language Requirements, Notified Body Audit Secrets and an authoritative QS Matrix from 35-year industry veteran, Ed Kimmelman.

A password is required to access the information. Password requests can be emailed to mmiller@crimsonlanguage.com.

Free Online Library of 350 Labeling Symbols

In order to create their professionally designed electronic library of 350 labeling symbols (63 different families representing 83 discreet meanings), Crimson Medical Translation invested hundreds of hours of research and development. The symbols are font-free vector graphics, available for download in Mac or PC format. Importantly, the Crimson library already includes many of the non-harmonized symbols contained in the new, soon-to-be-published, EN 980 standard. Current EN 980 symbols have been validated by E.U. Notified Body, KEMA (www.krqusa.com).

196 Must-Have IVD Danger-Phrase Translations

Based on a published E.U. Directive (67/548/EEC), Crimson's IVD Danger-Phrase translations are another valuable resource available on the www.medical-language.com website. The IVDD deadline is

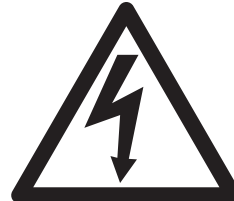
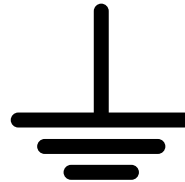
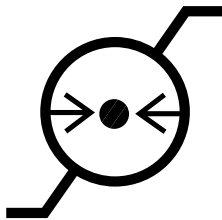
McKenna & Cuneo provides definitive guidance for MDD language requirements. The memo, commissioned by Crimson Medical Translation, includes a discussion of the Regulatory Framework, Labeling Requirements, National Implementing Legislation, and specific penalties for non-compliance.

Secrets of an E.U. Notified Body

Also available on the Crimson website is the inaugural edition of *International Compliance Report*. The first issue features an interview with Dr. Jeff Schakenraad, head of KEMA's Western U.S. Notified Body Division. Crimson's newsletter details the little-known, but critical, differences between "Process Audit with Partnership" and traditional "Compliance" audit for CE Marking. This little-known difference in Notified Body audit style can save you tens of thousands of dollars.

Quality System Matrix Untangles Relationship between ISO 13485:2003, ISO 9001:2000, and 21 CFR part 820

The newest addition to Crimson's collected online resources is Ed Kimmelman's QS Matrix. This valuable resource gives you the information you need to design a single quality system to satisfy the requirements of ISO 13485:2003, ISO 9001:2000, and 21 CFR part 820.



scheduled for Dec. 7, 2003 and many companies have not implemented all of the necessary requirements – including language and labeling – to satisfy the Directive.

Legal Guidance for E.U. Language Requirements

Authored by industry veteran Larry Pilot, this legal memorandum from the law firm of