

January 28, 2004

Marc H. Miller, CEO  
Crimson Medical Translation  
2949 Balboa Street  
San Francisco, CA 94121

Re: ISO 14971 Compliance

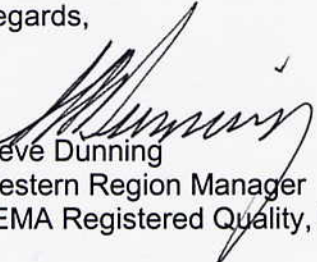
Dear Marc:

This letter is written to acknowledge the fact that your company's quality system is in full compliance with the tenets of ISO 14971 (Risk Management). Crimson has done an admirable job of identifying the key risk points in the language translation process and has designed a quality system that effectively addresses these issues. Specifically:

- Your overall process effectively reduces risk by controlling project specifications and handoff risk.
- The "Risk Analysis" section of your Quality Plan Proposal (client estimate) effectively communicates assessed risk to your clients.
- Your BackEdit process provides critical risk management through a linguistic QA check. Your use of the SAE translation quality metric to produce a measurable, statistically based scoring process is particularly insightful.
- Your use of the SAE metric to objectify translation vendor evaluation helps to control this acute process risk.
- Your extensive testing procedures for staff and vendors provides critical risk management in the areas of project management, desktop publishing, and formatting QA.

In the words of the auditor who performed your most recent surveillance audit, "The Crimson Medical Translation surveillance audit showed a management system that has been exceptionally well maintained." This, combined with the key risk management elements discussed above, indicates that the Crimson quality system is in full compliance with the tenants of ISO 14971 (risk management).

Regards,

  
Steve Dunning  
Western Region Manager  
KEMA Registered Quality, Inc