Medical device OEM’s and contract manufacturers:

10 Key Areas to Consider When Evaluating Suppliers
Medical device OEM’s and contract manufacturers: Suppliers

The funds have been approved. Key people have signed off on a new project and you have been given the green light to go ahead. Being part of a medical device commercialization team can be exhilarating but without the right planning, opportunity can quickly turn into disaster.

The clock is ticking. So how do you avoid those bumps in the road and keep your project running smoothly? A key part is doing your homework so that the suppliers you select to be part of your journey can help you race to the finish line instead of creating problems and obstacles along the way.

Although this might seem obvious, many medical device OEM and contract manufacturers can benefit from a reminder that a firm understanding of your project’s parameters, timeline and other key attributes is required upfront. Only then can you adequately match your needs with the supplier’s core competencies. The goal is to select a supplier—or a small number of suppliers—that can oversee multiple manufacturing disciplines and meet timeline and performance objectives.

Here are some key areas that should be included in your vendor evaluation before you entrust your valuable project to a third party.

1. Consolidating suppliers/minimizing validation efforts

We all know the adage, “too many cooks in the kitchen.” The same can be said about suppliers. By minimizing the number of suppliers you have on your team, your efficiency is improved. In the competitive, medical device world, it’s all about speed-to-market. With a tight number of critical suppliers, communications are likely to be clearer, redundant efforts are reduced or eliminated, and accountability is more evident.

The other major benefit of supplier consolidation is the reduction of validation requirements. This happens by eliminating the need to audit each supplier’s quality system to ensure they are capable of maintaining the product integrity over the long haul. Each supplier you select will have to go through the validation process for each component they produce to ensure compliance with various government regulations and OEM protocols. This means the medical device manufacturer has to spend both time and money on the process, which, in turn, negatively impacts speed-to-market.

An example might be a using a supplier that can produce many different metal components for a device. That capability could eliminate five other suppliers, resulting in savings of tens or hundreds of thousands of dollars. Additionally, minimizing suppliers could potentially remove six months from the project timeline.

2. Project management experience

Many medical device manufacturers are realizing the need to push responsibility for certain elements of the process further down the supply chain. Frequently, this can result in project management being shared between the OEM or contract manufacturer and the supplier. Therefore, it is critical to consider the supplier’s project management track record and expertise when doing your evaluation. Can they shorten your development time through their technical competence and design capability? Are they able to adapt and be nimble enough to accommodate changes during device modifications?

A correct decision will have a positive impact on the all-important speed-to-market timeline. An incorrect decision will not only prevent you from reaching your commercialization goals quickly, but it will also negatively impact future projects that are lined up in the development queue. Speed-to-market can only be improved if your supplier has excellent project management skills.

3. Geographic footprint

Where is your component manufacturing supplier located? Do they do all of their work under one roof or are their facilities spread out across the country, or even around the world? Does more than one facility need to be validated? Are the quality systems different? Will turnaround time be negatively impacted because more than one facility is involved? It’s important to understand where the supplier’s resources are located and what that will mean to your project.
An example could be a supplier who is able to make springs, metal stampings, wire-forms, laser machined tubing, surgical sharps, build assemblies and create new value-added processes under one roof. The benefit of not having to micromanage various aspects of the component build, and monitor the deliveries from many different locations, reduces the OEM time of involvement by reducing the supplier follow-ups.

4. **Confirming processing capability**

Is your supplier’s processing capability robust enough to support you throughout the entire development and commercialization cycle? Can they handle the demands of future production acceleration, should that become necessary? Do they have enough capacity or would additional cleanrooms, assembly, packaging, etc., need to be built? What lead times do they require and do they have tools available to grow the human resources needed for expansion?

The above questions can be daunting for many OEMs undertaking a new project. Therefore, it is important to evaluate the supplier’s engineering competency and ability to integrate the automation skills when needed.

Once a successful product makes its market debut, the speed of the program growth can be accelerated exponentially. This isn’t the time to be concerned with qualifying additional suppliers to supplement production. The supplier chosen needs to react swiftly to these fast paced shifts by having available capital to invest in new technology or equipment. They also need to be capable of expanding their team’s intellectual horsepower by harnessing new talent that may be found in the local university system. These capabilities help support the OEM’s future growth.

It’s essential to thoroughly understand the supplier’s capabilities and ability to adapt. So running through “what if” scenarios helps ensure that all of your bases are covered.

5. **Metrology capability**

Ideally, your supplier will have state-of-the art, in-house metrology capability. Components need to be accurately measured and data needs to be supplied to meet statistical requirements. Automated measurement systems and the ability to collect data without human interpretation has become more prevalent. The automation and speed of data collection reduces the ongoing cost of quality that will need to be maintained for the life of the program. This level of activity helps the OEM build the bridge needed to support the FDA submission on the device or project. The supplier’s ability to provide supporting measurements helps meet OEM statistical protocols and verify quality expectations.

Medical device manufacturers need to understand exactly what internal testing capabilities the potential supplier has, as well as the ability to add new measurement systems as needed to support the processes that are developed. These systems will be relied upon to support the program long after the development cycle has concluded. The cost of the metrology that affects the products made and the consistency of the product quality will lie in the balance of this analysis.

6. **Skilled workforce**

Learn as much as you can about your potential supplier’s workforce. What are their core competencies, what’s the retention rate and what part of the process is automated?

When you walk through the facility, do you get a sense of “world class” or “mom and pop?” Look at the strength of the engineering staff. Are they proficient in the disciplines that matter the most when executing your project? What do their software/hardware support systems look like? Has the company invested in the latest technology to support products like yours?

The fundamental questions about technological competence can be easily answered by visiting the potential suppliers. If the supplier was new to the OEM, an audit would be conducted at some point to delve deeper into the process layers to ensure that the supplier is capable of supporting various twists in the development road. An approved or known supplier may expand his technological capability without the OEM or contract manufacturer being aware. A visit can expand this level of understanding.
These considerations underscore the importance of a supplier visit. Walking the floor and witnessing the workforce in action can verify expectations very quickly. Witnessing the technology employed and the interaction of the teams will lead to questions that can be asked directly to the staff.

While having a mature workforce with hundreds of years of cumulative experience is a powerful asset for maintaining manufacturing capability, it is imperative to witness the interaction of the training programs that are taking place to ensure the knowledge of experience is being passed on to the next generation.

For example, state apprenticeship programs with sponsored employees and recruitment of top college prospects should be evident during these supplier visits/evaluations. It’s an indicator of supplier commitment to create an expert employee workforce in order to support OEM initiatives.

How is their customer service structured? Do these people have an excellent communications track record with customers?

The best suppliers support OEM projects with direct customer service representatives (CSRs) that have a personal relationship with engineering/purchasing staff working on projects. The CSR’s can maintain a continuous link to the customer and provide updated communications as needed.

7. **Customer list**

What medical device companies has the supplier worked with before? Ask for a customer list so that you are certain you are working with someone who has a track record of working with other innovative medical device manufacturers. Are they at liberty to discuss any recent successes?

In today’s business environment, non-disclosure agreements are typically executed during a new project initiation phase. Ability to maintain project confidentiality and protect intellectual property should be evident. Working confidentially on competing programs simultaneously is a fundamental attribute inherent in the best suppliers.

8. **Quality control system**

Having a robust quality system for the life of the project is critical to its success. Medical device manufacturers need to insure that they are commercializing a product that meets all of their specifications. Product failure is not an option—particularly for a product that can mean the difference between life and death. The supplier’s ISO 9001 and ISO 13485 certifications should be evident. Plus, a supplier who can demonstrate FDA Medical Device Establishment Registration and Listing capabilities as well as Good Manufacturing Practices illustrates their commitment to consumer safety and product reliability.

You want to make sure that your supplier is capable of providing you with quality planning. Control plans, process flow diagrams and Process Failure Mode and Effects Analysis (PFMEA) are in place so that a change is not made after approvals. Emphasis on the PFMEA design in your supplier’s environment will help understand the weakest part of their process and make sure adequate controls are in place to address ongoing issues.

9. **Managing timelines**

One of the most critical elements of any commercialization plan is speed-to-market. With competitive pressure on the upswing, an aging population and demanding performance requirements for publicly-held companies, the pressure continues for “do it right, do it fast.”

What is your supplier’s track record for delivering projects on time? Are they nimble enough to quickly handle project revisions?

Not only do you need top-notch production experts, but you also need great time managers. You want a supplier who will partner with you to provide innovative, practical solutions that will support the growth of the program. The supplier’s production and planning efficiencies usually reduce the need for the OEM to add additional staff.
10. Managing costs

All new product launches are driven by financial considerations. Budgets have been set in advance along with performance requirements and commercialization timeline expectations. What is your supplier’s track record in making things happen within budgetary parameters? Do they manage expenses appropriately? Or are less than efficient processes and unfocused workforce creating an environment that will negatively impact your bottom line. It’s important to understand if your supplier is capable of meeting your financial expectations.

A strong supplier project management involvement during the device development can save the OEM hundreds of thousands of dollars per device. If the number of suppliers needed to develop a device is reduced, less OEM engineering support is needed to monitor activity. The obvious benefit is a significantly reduced development timeline in addition to the costs savings advantage noted. The time savings can easily be 6 to 12 months, which improves product launch speed-to-market. The final benefit is the efficient production process that was developed—and growth that is now managed by the supplier—that can support increased market demand for the medical device product.

Conclusion

Using a reputable supplier whose core competencies match your requirements is critical to finding the right partner. Before you begin the vendor evaluation process, be prepared to consider several key areas including project management experience, processing capability, geographic location and workforce skillset. Reducing the number of suppliers needed to develop your medical device can have a major impact on cost savings and speed-to-market.

About Economy Spring, a division of MW Industries

Economy Spring is a manufacturer of advanced medical device components, including highly-engineered, precision metal components and assemblies such as springs, surgical sharps, needles, laser machined tubing, staples, titanium clips, and complex assemblies. The company deploys its end-to-end product lifecycle know-how and design expertise to shorten product development time and lower costs. Economy Spring’s 40-plus year track record helps deliver product reliability and performance in demanding surgical and drug delivery applications. The company is registered with the Food & Drug Administration and has ISO 9001 certified and ISO 13485 compliant quality processes. For additional information, please visit the website.

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