

# Risk Management for Service Outsourcing

## As in Manufacturing, Ensuring the Reliability of Contracted Services Requires Clients to Diligently Check Qualifications, Conduct Audits

Outsourcing's growing importance in medical device manufacturing is illustrated by double-digit growth. The primary rationale for outsourcing is, of course, substantial economic bene-



fits. However, the outsourcing trend also raises important risk management issues for medical technology manufacturers.

in an effective risk management program. Compliance risk for outsourced vendors can be mitigated through a combination vendor qualification, audit and process documentation. Liability risk, on the other hand, is based on the likelihood and severity of an adverse event resulting from the use of an outsourced product or service. Similarly, liability risk can be mitigated by demonstrating "reasonable care and consideration" in vendor qualification, audit and process documentation.

Moreover, outsourced service providers present companies with special risk management challenges, especially in the case of professional services. Certification to a recognized quality standard such as ISO 9001:2000 is rare. The systems and processes of service firms are often undocumented or ill-defined, making them difficult to audit. The average purchaser does not have the specialized knowledge to perform a qualified inspection of the finished service product. Perhaps most worrisome, services are intangible and therefore liable to "process fraud"—failure to perform the required process steps.

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- Regulatory risk
- Liability risk

Regulatory risk is based on compliance (or lack thereof) with the two standards that govern product and service outsourcing: ISO 13485:2003 (quality systems) and ISO 14971:2000 (risk management). Companies have specific outsourcing obligations under these two standards, and understanding their requirements is the first step

Because "services" encompass a variety of firms engaged in a wide range of activities, it is important to clearly define regulatory requirements and service type. Not all of a manufacturer's outsourced service activities necessarily lead to regulatory or liability risk. Familiarity with the requirements for outsourced services is the first step to effective risk management.

Steve Dunning, the head of the western regional office for KEMA in



Marc H. Miller  
Crimson Medical  
Translation

the U.S., the well-known Dutch ISO registrar and notified body, cautioned that medical technology companies can't blindly turn over their services to outside vendors.

"ISO 13485 requires medical technology companies to maintain strict control over important outsourced services. In cases where service output cannot be easily verified by subsequent monitoring or inspection, the service process itself must be validated and, if necessary, supervised and controlled," Mr. Dunning said.

### Two Key Issues

The manufacturer's obligation to validate service processes is clear, but how do you determine whether an outsourced service qualifies as important? Notified body guidance, currently used by Health Canada in its CMD-CAS audits, offers some assistance:

"The two main issues a notified body should address when reviewing subcontractors are:

- Whether the subcontractor has a substantial involvement with the design and/or production of the device.
- Whether the subcontractor is undertaking the supply of a part, material or service, which may affect the compliance of the device with the essential requirements."

Therefore, a service provider's substantial involvement with design or production or its effect on compliance with essential requirements (the Medical Device Directive or the In-vitro Diagnostics Directive) is what determines relative importance. From a liability point of view, the service's proximity to a potential adverse event is what determines relative importance. Examples of important service providers include design firms, translation providers, QA consultants and contract audit providers.

In general, risk management for important service providers rests on vendor qualification, audit and

process documentation. However, considering the wide variety of service providers, "how to" risk management guidelines can be extremely valuable. The following are examples of risk management strategies for two

important service provider types: contract audit providers and language (labeling) translation providers.

The newly adopted ISO 13485:2003 differs most significantly from its predecessor in its changeover to a

## Services Risk Management

“process audit” model. Ironically, the new emphasis on process audit means that although companies are still responsible for vendor audits, most do not have the necessary audit skills in-house. This, in turn, creates a need

Nicolle Caserma, head of RA/QA consulting firm Critical Path ([www.criticalpathconsultants.com](http://www.criticalpathconsultants.com)), pointed out that this is a common problem. “Most companies have at least three to five major vendor cate-

culties. These reasons, along with cost transparency, have driven many medical technology firms to outsource their language translation requirements.

### A Crucial Checklist

The first step for effective risk management is qualification. For audit and translation service providers, qualification should include:

- **Specialization:** Providers of outsourced audit services should have demonstrable, specialized expertise in process audit methods and techniques. They should also have specialized knowledge of the type of supplier that they are auditing.

Translation service providers must be specialized in medical translation. They must have a documented system for recruiting, screening, testing and auditing medically specialized translation resources.

- **Certification/Documentation:** Outsourced audit providers may have certification to a quality standard such as ISO 9001:2000; they should also hold ASQ, RAPS or RAB audit certifications.

Translation providers should be certified to ISO 9001:2000. Their quality system documentation should contain a vendor Selection Maintenance and Audit (SMA) for medical translation, a process for linguistic QA like the one provided by the Society for Automotive Engineers (standard J2450) and standardized file management and directory structures to guard against handoff errors.

- **References:** Documented letters of references provide important evidence of past performance. As such they also serve as an initial risk management background for the service provider.

Services vendors are notoriously difficult to audit. Although working with a vendor certified to a quality standard such as ISO 9001:2000 is the easiest path—you can effectively rely on the

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*—Steve Dunning, KEMA*

for outsourced audit services—consultants who are thoroughly familiar with the target vendor’s processes and the unique requirements of process auditing.

“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,” added Dunning, who is based in Lafayette, CA.

A major Silicon Valley device manufacturer recently was overheard saying “Our challenge is that we have a large number of vendors, but we don’t have the internal competence to audit them all.”

gories, and very few manufacturers have the necessary resources to audit in all of these areas.”

Both Dunning and Caserma recommend outsourced vendor audits as a solution. Although outsourcing in one area to solve another outsourcing problem may seem counter-intuitive, there is a distinct advantage. A well-structured audit means that a qualified (process audit) resource can evaluate a subject area with which they are familiar.

Large device manufacturers occasionally maintain in-house translation resources. However, production staff that deal with these internal translation resources can experience turnaround and responsiveness diffi-

### What is the optimal structure for outsourced audits?

Steve Dunning, who heads up KEMA's western regional office in the U.S., 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 to current practice, Dunning does not recommend routine audit as a monitoring method in many cases.

"Ongoing information flows are the most useful, the most cost effective, and provide the most insight into your vendor's processes," he said. Instead, a more effective practice might be continuous monitoring of several key metrics, including real-time updates that can be achieved through software. Continuous monitoring allows problems to be detected early on, compared with periodic audits. Web portals that allow customer-vendor interaction, for example, have grown more popular in recent years.

third party auditor's results—service company certification is relatively rare. In fact, the intangible nature of the service activity means that client companies are usually forced to focus on indirect indicators.

### Audit Considerations

For example, translation vendors should provide clients with documented workflows and processes in the critical area of resource selection and audit. They should also have well-defined systems and methods for in-process QA. If the company is not certified to ISO 9001:2000, then a documented semblance of the ISO quality system should be in place along with auditable system inputs and outputs.

Auditing an outsourced audit provider is less clear-cut. Potential items for audit include the audit plan, audit reports that have been prepared for other clients and notified body feedback on the results of outsourced audits.

Due to the intangible nature of services, they are especially liable to process fraud. Process fraud occurs

when service tasks are specified, billed and paid for but not performed. In some cases, failure to perform specified service tasks is rather obvious. For instance, if your cleaning service does not routinely empty the wastebasket, the performance failure is clear. However, if your translation service does not perform linguistic QA as specified or your outsourced auditor does not thoroughly examine your vendor's systems, the failure may be less obvious. The regulatory and liability risks involved are evident.

In a services environment, the best guard against process fraud is signed process documentation and/or detailed audit reports for specified services. In the case of outsourced vendor audits, the service provider's product—the audit report—should be clearly defined at the initial consulting phase of the engagement (see sidebar). The report must contain sufficient detail to confirm that audit tasks were faithfully carried out. A diary or time log within the text of the report can help.

Required process documentation for translation services risk management includes:

- **Process validation forms:** your service provider should provide you with a signed table of tasks/resources that were involved in your project. Translation tasks must include native language translation, translation by a second native language translator and linguistic QA. If formatting services are specified, then formatting QA must also be provided.

- **In-process QA documentation:** linguistic QA according to a recognized standard (such as SAE J2450) should be supported by documented records.

- **Quality certificate:** a signed certificate, specifying services and warranting results, is the final piece of translation risk management documentation.

While the growth of outsourced services brings many economic benefits, it also brings potential risk. Managing outsourced services risk depends on a company's ability to effectively qualify the service provider, audit its operations and document its service processes. The lack of these basic outsourcing controls opens a medical technology company to severe compliance and regulatory liability. ❖

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*Marc H. Miller is the CEO of Crimson Medical Translation, an ISO 9001:2000-certified, ISO 14971-endorsed language translation, graphic design, layout and formatting firm serving the medical technology industry. A former senior research fellow with S.I.A.R., an international medical technology strategy firm, Mr. Miller is a graduate of Harvard University and the Scottish Business School at Stirling University. He can be reached at (877) 824-8800 or by e-mail at mmiller@crimsonlanguage.com; more information about services risk management is available at: [www.medical-language.com](http://www.medical-language.com).*