

# THE HIDDEN COSTS OF MULTIPLE-VENDOR CONTRACT MANUFACTURING

Review any directory of medical device outsourcing resources and you'll see an assortment of offerings and services: design and engineering, components, assembly, legal, regulatory, sterilization and many more. You can find virtually any company to handle any part of the medical device manufacturing process.

While it can be challenging to pick among the thousands of available resources, companies looking to outsource medical device manufacturing are first faced with an important strategic decision: should we opt for a selection of unrelated service providers or a single-source contract manufacturer that can handle every step of the process?

Piecing together a group of discrete resources can have advantages. You can find companies that specialize in processes and techniques that are particularly well-suited to your specific device – a "dream team" of partners who are the leaders in their respective disciplines. You may opt for a collection of suppliers that share a focus on speed or cost savings, for example. Or you may simply find it comfortable to work with established vendors out of familiarity.

However, more often than not, the decision to use multiple suppliers on a medical device can have a variety of unintended consequences that could delay the project timeline, increase costs and lower finished quality, in addition to creating undue workload and stress for the internal project team.

In fact, the industry appears to be headed toward a more integrated approach. A 2012 survey completed by industry magazine MD+DI and ITG Market Research showed that 41 percent of respondents predict that their companies will increase the use of contract services. The survey identified a notable shift in the types of services that will be outsourced

in the future to include contract legal and regulatory services, as well as R&D and design capabilities in addition to core manufacturing services. The movement toward a vertically integrated, single-source contract manufacturer has many benefits.



**41 percent**  
of respondents predict that their companies  
will increase use of contract services.

## REDUCE SUPPLIER AUDITS AND VALIDATION

Consolidating design and engineering functions with manufacturing provides significant synergies. The design team will lean heavily toward materials and components from suppliers who have already been audited and are part of the company's existing supply chain. Auditing and qualifying new suppliers can take weeks (if not months), and consume hours upon hours of time. Three professionals, each spending 20 hours on an audit remove 60 hours that could be allocated more productively. (Not to mention the cost of their salaries and expenses associated with the audit).

Similarly, engineers will generally design devices with pre-validated components and materials from these suppliers, eliminating the time and expense required with the validation process.

While multiple vendors can all be ISO certified and follow similar quality protocols, there is no assurance that their data monitoring, collection and storage systems will be compatible. Proper documentation is essential if a quality issue occurs or the FDA comes knocking. Continuity of data is as critical as the continuity of engineering or manufacturing processes.



### MINIMIZE VARIABILITY

Engineers intimately familiar with their manufacturing processes understand how to design to make the most of their equipment and processes while minimizing manufacturing variability. Quality needs to be designed into the product based on the capabilities (and limitations) of the manufacturing. Even the most automated pieces of equipment have variabilities and the most rigorously controlled assembly operation has idiosyncrasies. Engineers can account for limitations with smart design. After all, you can't inspect quality into the product. It needs to be designed and built in.

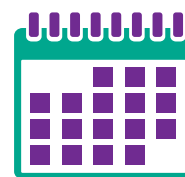
Another example involves designing for sterilization. A separate design team might select a valve and tubing configuration that would not permit ETO to flow completely through the device. Or an engineer could select a component that would discolor under gamma sterilization. Complete communication and understanding of all phases of manufacturing among all team members can mitigate the chance for downstream problems.

Furthermore, it is essential that all parties involved with the process have the same interpretation of the user requirements document. An engineering team that writes the document one way and a separate manufacturing team that interprets it differently could result in a final product that is inconsistent with the desired function. A comparable problem can occur with quality specifications. Measurement capabilities can vary from manufacturer to manufacturer. Are they using the same equipment and is it consistently calibrated? The more entities involved with the process, the more unpredictable the outcome.

### REDUCE MANAGEMENT TIME AND COST

Compiling a team of separate vendors places the responsibility for coordinating them on the internal project management team. They need to ensure that each vendor is aware of its step in the process and when their portion will occur. A 2012 report by The Hackett Group observed that over 40 hours per month of operations management could be saved when consolidating suppliers. Each external supplier relationship adds an additional \$700 to \$1,400 in internal costs, allowing a 3.35 percent cost reduction for indirect spending and a 9.18 percent cost reduction for equipment and supplies when cutting unneeded contacts.

Working with an integrated contract manufacturer eliminates the need to manage multiple vendors and can reduce costs. One project manager is responsible for the entire timeline, from the earliest design stages through assembly and sterilization.



40 hours

per month of operations management could be saved when consolidating suppliers.

Additionally, the development of an integrated project timeline can minimize delays between stages of the manufacturing process. A seamless transition is critical. If parties are not talking to one another, they will never understand the upstream requirements of the product. It's analogous to having adjacent conveyor belts: if they're

too far apart, items will fall through the crack. If there is an overlap, items will pile up.

The issue of accountability is a final benefit. If there is a product failure or quality issue with a device that involved multiple vendors, it is unlikely that one of them will step forward and take ownership of the problem. The more likely scenario is a round of finger-pointing followed by a call to the lawyers. Centralize the entire process with an integrated manufacturer and there's no question about who is responsible for resolving an issue. As one client has expressed, he likes only having "one throat to choke."



**3.35 percent**

cost reduction for indirect spending is allowed by each external supplier relationship.

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#### PREPARE FOR A LONG PRODUCT LIFECYCLE

While a collection of multiple vendors could occasionally prove advantageous in the short term, the use of an integrated contract manufacturer can deliver benefits over a longer product lifecycle. For example, a contract manufacturer that also provides sustaining engineering capabilities will be better able to address improvements, enhancements and changes to the product as feedback returns from the field. Does tubing length need to be changed? Do pressure requirements need adjustments to ensure proper device operation? An integrated team can evaluate options from a sustaining standpoint rather than starting anew. As with initial design, they can work as a team to update components and processes without triggering the need to conduct additional auditing or validation.

Likewise, the longer an integrated team works on a medical device from design through production and sterilization, the more institutional knowledge they can provide. Rather than acting as a disparate collection of independent vendors, a vertically integrated contract manufacturer acts as a full extension of the customer's team to provide critical insight and history about everything from material selection to engineering. They have a holistic understanding of how and why the

product has evolved to the current state, providing knowledge that can offset employee turnover or corporate restructuring on the customer side.

Finally, the extent of each partner's experience should also be considered when evaluating a long-range product lifecycle. Should a product prove successful in one country, is the contract manufacturer prepared to provide engineering guidance, change packaging or obtain regulatory approvals to enable distribution outside of the original country of manufacture? Can they use components that have already been validated in accordance with each country's regulations? Once again, an integrated multi-national team can provide meaningful, fruitful guidance where individual service providers might struggle.

#### WHICH MODEL WORKS BEST?

Of course, there is no one model that works best for every company. Some might opt for an approach akin to selecting a group of "All Stars" to play together on the same field or court. However, judging from the lackluster level of teamwork evidenced in such sporting events, that direction might not be ideal for something as critical as a medical device.

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**12 percent**

growth will be realized by supply chain outsourcing in the upcoming year.

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A 2015 report by Manning Advisors LLC predicts that supply chain outsourcing will grow 12 percent globally and 6-8 percent in the United States in the upcoming year. As the design, production and distribution of medical devices becomes increasingly complicated and regulated, there is tremendous value in consolidating resources with a single contract manufacturer that can provide an integrated team to steward a product from conception through many years of production. The long-term benefits in terms of time to market, overall quality, thoroughness of documentation and accountability will typically outweigh any perceived short-term benefits of a multiple-source approach.

## AN INTEGRATED RELATIONSHIP IN PRACTICE

The contract manufacturing partnership between B. Braun Medical Inc. and Mobius Therapeutics to develop a kit for one of their drug products demonstrates how the integrated approach can provide a number of strategic benefits.

Mobius is the second life science company started by entrepreneur Ed Timm. Mobius initially approached B. Braun for contract packaging services. Timm said he identified Mobius' core proficiencies in commercialization, regulatory affairs, and finance, and opted to outsource the remainder. He said it allowed him to capitalize Mobius with only \$3 million and gave him the flexibility to deploy that limited capital where he could realize the best return.

While Mobius did not face any unexpected challenges with package design, it needed to source products and scale commercial production. B. Braun sourced all the components for the Mobius Kit – most of which originated from audited and qualified suppliers.

Outsourcing to B. Braun's OEM Division for kit production also allowed Mobius to maintain a strong relationship with the FDA, said Timm. Supplying the agency with thorough data collected and supplied by B. Braun was critical to that relationship, he said.

Mobius also relied on B. Braun to manage the supply chain and the vendor relationships, from components, to packing, to sterilization, in order to reduce points of contact to one: the B. Braun account manager. Mobius depended on B. Braun's quality systems process to ensure vendor compliance and documentation to specifications.

"The ability to scale was also a factor in choosing to work with B. Braun," Timm said. Mobius sought a partner that could increase production as demand expanded without

dedicating capital machinery or assembly space. B. Braun sources all components for use in the kit and largely controls vendor relations, with the exception of Mobius' filled and finished drug product, according to Timm. B. Braun also controls the purchasing and inventory of the drug product, as well vendor qualifications, pricing, forecasting, ordering, delivery terms, specifications, and more.

Ed White, account manager at B. Braun, says he and Timm have developed a mutually beneficial relationship since the partnership began.



"B. Braun's OEM Division is in the business of helping other companies design, develop and manufacture new products that improve outcomes," he said. "Once Ed Timm gets an idea, we're his research arm. Mobius and B. Braun are both committed to moving in the same direction."

Timm agreed. "Through a comprehensive degree of transparency between Mobius and B. Braun, we are able to develop products that not only meet engineering specifications, the products meet strategic market needs as well."

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