

The State of Contract Manufacturing in MedTech

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Introduction

Contract manufacturing enables a company to leverage an expert in one or more areas of the design and manufacturing processes without requiring large capital investments. Design, engineering, component fabrication, assembly, or even full-service capabilities are among the options medical device OEMs can find in a contract manufacturing partner. This allows the firm to remain focused on core competencies and strategic planning.

As medical device OEMs are more willing to embrace these practices, specialist companies familiar with the strict regulatory environment will continue to emerge. Quality, time to market, project experience, and cost controls are a few of the many reasons medical device OEMs select a service partner.

However, questions, challenges, and concerns associated with contract manufacturing remain. This market monitor research report will examine the trends in contract manufacturing in the medical device design and development industry as well as the considerations that need to be addressed in the proper selection of a contract manufacturer. It will also identify and resolve issues about contract manufacturing within the medical device space and lay out necessary steps OEMs need to take to get the most value out of contract manufacturing partners.



Research Methodology

One survey conducted by *Medical Design Technology* in August and September 2015 included nine questions and was fielded by 180 design engineers. Another online survey included 11 questions and was fielded by 133 design engineers in November 2015. The information contained in this report is of a general nature, and is not intended to reflect the circumstances of any specific individual.

The State of Contract Manufacturing in MedTech

By Sam Brusco, *Medical Design Technology*

A 2014 Accenture manufacturing skills and training study reports that more than half of companies intend to increase U.S.-based production by at least five percent in the next five years. That's all well and good, but a problem has emerged as a result. The study also reports that more than 75% of manufacturers are experiencing a serious shortage of skilled manufacturers. Because this shortage may result in higher costs of production and revenue, it's possible that manufacturers might see earnings reduced by up to 11%.

Add the fact that the skilled manufacturing workforce is approaching retirement age, and some serious storm clouds may be brewing for the manufacturing industry. How can OEMs expect to accelerate production when the pool of skilled manufacturing workers appears to be shrinking?

To address this problem, many medical device OEMs are turning to contract manufacturers to help with the production process. In addition to providing a leg up for the diminishing manufacturing workforce, using contract manufacturing services may help lower costs, speed time-to-market, and increase investment returns.

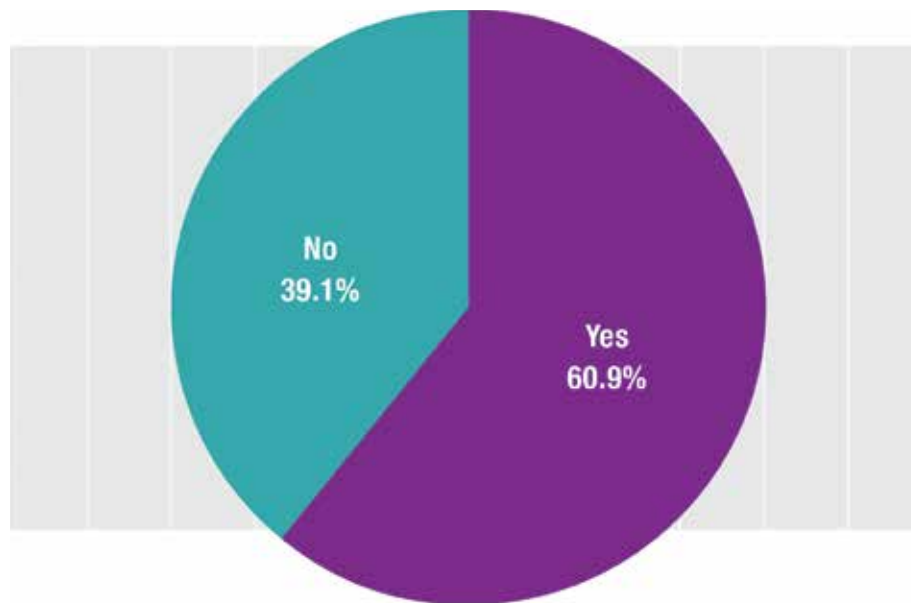
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State of the Market

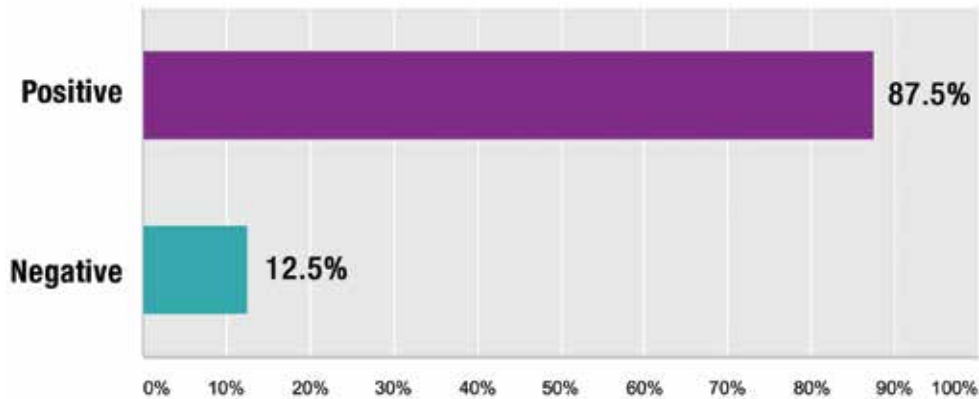
Using a contract manufacturing partner isn't just something medical device OEMs are dipping their feet into, either. According to a survey of 180 medical device professionals by *Medical Design Technology* in September 2015, 58.3% of OEMs have used a contract manufacturer (CM) for a medical device project. And all signs seem to point to an increase in soliciting CM services. According to the survey, half of OEMs are using contract manufacturers about the same as they were five years ago, while 37.5% are using contract manufacturers more often.

Has your company ever used a contract manufacturing firm for an aspect of medical device development/manufacturing?



According to the September 2015 survey, on the surface, the experience of using contract manufacturing services seems to be favorable. What's more, they appear to be catering to the dynamic and rapidly evolving medtech market — 83.5% of the respondents believed that contract manufacturers are current in serving the needs of today's medtech customers. OEMs also seem to agree that using a contract manufacturer is important in order to increase company standing and revenue: 85.1% of the respondents agreed that an OEM's ability to grow and remain profitable today relies on contract manufacturing.

Overall, how would you consider your company's experience with a contract manufacturing partner?

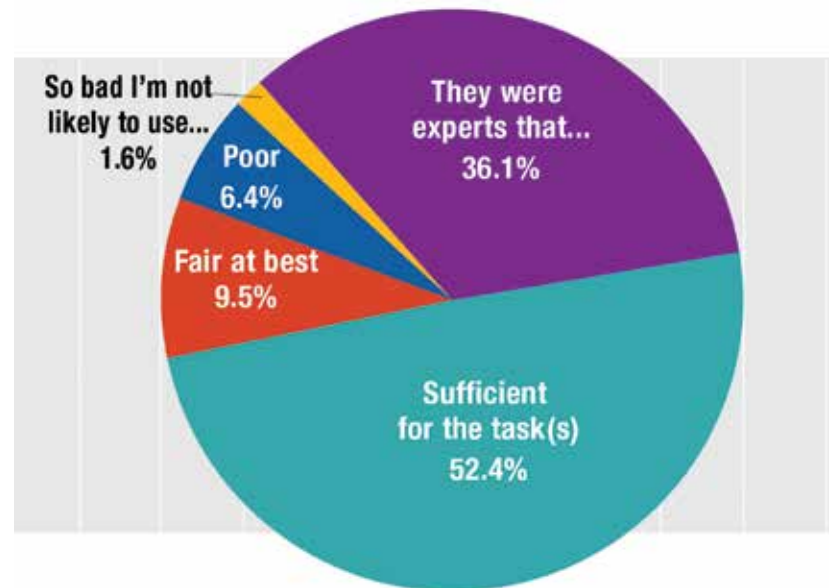


A more recent survey of 133 medical device OEMs, conducted by *Medical Design Technology* in November 2015, reports that reliance on a contract manufacturer is indeed increasing—60.9% of these respondents said that they had used contract manufacturing services, nearly a three percent increase from a mere two months prior. OEMs continue to express favorable opinions of working with contract manufacturers, as well; 87.5% of the respondents reported an overall positive experience with a contract manufacturing partner.

Common Criticisms

The needle shifts a bit when OEMs were asked to rate specific experiences collaborating with contract manufacturers. Only 30% of respondents reported that the contract manufacturers were experts that could perform manufacturing services better than their own company, and 52.4% said that contract manufacturers were merely sufficient for the task(s) required. That's a common criticism of contract manufacturers as many OEMs feel that these "one-stop shop" services might sacrifice quality for convenience, as well as a lower overall cost of production.

Overall, how would you rate your experience with contract manufacturers?



Quality vs. Cost

Unfortunately, it holds true that less expensive contract manufacturing services aren't always reliable. One respondent expressed the concern that, "Inexpensive is not always better, some smaller 'mom and pop' shops vie for business to build your product, but create and end up with a less reliable product." In addition, finding a balance between the OEM's and contract manufacturer's capabilities can be difficult, as one respondent explained that contract manufacturers "need to be able to balance what they can and cannot do with what we have in-house; it's not always a clear process." Even if the contract manufacturer provides an affordable service, hidden costs may end up revealing themselves in a nasty way, as one respondent notes, "You must monitor continuously and make expectations very clear. Deal with all cost issues up front and don't expect the manufacturer to absorb costs."

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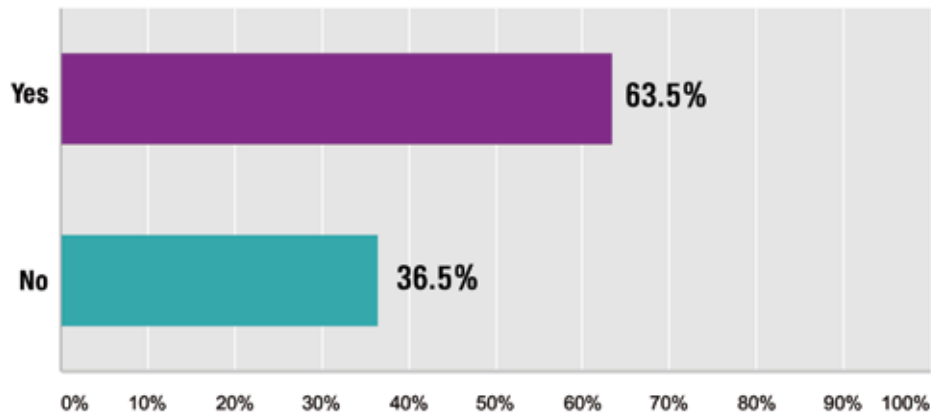
This remains to be an evergreen problem for medical device manufacturers in particular. It seems to be a tug-of-war between quality and cost when deciding on whether to manufacture medical devices in-house. On the one hand, manufacturing a device in-house ensures that the OEM is involved in every step of the process. If the OEM has the necessary manufacturing personnel and resources, they can collaborate with engineers to manufacture a product that is almost certain to meet quality standards.

On the other hand, in many cases the OEM doesn't have the resources (which the Accenture survey points out to be trending upward) or the money to undertake manufacturing themselves. Therefore, it's pretty much necessary for them to outsource the manufacturing work.

Communication Is Key

An off-site contract manufacturer makes communication more difficult. Because of this, if resources weren't an issue, 63.5% of respondents would prefer contract manufacturers to have all capabilities in house, rather than outsourcing. One respondent describes a problem arising from lack of communication with a CM partner, "We assumed the contract manufacturer would apply standard first-article and incoming inspection to material they procured." The respondent reported that "In the end, they didn't do any of this because they considered everything they were doing for us was prototype, and not production equivalent. This

If resources weren't an issue, would you prefer to have services that are provided by contract manufacturers performed in house?



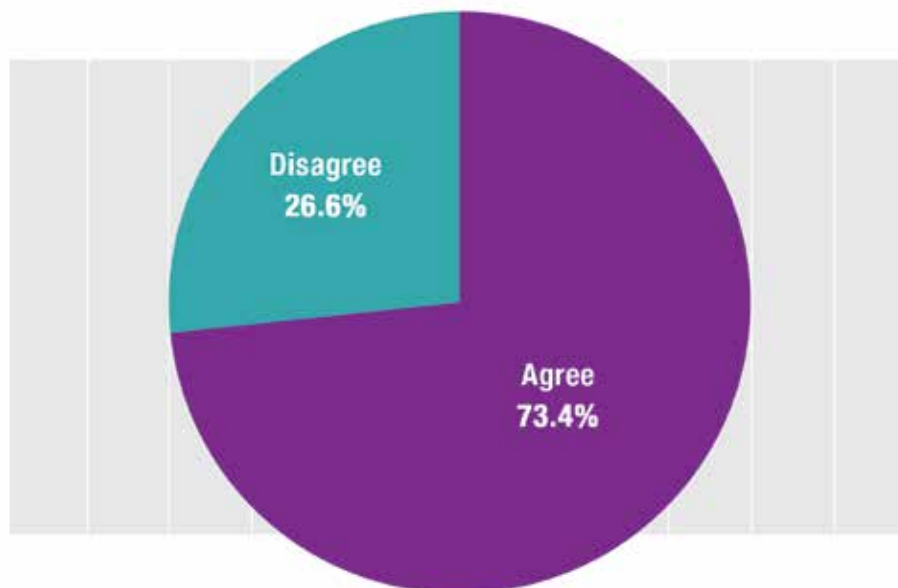
was a communication breakdown with guilt on both sides." As with most other facets of life, in an effective OEM-contract manufacturer relationship, constant and clear communication is key. The problem becomes compounded when OEMs decide to solicit the services of a Chinese contract manufacturer in order to significantly cut down on costs. This might present a potentially difficult communication situation between the OEM and contract manufacturer. Due to language and time differences, there might be a more difficult communication barrier. Fortunately, OEMs are wary of this, as one respondent warns, "Working with CMs in Asia is difficult for more than one reason: communication is not easy, and time zone differences with the U.S. The main difficulty is with New Product Introduction. MedTech contract manufacturers seem to be set up more for transferring existing products to be manufactured overseas, where they can basically copy existing procedures and no innovation is needed."

Even if OEMs consider all of these factors, they can't guarantee that the quality of product will be exactly to specification, particularly if the contract manufacturer isn't familiar with the medical device space.

Vetting Service Providers

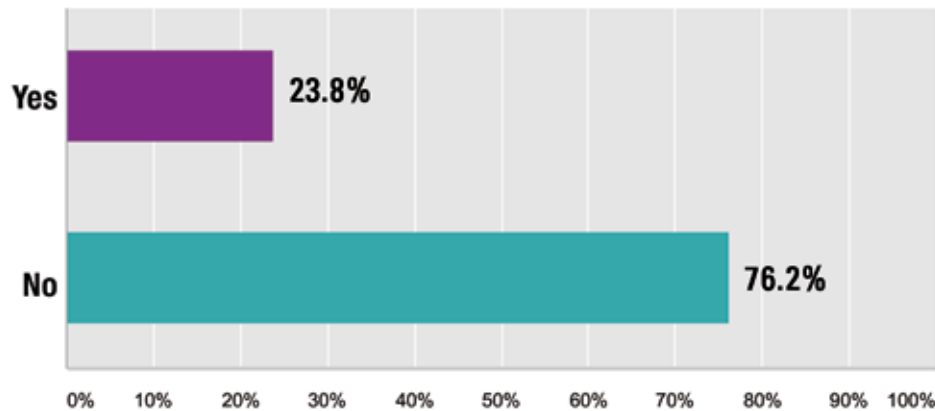
The solution may lie in a more comprehensive screening process for choosing a contract manufacturing partner. Selecting an appropriate provider is integral to streamlining the production process. Perhaps most important in order to select the appropriate manufacturing partner for medtech OEMs is level of experience in the medical device industry. Medical device OEMs certainly agree, as 73.4% of respondents state that when selecting a contract manufacturing provider, a lack of experience in the medtech space is a deal breaker. One respondent went out of their way to make sure *Medical Design Technology* knew it. “Previous medical device manufacturing experience in the same class of medical devices is a critical requirement,” the respondent says. Not much of an argument there.

**When selecting a contract manufacturing provider,
is lack of experience in the medtech space
specifically a deal breaker?**



Also, the medical device space is unique in that it requires a specific set of regulations. For example, most medical device market regulators require manufacturers to implement a quality management system (QMS) like the ISO 13485 certification, the preferred or required method for medical device OEMs to meet QMS requirements. Medical device OEMs are not comfortable using contract manufacturers who don't have relevant certifications; 76.2% of respondents would not use a contract manufacturing partner without certifications specific to the medical device industry.

Would you use a contract manufacturing provider who didn't have medical device relevant certifications (for example, ISO 13485)?



So perhaps it's time that contract manufacturing providers allow themselves to be publicly evaluated in order to best serve medical device manufacturers' specific needs. OEMs would certainly benefit from a compendium of contract manufacturers' statistics—things like areas of expertise and documented certifications could be put on display for OEMs to review. Medical device OEMs seem to think along the same lines: one respondent suggests they "would be interested in rating and advisory networks" for contract manufacturing services, while another recommends "Yelp type feedback and rating of particular companies."

These types of reviews may exist on a case-by-case basis, but a standard resource for medical device OEMs to browse through potential contract manufacturers does not yet exist. This is important because medical device OEMs need to be able to see how other OEMs fared when relying on a specific contract manufacturer.

Conclusion

Medical device OEMs are generally content with contract manufacturing partners, but the statistics and comments point to the fact that they want more than a run-of-the-mill manufacturing experience. More industry-specific experience and considerations for the nuances of the medical device manufacturing process are chief among the concerns, to the point that OEMs won't even glance at a contract manufacturer without the necessary credentials. More than anything, they want to be able to communicate effectively and be sure of the services they're getting right from the very start.



About the Author

Sam Brusco is the associate editor of *Medical Design Technology* magazine. He frequently provides analysis on trending topics in the medical device development space. He hosts *Medical Design Technology's* monthly newscast, *The Pulse*, and regularly conducts interviews with medical device industry professionals.