You’re Only as Good as Your Suppliers

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A few years ago, parents didn’t take kindly to the epidemic of lead-based paints being used freely in the manufacture of toys that made their way into their infants’ playpens. Rightfully so, those toxic toys became front-page headlines and outrage spread across the land.

That was just one moment among many when the rest of the world began to realize that the super fast-growing economies in Asia were often producing goods and components without the quality assurance procedures that are routine elsewhere. In some industries, companies that ran to set up operations in Asia have now done a 180-degree reversal, moving more offshore operations back home.

In other companies, there has been a constant struggle to keep qualified engineers, chemists and trained line workers in place in Asian facilities. This can be a truly daunting challenge as trained workers move quickly to better opportunities and better paychecks whenever they can, such that training and re-training an ever changing workforce consumes time, attention *and* resources that somewhat erode the bottom line advantage of the lower-wage workforce. Indeed, one medical device manufacturer with operations in China is reported to have its *entire* staff disappear overnight when a larger facility opened up down the road.

To maintain the modicum of quality standards, many are rediscovering the reasons why the Japanese auto industry pioneered poka-yoke assembly techniques years ago — where extra steps are built into manufacturing processes to take the potential for errors by less-trained workers out of the equation. But the truth of the matter is that the lion’s share of overseas suppliers of ingredients and components of U.S. FDA [1]-regulated companies have not invested huge sums to safeguard quality because so far they haven’t had to — UNTIL NOW.

While toxic toys may have grabbed the headlines, the growing reliance of processors to use supplies and components made in low-cost Asian facilities has orders of magnitude more potential to harm public safety. This fact hasn’t been lost on FDA regulators or their European equivalent, the European Compliance Academy (ECA).

In fact, it provides partial explanation for why the failure rates among processors are on the rise. It’s not that today’s products are more inferior than those of a few years ago, it’s just that regulatory bodies have stepped up oversight efforts. (For discussion of some recent examples of greater regulatory enforcement, see “How to Avoid and Respond to Public FDA Criticisms—Form 483 Letters—for Temperature, Humidity and other Controlled Environments” [2]).

Before, supervision of suppliers in distant lands was lax or non-existent. It is not so today, as risk-based models drive the direction of the FDA, ECA, MHRA and other regulatory agency inspections. Overseas manufacturers that must function within tight tolerances for quality seem to be towards the top of the list of regulators’ “high-risk” list.

True, it’s always been the case that you are only as good as your suppliers and the quality assurance procedures your company uses to safeguard ingredients’ purity and components’ integrity. Now, however, you can expect that if you don’t find the problems before regulators do, your operations will receive 483 letters, warning letters, recalls or other sanctions with potential damage to your brand and bottom line.

If a processor does not have the equivalent of an in-house FDA that knows the rules and enforces oversight on its supply chain, it would behoove them to find ways to do this post-haste *before* regulatory representatives arrive at the door.

One resource to look to is the in-house regulatory experts of your instrumentation suppliers. For Veriteq, a Vaisala company, my job is to do just that, and I’m on call to pharmaceutical manufacturers that want to know what we have seen in the U.S. and worldwide.

To continue this discussion, please contact Appel via ken.appel@vaisala.com *[3] or visit* www.veriteq.com *[4].*

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