



Soliciting a staffing managed service provider in today's medtech industry

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In the world of compliance and risk management, supplier management is garnering much more focus and attention, especially in relation to the pending 2016 update to ISO 13485. During the latest meeting of the ISO 13485 Technical Committee Working Group, some key observations were made: "The new standards need to be more applicable to the entire supply chain in the medical device industry, to be relevant to suppliers of components and services, as well."¹

The concern is that too many medical device and healthcare product manufacturers are not monitoring their suppliers close enough, and as such the risk of system's non-compliance and product/service issues could be higher than they need to be.

This problem is especially acute in areas that have previously seen little or no scrutiny. One such area is the application and management of temporary labor.

The use of On-Site Managed Services Providers (MSP), in adding value to the application of temporary labor, clearly suggests that temporary labor is very significant in terms of headcount as well as cost containment. And this is only expected to grow. As more medtech firms look to carve more cost out of the process, the use of temporary labor and its related support services is expected to grow. Ardent Partners, a research and advisory firm focused on defining and advancing supply management, predicts that, by 2018, nearly 45% of the world's total workforce will be contingent.²

This issue is especially troublesome where contingent or temporary labor is used to manufacture medical devices or healthcare products. No regulator, certification organization or customer responds without angst when learning that temporary labor is going to be used to build a medical product. And that is due to the nature of contingent labor! It is applied for a project, an initial product ramp-up or to hedge against uncertain order cycles or market conditions. But because it is temporary it is often treated as such, without much investment in training or orientation. As a result, issues are certain to develop.

Temporary labor contracts are major procurements. For contracts covering the temporary labor workforce and their support functions, the values can commonly range from \$2M to

\$20M in annual spend. By any measure these are significant procurements. And because of what they address (the labor to build the product), they could be considered strategic procurements.³

Pending updates to ISO 13485-2016 are expected to have more stringent requirements regarding risk management. And supplier management is a key focus area of risk management.

So what can a company do to protect itself in this increasing risk-adverse and cost-sensitive business, especially in the area of contingent labor?

The company should:

1. Better define your requirement to your potential staffing providers.
2. Hold them to the same standards you do for your other strategic suppliers (e.g., mandate ISO 13485 Registration).
3. Require them to report key compliance and performance metrics like other key suppliers; and
4. Audit them and their records like you would other key suppliers.

Think about it! These temporary workers should be tested, screened and qualified against a defined position requirement; they should be trained and made ready for the stringent manufacturing / facility requirements of a medical products manufacturer; and they should be oriented to your culture, policies and procedures—all before they hit the manufacturing floor. And if you are doing this, rather than an MSP, you are not optimizing your costs or supplier selection.

A good start would be to lay a good foundation. Make sure that, up front in the procurement process, you have solicited a well-structured and comprehensive statement of work that represents the requirements you have as the responsible party in the relationship. Yes, at the end of the day you are held responsible for the products or service of your suppliers in this industry.

It's time to take temporary labor more seriously. Treat them as you would any other key or strategic supplier.

For your convenience, [a free SOW template](#) is available for your use. This template has been vetted by veteran medtech procurement managers and should provide a good launch point for your journey into this very important area of risk mitigation.



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1. OBELIS EUROPEAN AUTHORIZED REPRESENTATIVE CENTER, NEW Revision to ISO 13485:201x postponed to 1Q

2016; http://obelismedical.net/revision_to_iso_13485201x/. ↵

2. Contingent Labor Streamlines Manufacturing Operations, Mark Crawford, Area Development On-Line. ↵

3. Long-range plans for ensuring timely supply of goods and/or services that are critical to a firm's ability to meet its core business

objectives; <http://www.businessdictionary.com/definition/strategic-procurement.html#ixzz3TACqJVzp>. ↵