

Supplier Control: Growing Regulatory Concern for Outsourcing

Step back with me for a moment...to 2007. The Dow Jones Industrial Average was happily climbing from 12,000 to 14,000, Bear Stearns and Lehman Brothers were successful going concerns, Al Gore received a Nobel Peace Prize, and the Red Sox won their *second* World Series (yes, I live in Boston, Mass.). Life was simpler then, wasn't it?

Plus Ça Change ...

However, even in the white-picket-fence world of 2007, trouble was brewing. In that year, 52 percent of the U.S. Food and Drug Administration's (FDA) warning letters included a mention of supplier issues. From 2006 to 2007, FDA warning letters with purchasing control deficiencies increased 31 percent (there was a further increase of 40 percent from 2007 to 2008). An article in the industry regulatory publication the *Silver Sheet*, in May 2007, reported that poor supplier controls were beginning to draw the attention of regulators such as Kim Trautman, FDA's medical device quality systems/GMP expert. Noted Trautman at the time: "Data often indicates that companies are reporting supplier troubles as the root cause of failure in their devices."

Fast-forward two years. Diethylene glycol-contaminated toothpaste has led to several deaths—as has tainted heparin, pre-filled syringes, peanut butter and melamine milk. Each instance was caused, in large part, by poor supplier control. In retrospect, Trautman's warnings look prescient—and this observation was made abundantly clear to the dozens of manufacturers and suppliers who gathered recently in Bethesda, Md., for the first-ever supplier controls seminar by the Washington, D.C.-based Advanced Medical Technology Association (AdvaMed).

Past is Prelude

Featuring senior representatives from FDA

and the Global Harmonization Task Force (GHTF), along with major device manufacturers such as North Chicago, Ill.-based Abbott Laboratories; Medtronic Inc., headquartered in Minneapolis, Minn.; and Boston Scientific Corp. in Natick, Mass., the AdvaMed seminar served as a stark reminder of outsourcing risk. Using her cautionary supplier control interview in 2007 as a point of departure, bringing the attendees up to date, Trautman said: "Supplier control is a much bigger issue now than it was in 2007. Even though issues with toothpaste and nuts are not directly in the device sector, these events still greatly affect FDA thinking and controls. The emphasis on the linkage between supplier control and risk management will continue to increase."

In other words, in preparation for upcoming FDA audits, manufacturers would be well-advised to carefully review their supplier control practices.

To underscore the importance of this message, Trautman is delivering her supplier control sermon directly to a number of influential industry groups, including this year's annual conference of the Regulatory Affairs Professionals Society (being held in Philadelphia, Pa., from Sept. 13-16).

Propelled by the rapid globalization of the industry's supplier base, a number of well-publicized signal events, along with the growing emphasis on risk management, supplier control has caught the attention of other regulators, too.

Observes ISO 14971 co-author and 25-year FDA veteran, Dr. Harvey Rudolph: "Until recently, outsourcing has often been pursued by companies in a less-than-thought through manner."

Now, supplier control issues are getting special attention in ISO 13485 registration audits, and all regulators are expressing newfound concerns about supplier risk management—not just FDA.

The effect of these concerns is being felt



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across the entire supplier base—from critical OEM component manufacturers to labeling translation providers. Regulatory emphasis on supplier control has prompted device manufacturers to increase supplier audit staffing—thereby increasing audit scope and frequency. It also has prompted manufacturers to consider “supplier parity” (equivalent levels quality system certification), leading directly to an increase in supplier registrations to ISO 13485.

Finally, regulators’ concerns have pushed manufacturers to examine best practices for appropriate control of outsourced processes. For instance, notified bodies are now examining manufacturers’ labeling translation procedures for evidence of effective control, with several receiving observations for poorly documented procedures and/or weak controls.

Purchasing Controls Key

In her AdvaMed presentation, Trautman offered simple but effective guidance for manufacturers considering their supplier controls. Referring to the preamble of the 1996 Quality Systems Regulation, Trautman noted: “Purchasing [supplier] control and acceptance activities are two sides of the same coin. It is important to understand, in the first place, what is the risk that the supplier represents? What assurances do you need to effectively mitigate that risk? Effective purchasing controls can provide a valuable rationale for decreased acceptance activities and vice versa.”

However, she also cautioned against superficial approaches.

“The regulation gives you the rope...to pull yourself up and do a good job or to hang yourself if you do a poor job,” she added.

One important new piece of guidance aims to help manufacturers steer clear of the regulatory hangman. In February, the GHTF published “Guidance on the Control of Products and Services Obtained from Suppliers.”

Because representatives from the major regulatory bodies sit on the GHTF study groups, their published guidance documents generally provide an excellent forward indication of national regulation. GHTF’s recently published guidance serves as another, global, indication of the growing importance of supplier control.

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One Throat to Choke

In addition to illustrating risks and valuable mitigations for effective supplier control, presentations at the AdvaMed seminar reflected a growing emphasis on supplier consolidation for more effective management. This emphasis is in line with a broad strategic push by FDA to assert more control over the medical device supplier base by placing added regulatory focus on manufacturers’ supplier control systems. By clearly assigning responsibility for outsourced processes, products and services with the manufacturer, FDA hopes to apply a “one throat to choke” principle. Faced with increased regulatory scrutiny, manufacturers are, in turn, taking a similar approach by consolidating their own lists of approved suppliers.

The trend toward supplier consolidation, noted in a May 2008 MPO article (“Risk Management Drives Supplier Development...and Demise”) has been accelerated by regulators’ emphasis on supplier control. It also has been accelerated by the most severe economic downturn since the Great Depression. According to business credit report provider Dun & Bradstreet, based in Short Hills, N.J., there has been a 35 percent increase in supplier bankruptcies—leading to additional churn in manufacturers’ approved supplier lists. This, in turn, increases the practical value of structured supplier selection, evaluation, and acceptance.

“It’s the Economy, Stupid”

Certainly, today’s economy provides a grim background to nearly every discussion of supplier control, quality and risk management. In addition to the business risk posed by supplier bankruptcy, a poor economy broadens the incentive to choose cost over quality in areas that are directly tied to patient safety. This is true for suppliers as well as manufacturers.

On the supplier side, the temptation of economically motivated adulteration (EMA)

is considerable—prompting an FDA open meeting on the subject in May of this year. Suppliers based in certain countries, such as China, are a special concern and focus for FDA. Ranging from premeditated fraud to a simple, undocumented, cost-based specification changes, EMA already has had adverse affects for patients and manufacturers alike.

However, suppliers aren’t alone in bending to economic pressures and placing cost above quality. A recent e-mail from the manufacturer of a Class III woman’s health device to the supplier of a critical service reads: “After reviewing the three quotes I obtained, I’ve chosen to move forward with a company whose pricing came in the lowest ...”

Follow-up conversations revealed no risk acceptance criteria in place, neither were regulatory input sought or required for the supplier selection. In fact, the manufacturer had designated an unqualified resource for a decision with real risk management implications for patient safety and business operations.

Between the Devil and the Deep Blue Sea

Increasing scrutiny of supplier control processes, combined with current economic pressures, will continue to exert considerable pressure on device manufacturers in the foreseeable future. In order to make appropriate decisions, manufacturers can look to recent FDA statements and GHTF publications for guidance. Perhaps, most importantly, manufacturers should follow Trautman’s advice to choose “risk averse suppliers.” They must also make patient safety the fundamental basis for all supplier control decisions. ❖

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