

## Resource Corner

### Valuable ISO, MDD, IVD, and Other Regulatory Resources Available now at [www.medical-language.com](http://www.medical-language.com)

During the past year, over 1,000 RA/QA professionals have requested a password for the Crimson Medical Translation website ([www.medical-language.com](http://www.medical-language.com)). Industry leaders such as Johnson & Johnson, C.R. Bard, Medtronic, Genzyme, Eli Lilly, Beckman Coulter, Siemens Medical, Bayer, Medrad, and Axis-Shield have all accessed the regulatory information posted on the Crimson website. Why? Because in this one location you can find free resources like Crimson's IFU Labeling Symbols Library, ISO Quality System Matrix, Vendor Outsourcing Guidance, Legal Guidance for EU Language Requirements, and much more.

These valuable, hard-to-find resources have been produced in association with Notified Bodies, ISO registrars, and RA/QA consultants. They provide you with critical support to help you do your job more effectively.

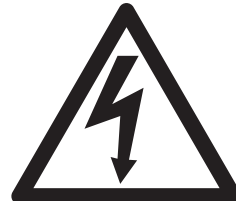
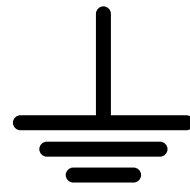
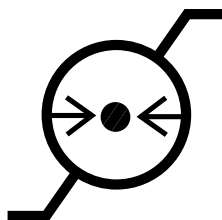
A password is required to access the information. Password requests can be emailed to [mmiller@crimsonlanguage.com](mailto:mmiller@crimsonlanguage.com).

#### 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 EN 980 standard. Current EN 980 symbols have been validated by E.U. Notified Body, KEMA ([www.krqusa.com](http://www.krqusa.com)).

contains interviews and information from Steve Dunning (30-year industry veteran, Manager of KEMA's Western Region) and Nicolle Caserma (RA consultant). The research covers topics such as:



- How do ISO 13485 and ISO 14971 relate to your vendor outsourcing program?
- How does Health Canada (CMDCAS) determine "Critical Vendors"?
- How can you effectively audit vendors in the absence of qualified internal resources?
- How can you avoid the most common vendor risk management mistake?

#### 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.

#### Vendor Outsourcing Under ISO 13485 & ISO 14971

Crimson surveyed over 500 RA/QA professionals to identify the top three regulatory issues currently affecting the industry: ISO 13485:2003, ISO 14971:2000, and product/service outsourcing.

As a next step, the company interviewed regulators and industry insiders to provide guidance on these critical issues. Crimson's "Regulatory Update: Vendor Outsourcing, ISO 13485:2003, and ISO 14971:2000"

## Regulatory Update:

### THE 3 MOST IMPORTANT ISSUES FACING RA/QA TODAY:

#### — VENDOR OUTSOURCING

#### — ISO 13485:2003

#### — ISO 14971:2000

- How can you make the best use of your scarce audit resources?
- How does Health Canada define a "critical vendor"?
- What are the 3 things you can do to avoid the most common vendor risk management mistake?
- Learn how to position vendors according to product and business risk factors

"Companies are really looking to lower their production costs..."

- Bill Gaffney, UTI (MD&DI Guide to Outsourcing, March, 2003)

The medical industry's drive to lower production costs is having a profound effect on the product and service outsourcing business. The effect is underscored by a double-digit annual growth rate and is illustrated by new publications such as *Medical Product Outsourcing* (launched in May, 2003). Although powerful economic forces are driving the move to outsourcing, companies are still faced with stringent regulatory requirements. The situation is further complicated by the fact that industry is in the process of digesting the two standards that will largely govern outsourcing: ISO 13485:2003 (quality systems) and ISO 14971:2000 (risk management). Understanding their implications is key to creating a program that will hold up under the scrutiny of your ISO Registrar or Notified Body.

#### Understanding the Standards

The newest version of ISO 13485 was officially adopted this year. Largely identical to ISO 9001:2000, the newest version of ISO 13485 emphasizes process audit – a change from the previous standard and one that has important implications for outsourcing. A QS Matrix that definitively maps out the correspondences between ISO 13485:2003, ISO 9001:2000, and 21 CFR part 820 is available for free download at [www.medical-language.com](http://www.medical-language.com). A password is required. Please send your email request to [mmiller@crimsonlanguage.com](mailto:mmiller@crimsonlanguage.com) and include "QS Matrix" in the subject line.

ISO 13485:2003 specifically addresses the responsibility of the outsourcing organization when it states:

*The processes required by this International Standard, which are applicable to the medical device(s) [and IVDs], but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organizations quality management system.*

In other words, outsourced processes are governed by the same standards that govern the quality system of the manufacturer, including validation, audit – and risk management. It is accepted that risk management principles can be applied to the use as well as the manufacture of a medical device or IVD. Therefore, the definition of risk, as provided by the standard, is useful in analyzing the two outsource-manufacture-related risks:

- a) the probability of the occurrence of harm, that is, how often the harm may occur
- b) the consequences of that harm, that is, how severe it might be

KEMA, the well-known Dutch registrar, pioneered the concept of process audit some 16 years ago. Since then, the company's approach has been thoroughly validated and is now the official audit approach under ISO 13485:2003. As head of KEMA's Western Region office, Steve Dunning has earned valuable insights into audit, risk management, and product outsourcing. Says Dunning, "13485 states that you are ultimately responsible for your outsourced processes. Since these processes are governed by a company's quality system, they are subject to risk management assessment." Dunning goes on to explain, "Outsourcing is probably the best example of how product risk and business risk intersect. Our clients want to know how to effectively maintain control of outsourced processes [product risk] within acceptable financial limits [business risk]". The nettlesome issue of scarce financial resources vs. regulatory requirements can be especially acute when it comes to structuring an effective vendor audit program. Fortunately, there are a number of strategies, tools, and techniques that can help.

Interviews and information from:

#### Steve Dunning, JD

Manager, Western Region for KEMA-Registered Quality (over 11 years), IRCA, RAB Accredited Lead Auditor (ISO 9001, ISO 14001), CMDCAS Certified Lead Auditor ISO 13485, former Sr. Engineer with Dow Chemical and CD Medical, Inc..

#### 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 firm / medical technology industries)

#### Nicolle Caserma

Head of Critical Path (regulatory consulting for ISO 9001:2000, ISO 9001:1994, ISO 13485, EN 46001, MDD 93/42/EEC Annex II, and 21CFR Part 820), former Sr. Quality Engineer and ISO Management Representative

# Outsourcing Under ISO 13485:2003 & ISO 14971:2000

## Design an audit program that makes best use of your resources

Given that a typical medical manufacturer may have over 100 vendors in their “approved” database, how can you design an audit program that makes the best use of your scarce resources? Nicolle Caserma of Critical Path Consultants (RA/QA Consultants) has developed a *Vendor Risk Management Grid* and guidance document to help companies map an appropriate audit strategy (Vendor Grid is available for free download at [www.medical-language.com](http://www.medical-language.com). A password is required. Please send your email request to [mmiller@crimsonlanguage.com](mailto:mmiller@crimsonlanguage.com)).

Says Caserma, “The Vendor Grid is an analytical tool that helps you to position vendors based on two criteria: inherent product/service risk and purchase volume. The point is, vendors who provide critical components that represent high dollar outlays for the company require increased scrutiny.”

Dunning agrees, “ISO 13485 requires you to have documented systems for vendor management where appropriate – but first you have to perform some type of risk assessment to determine what’s ‘appropriate’. An analysis such as the Vendor Grid is valuable because it makes the relationship between product/process risk and business risk explicit.”

## Who does Health Canada consider a “Critical Vendor”?

Notes Dunning, “There is important Notified Body guidance on the subject [who should be considered a critical vendor] that is currently being used in Canada’s CMDCAS audits”. The Notified Body guidance document is available for free download at [www.medical-language.com](http://www.medical-language.com). A password is required. Please send your email request to [mmiller@crimsonlanguage.com](mailto:mmiller@crimsonlanguage.com)

## How do you effectively audit vendors in the absence of qualified internal resources?

After segmenting your vendor list to determine relative priorities, the next step is determining audit requirements. This can be another problem area. According to one major Silicon Valley device manufacturer, “Our challenge is that we have a large number of vendors, but we don’t have the internal competence to audit them all.”

Caserma notes that this is a common problem. “Most companies have at least 3-5 major vendor categories. Very few manufacturers have the necessary resources to audit in all of these areas.”

As a solution, both Dunning and Caserma recommend outsourcing your vendor audits. Although using outsourcing in one area to solve another outsourcing problem may seem counter-intuitive, there are distinct advantages.

Explains Dunning, “The shift to process audit, required as part of 13485:2003, means that even fewer people are really qualified to perform this work. And when you add the wide variety of vendors to be audited – no one company can effectively manage it all”. When qualifying resources for vendor audit, Dunning recommends screening for subject-area expertise and process audit experience.

## What is the optimal structure for outsourced audits?

Dunning recommends a structured approach to get the most from outsourced vendor audits:

- *Consulting phase* – The prospective auditor must thoroughly understand the company’s outsourcing objectives. As in any professional services engagement, personal chemistry and appropriate credentials are vital.

- *Audit phase* – The audit phase should focus on validating the vendor’s processes and identifying key evidence for on-going monitoring.

- *Monitoring phase* – The final phase focuses on establishing mechanisms for information flows back to the company. Contrary, in many cases, to current practice, Dunning does not recommend routine audit as a monitoring method: “On-going information flows are the most useful, the most cost effective, and provide the most insight into the vendor’s processes.”

## What is the most common vendor risk management mistake – and how can you avoid it?

Of all the risk management strategies employed by manufacturers, Dunning says that the most effective, and perhaps the most overlooked, are professional agreements, contracts, and statements of work: “Many companies make the very simple mistake of not clearly defining requirements for their outsourced vendors.”

Dunning describes casual business agreements and vague work statements as the most common culprits leading to poor vendor outcomes. “Generally, QA/RA needs to do a better job of managing business relationships with suppliers,” he says pointedly. Dunning has three simple steps for improvement:

- 1.) Clearly define the scope of work. This can be done in conjunction with your outsource audit partner.
- 2.) Make certain that deadlines – delivery or cycle times – are explicitly stated, and that a clear change order mechanism exists.

- 3.) Demand evidence of performance. For critical vendors, certification may not necessarily be enough to guard against process fraud.

Dunning cautions against leaving vendor business relationships solely in the hands of the financial function. “Purchasing generally has better controls in place for vendor management. However, these controls often focus solely on price. It is up to QA/RA to set the appropriate quality and timing requirements – clearly, quality trumps cost when it comes to vendors that handle high-risk products and services.”

## Reconnecting your business with ISO 13485:2003

As a veteran ISO Registrar, KEMA’s Dunning has an extremely broad and well-informed perspective on medical manufacturers. What he sees is an enormous opportunity for companies to use the framework of ISO 13485 to enhance their business function – a process that he terms “reconnecting the organization”.

Explains Dunning, “Medical technology companies are largely product-focused, which is a natural result of their engineering orientation. However, there is a tremendous opportunity for companies to use quality

systems like 13485 or 9001 as the basis of their entire business management system.”

“All of these techniques that we’re using to improve product quality can also be used to enhance business performance,” he continued. “For example, I see our electronics industry clients moving in this direction – using ISO quality standards as the basis of their product processes and their business processes.”

Assuming this is the case, the skill set of highly trained RA/QA professionals will become more and more interesting to top management. And, given the demonstrated connection between quality and profitability, top management can realize tangible benefits from RA/QA experience.

# Risk Management: Professional Service Vendors

Given the growing importance of outsourcing, vendor risk management has also grown in importance. Analytical tools, such as Nicolle Caserma’s Vendor Risk Management Grid, can help you identify priorities and make smart allocations of time and resources.

Quadrant IV of Caserma’s Grid contains vendors that provide critical services (as defined by NB-MED/2.5.2/Rec1 – available for download at [www.medical-language.com](http://www.medical-language.com)), but represent relatively lower purchase volumes. Interestingly, professional services firms often fall into this vendor category. If we include vendors for both product and business processes (as suggested by Steve Dunning of KEMA), we notice that law firms and accounting firms fall into this category, along with more traditional, product-related vendors, such as language translation firms.

One unique feature of many professional service firms is that the quality of their work is difficult for a layman to determine. Accountants and attorneys provide tangible work product in the form of documents, but how to judge if they were produced accurately? Translation offers the same challenge: unless you are fluent in both source and target languages it is impossible to form an opinion as to quality.

Dunning’s advice regarding business agreements for outsourced vendors is particularly relevant for professional services firms: “Demand evidence of performance. For critical vendors, certification may not necessarily be enough to guard against process fraud.”

Even if you are provided with a translation certification (“they have limited value”, according to Dunning), you are basically accepting the vendor’s word that all required tasks were performed as specified – a sometimes-risky assumption.

A better approach, as outlined by Dunning, is first to develop a project scope, complete with quality requirements. Crimson recognized that the common translation-edit-proofreading process was inadequate for the stringent quality requirements of technical medical translation. Our process adds a proprietary linguistic QA step, termed BackEditing™, that checks for semantic accuracy. Evaluation (according to the translation quality metric SAE J2450) demonstrates that, on average, BackEditing™ eliminates one serious error every third page and two minor errors on every page (a serious error is one that may result in patient harm).

Of equal importance is proof of performance. As an ISO 9001:2000 certified facility, Crimson can provide clients with a “Process Validation Form” – a document that explicitly indicates and provides sign-off for each specified process step. This ensures that each required step is faithfully carried out and helps to guard against process fraud.

Crimson also provides clients and prospective clients with a “Risk Management Kit for CE Labeling” on its website ([www.medical-language.com](http://www.medical-language.com)). The Kit contains not only a sample Process Validation Form (can be used with any translation provider), but also a translation SOP and guidance document authored by Critical Path Consultants.



Marc H. Miller is CEO of Crimson Medical Translation. Crimson is the only translation company to receive ISO 9001:2000 certification for a specialized Medical Translation Quality System.