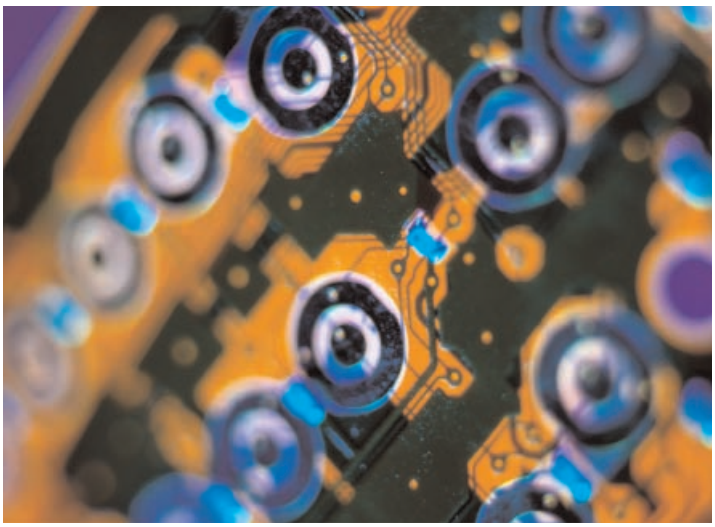

Choosing the Right EMS Provider for Medical Products Outsourcing

By Ed Evangelista

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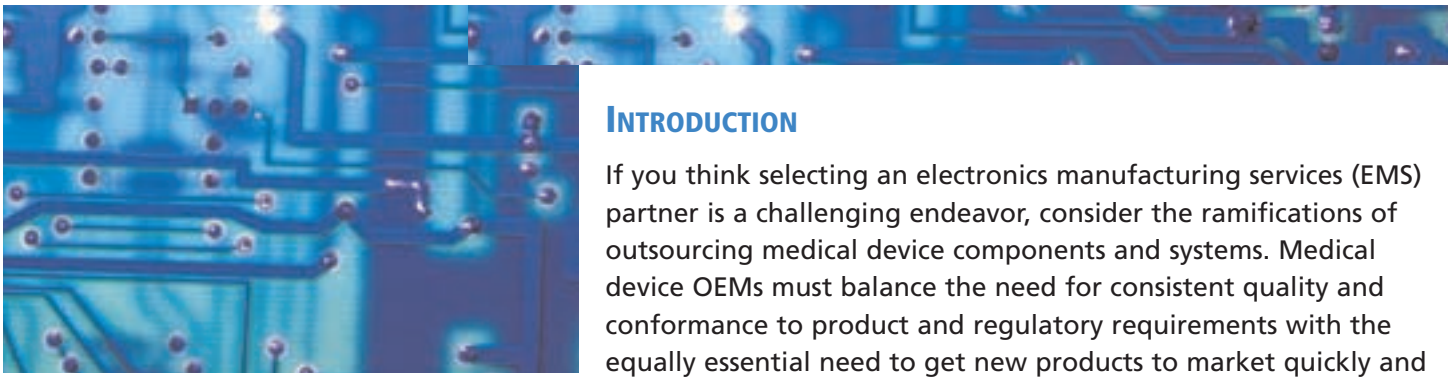


Introduction

If you think selecting an electronics manufacturing services (EMS) partner is a challenging endeavor, consider the ramifications of outsourcing medical device components and systems. Medical device OEMs must balance the need for consistent quality and conformance to product and regulatory requirements with the equally essential need to get new products to market quickly and efficiently. Given the level of investment needed to develop new products and shepherd them through the regulatory process, medical device manufacturers typically focus on product design, technological innovation, and market access to maximize their opportunity for success. Expending resources (both human and financial) on infrastructure to support an adequate manufacturing operation can dilute focus from their core competencies. Just as design partners can serve as a source for technological innovation, a competent EMS provider will serve as a source for business, manufacturing and operational innovation and efficiency that can be leveraged for competitive advantage. The key in the selection process is determining who can provide a seamless and efficient extension of your operation while conforming to the critical requirements imposed by the FDA and other regulatory bodies.

Each year, OEMs spend billions of dollars outsourcing electronics production, and much of this expenditure is wasted. Why? Because choosing the wrong supplier can result in significant cost, product quality, and customer retention issues.

Consider the risks of a wrong choice:

Cost overruns. Quotation accuracy from both the OEM and the EMS provider is essential if cost overruns and price creep are to be avoided. It begins with the quality and thoroughness of the quotation package, which must adequately identify your expectations and requirements. A robust evaluation process insures proper alignment with a qualified contract manufacturer. Failure at this early stage erodes margins quickly, especially if a mid-project change in vendors is required.

Downstream quality problems. The only thing worse than poor quality at your CM is the latent quality problems that won't appear until days after your product ships and is in use. While inspection can improve quality yields, robust process controls will build reliability into your product. And that only comes with experience building products similar to your own. Whether you choose to make product in-house or outsource, it is important to recognize that YOU are ultimately responsible for the quality of the product delivered to your customer. FDA 21 CFR Part 820 was established to regulate the quality systems used in the manufacture of medical devices. It can serve as the foundation for assessing a prospective CM's ability to consistently provide product that conforms to your requirements. Once the selection process is complete, frequent process audits and business review sessions will maintain the focus on operational excellence.

Jeopardizing your production pipeline. Ineffective material management and capacity planning, poor quality yields, insufficient administrative or engineering bandwidth, or simply a misalignment between your business model and your EMS partner can dismantle your production pipeline.

Supplier turnover and churn. Misalignment between a supplier's and customer's business models (ECO activity, schedule flexibility, mix/volume/complexity, etc.) will result in dissatisfaction and terminated relationships—introducing the added expense and risks associated with transitions to new vendors. Turnover is especially risky for medical OEMs for whom the initial EMS qualification and selection process tends to be longer than typical supplier audits. The upfront investment made by both the OEM and the CM to establish a viable working relationship and a high level of trust demands a robust selection process capable of exposing potentially flawed suppliers.

Intellectual property (IP) loss. Many medical OEMs employ advanced technology that provides a significant competitive advantage. They are highly sensitive to IP theft. Selecting a CM that has the necessary security and controls in place to safeguard that information is a prerequisite for consideration.

But perhaps the greatest risk of poor EMS partner selection is the prospect of losing your customers. As product recalls have taught automobile manufacturers, customer loyalty erodes each time a cost, quality, or delivery problem is discovered. Devoting the extra time to conduct a thorough supplier evaluation will pay huge rewards for your company.

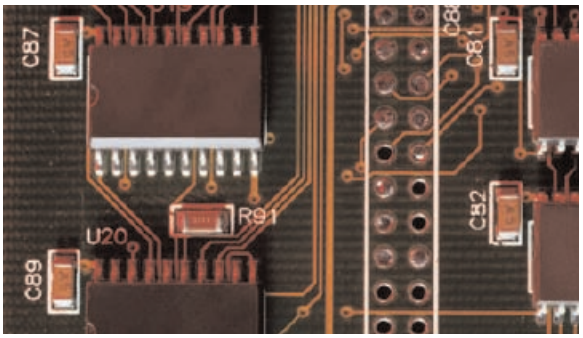
As you build a list of potential EMS partners, there are three qualifying criteria that candidates should exhibit to merit further consideration:

1. A history of product quality that meets specifications and your appropriate certifications (UL, CSA, FDA, ISO, Mil, etc.)
2. A record of on-time delivery performance
3. A feedback system that measures delivery and quality performance, identifies gaps between actual and target performance, and mitigates the gap through formal corrective actions

Identify and communicate your performance expectations on these criteria. If the vendors are not meeting these expectations, or won't show you metrics to back them up, eliminate them from consideration before too much effort has been expended. Dealing with suppliers who don't measure quality and delivery and can't demonstrate that they operate within your standards is too risky, no matter how low the price.

The selection process becomes more complex once a list of suppliers that meet these minimum requirements has been compiled. Virtually all reputable EMS vendors will assure you they can handle your project at an attractive price. So how do you pick the best one to meet your needs?

I've toiled in the EMS vineyards for over 20 years and witnessed the best and worst of contract manufacturing. Throughout that journey, I've observed there are a set of truths that result in successful outsourcing. I encourage you to embrace these guidelines as you establish new relationships with medical device EMS partners.



Evaluate suppliers on three key process capabilities.

The first capability is administrative; how they process orders, acquire raw material, and plan production. Will their administrative capabilities fulfill your outsourcing requirements? For example, how frequently do they run an MRP? Is that frequency adequate to capture your production schedules rates of change? Make sure they have a mechanism to identify misalignment between your need dates and their ship dates. And understand when this misalignment will be communicated.

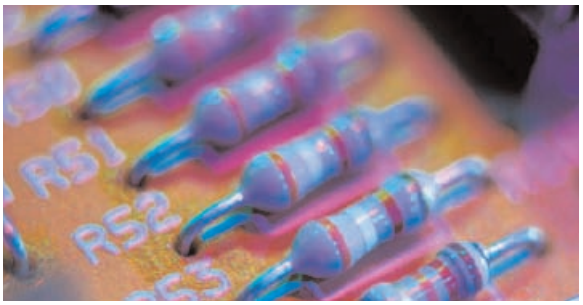
The second is product/process capability – the ability to build the exact product you need. Do your PCBA's contain micro-BGA's? Then the supplier should have the appropriate equipment to properly place this type of component and X-ray capability for inspection. Is no-lead in your future? Then the reflow oven should be no-lead certified compatible, capable of running at higher temperatures to accommodate lead free components. Consider copper cable assemblies, a commodity that is viewed as low technology but provides more than its fair share of pipeline problems. By virtue of higher labor content, this can be one of the most difficult processes to manage, from both a scheduling and process control standpoint. A cable and wire harness CM building 6-inch power supply harnesses consisting of 5 wires and 2 connectors is not likely to possess the expertise and process capabilities required to build a large harness consisting of 2,000 connection points and spanning 8 feet in length. The technology may look similar, but the supplier's product/process capability is vastly different and may not be the right choice for your application.

The third key process is Engineering Change Order (ECO) capability. Medical OEM's are hesitant to change their designs, and for good reason. Some changes may require regulatory review and approval, a painful and time consuming process. But when an ECO is required, it touches the supplier's operation in virtually every area—production, inventory, engineering, and quality. When an OEM issues a change order, it triggers a complex chain of events.

The supplier must:

- Create a new bill of material and product structure to cost out the new configuration
- Determine the impact on finished product stock and any required rework
- Buy material to rework finished product, create process instructions that meet the new design, and complete the rework
- Repeat the above steps for any work in process
- Create new process instructions for the product yet to be produced

Ask your prospective CM to explain their ECO process. Make them demonstrate how they do it and how long it will take. Observe their controls. Obtain sufficient evidence that their process of product change is conducted in a controlled fashion.



Define your outsourcing strategy.

To evaluate EMS suppliers, you must first identify an outsourcing strategy. Medical OEM's are very protective of their technology. They may view their manufacturing operation as a necessity to achieving the required level of quality. Consequently, outsourcing often begins by selecting low-level commodity-based services, such as PCBA's and cable assemblies. It is quite common for the customer to consign some or all of the raw material, maintaining greater control over the material planning and acquisition process and minimizing the risk associated with a vendor managed pipeline. Frequently, consignment is a short-term strategy to deplete the OEM's raw material inventory, evolving into a partial or full turnkey model where the supplier controls the acquisition of material. If consignment is a long-term strategy, then the OEM might be well served by utilizing a smaller, local CM that will give the contract lots of attention.

But suppose low-level production is just the starting point. Eventually the OEM plans to outsource higher level products as full turnkey (the supplier acquires the material and manages the pipeline). Many medical OEMs prefer to keep final assembly and test capabilities in-house, maintaining the final level of control before product shipment to the end customer. With this strategy, the OEM should focus its search on vertically-integrated CMs that can build at the highest level the OEM is willing to outsource and deliver a functionally tested assembly that can be quickly integrated into the final product. (Vertical integration occurs when a single firm can produce multiple services, such as PCBA's, interconnect assemblies, box build, etc. more efficiently and cost effectively than a group of firms, independent of each other.) This approach compresses the supply chain and eliminates margin stack up. Administrative services like order processing, raw material acquisition and production planning are more important in this model and should play a key role in the evaluation process.

Process integrity is a critical element that must be considered in every outsourcing strategy. I am referring to documented procedures that clearly define the methods to be used, the performance expected, the means to measure that performance, and a metrics system for evaluation. This applies to all operational processes, including order entry, material acquisition and acceptance, supply chain management, production process engineering, deviation control, manufacturing, and quality assurance/test/product acceptance. Product-related factors (supply chain, process control, etc.) should be documented in the form of detailed manufacturing instructions, quality control plans, and test protocols. These should be validated during the first article and pre-production stages. Process integrity insures that vehicles are in place to monitor performance criteria and identify areas that are trending in the wrong direction before they escalate to non-conformance. The real challenge is maintaining process integrity while fostering an environment of innovation. This can only be achieved within a system that identifies opportunities for improvement, communicates those opportunities to the customer for review and then implements the improvements only upon formal customer authorization.

So identify your outsourcing strategy, then select a CM that can evolve up the value chain, scaling with you in terms of capability as well as capacity.

Match your business profile to the prospective vendor.

An OEM creates a successful outsourcing relationship by aligning with a contract manufacturer that maps and scales well to its own requirements. That means selecting a CM with a business profile similar to your own. This is often defined in terms of product mix (the number of assembly part numbers to be outsourced) and product volume.

Low-mix, high-volume CMs are set up to pump out large quantities of a single unit. They don't usually have the infrastructure to handle varied and complex products. Instead, these manufacturers are set up to run large volumes of products (i.e. cell phones, consumer electronics) at the lowest possible cost.

High-mix, low-volume CMs tend to make a variety of highly complex products (i.e. medical devices, industrial automation, analytical instruments) in small batches. The very nature of this model requires considerably more infrastructure to support your needs, especially as they relate to regulatory and quality requirements. After defining your present and future expectations, ensure that the EMS provider's product and process technologies map to your own. Walk the company's floor and see if there are products similar in style and complexity as the product you plan to outsource. Look for evidence the CM can support the technologies you require today and will need in the future. For example, you may require simple through-hole printed circuit boards now, but you're developing more complex products that will incorporate surface mount technology (SMT). Or your future products may be subject to the new lead-free processing regulations. Make sure the CM offers these technologies. Map to a supplier with technical capabilities that match your strategic plan to ensure a long-term partnership.

Flexibility – the must-have for high-mix, low-volume products.

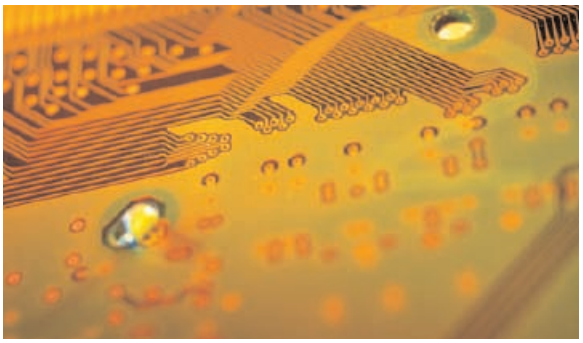
High-complexity, high-mix, low-volume electronics manufacturing does not run smoothly. Production has its starts and stops. Products may require reconfiguration. So supplier flexibility is a prerequisite. The vendor's ability to rapidly flex production levels and quickly reallocate resources is very attractive.

The OEM must understand how much flexibility they need. Does your business volume bounce up and down like a yo-yo? Are your products introduced in shorter and shorter cycles? Are your systems highly configurable?

High-mix, low-volume OEMs are constantly reacting to their customers' ever changing requirements. Three weeks from delivery, they say, "I don't want this bell, I want this whistle. The things I thought I wanted, I don't want at all. And the things I didn't think I wanted, I want them now. And by the way, I don't want to shift my schedule to the right." If that sounds like your customer base, then you must have a CM with flexibility – and the infrastructure that allows change to seamlessly flow up and down the supply chain.

Some vendors call this flexibility "expediting." I call it reaction to volume variability. It means the supplier can smoothly handle production volumes that fluctuate wildly and don't normalize at any one level for any period of time. Volume variability wreaks havoc on an inflexible CM. For example, a truly flexible supplier has developed systems that slam on the brakes to avoid the liabilities of purchasing too much material—or accelerate material procurement to meet a ramped up production plan.

Recognize that flexibility beyond a certain level comes at a cost. You can't have it both ways. Low cost typically means lower overhead and production efficiencies achieved through higher volumes. Increased flexibility often requires higher overhead to manage and execute the higher rate of change.



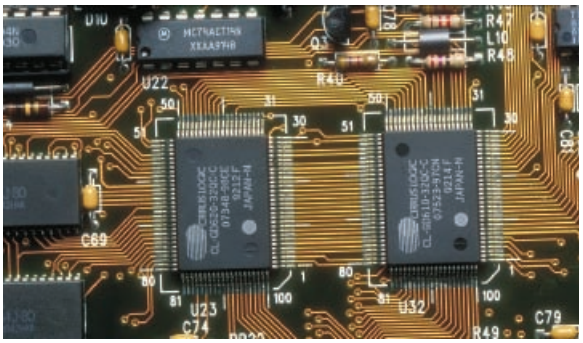
Find a personality "fit."

The supplier's culture and personality should fit well with your own to ensure a strong working relationship. Consider the nature of your outsourcing approach. Are you looking for a tactical relationship where you place the order and the supplier simply processes it? Or do you want more of a strategic association, where you're asking for additional assistance and value from a CM to help you move forward.

For a tactical relationship, focus on chemistry with the vendor's program manager and front-line operators—the people who will handle your key transactions (engineering, quoting, change orders, schedules). In this approach, the CM becomes an extension of your factory floor, where you send orders and they send you product. Make sure the supplier has a solid operations staff, because they will be your primary contacts.

If you require a more strategic relationship, then target the CM's management team. They will be running what-if scenarios, developing administrative as well as technical process improvements, and offering feedback. You must trust their managers' experience and accept their counsel to benefit the most from this partnership.

It is vital to determine, as early in the process as possible, whether a relationship based upon mutual trust can be established. Given the complexities of the outsourcing process, honest, two-way communication is essential to program success. That means establishing a comfort level where bad news can be delivered in either direction with the expectation that a joint resolution will be found. Any sense that the relationship will not support such an expectation should be cause for immediate concern.



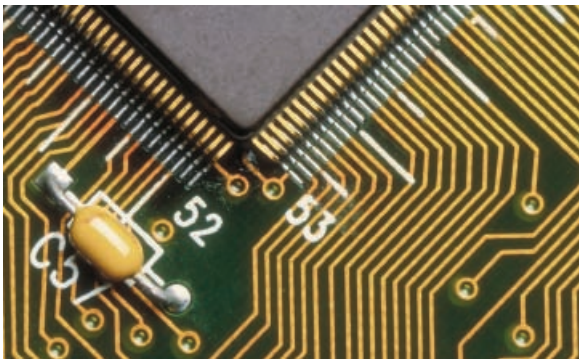
Understand your new product introduction strategy.

Will your EMS provider become an active partner who collaborates on new product introduction (NPI)? Or will you design something, throw it over the wall and let your supplier build it? Your NPI strategy should impact your CM selection.

There are differing schools of thought when it comes to NPI for medical OEMs. An OEM may engage with a particular CM that possesses specific design expertise in a technology that lends itself to their products. In this case, the CM becomes a design partner as well as a source for manufacturing services. The OEM achieves a significant benefit by leveraging the supplier's expertise, especially as it relates to technology and the ability to rapidly bring a product to market. However, if the OEM possesses the necessary design expertise in-house, then attention can be focused upon choosing the best manufacturing partner. A third approach involves the collaboration of the OEM, a design firm with the requisite skill set, and a CM who specializes in the production and administrative model that best matches the OEM's requirements. A carefully planned and executed strategy in any of these methodologies can generate significant advantage to the OEM.

An OEM who does not want a collaborative partner would be expected to provide very clean and documented packages that tell the CM exactly what they want. An OEM partnering with a CM on NPI will work a lot from concepts. They may have prints and documentation, but need prototypes to validate the design. Questions such as "How do we make the product better? How do we make it more repeatable for manufacturing? How do we build it with lower lead times and less cost?" are ones a qualified CM can help answer. If you need support to build it better, faster, and cheaper, it's critical your EMS partner embodies the value-added engineering assets for successful NPI.

NPI requires that, at the bare minimum, the supplier is developing the process needed to build the product. But in some cases, the OEM may require product development assistance at the CM level as well. If this is your expectation, then make certain your supplier either has the appropriate internal design resources to support your requirements or, at the very least, has access to external resources that can quickly and seamlessly be introduced to the process.



ERP is a key capability.

Enterprise Resource Planning (ERP) is a critical element in the EMS partner selection process. A robust ERP solution enables a vendor to respond quickly and efficiently to expedites (schedule pull-ins) and de-expedites (schedule push-outs). Usually hidden below the waterline, the supplier's ERP process manages both inventory and capacity.

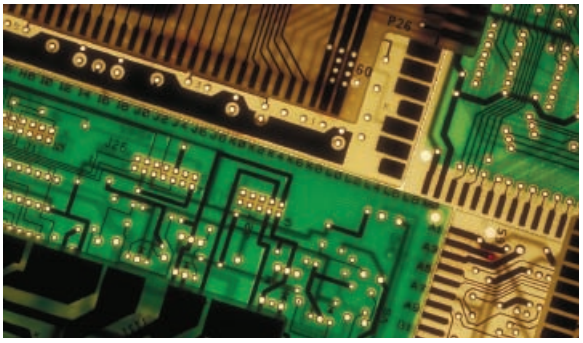
Typically, the majority of the CM's cost is tied up in material. Ineffective inventory and purchasing controls can drive material

levels out of alignment with current and short-term demand. This ultimately increases liability to the customer and/or affects the CM's ability to respond to schedule fluctuations.

The OEM should look for these capabilities when evaluating the supplier's ERP solution:

- A closed-loop system that quickly identifies misalignment and initiates action to correct material and production bottlenecks upon discovery plus incorporates a communications system that notifies the OEM
- A robust process (software/people/procedures) that generates timely information for immediate action by front-line people
- A system that identifies production gaps and balances supply with demand

Remember, ERP systems exist because resources such as material and labor are finite. The good ones are very effective at reducing the risk associated with late deliveries and expedited demand. A vendor's ERP solution should accurately track the entire process, from material acquisition to final production. Make sure it identifies problems virtually immediately so resources can be deployed to bring the process back into alignment.



Buy on total acquisition cost, not price.

Do you focus solely on the selling price when buying EMS services? It's important, but the selling price should only represent a starting point in calculating the true cost of contract manufacturing. Your end game must be total acquisition cost (TAC).

TAC represents the total cost of doing business with a supplier. Theoretically, if all goes as planned, the selling price makes up the total cost. But invariably, problems occur which add to that cost. TAC is commonly made up of variable costs. When a supplier delivery is late, it might require increased expediting from your purchasing department and overtime from your production line. Whether you tabulate these costs or not, they do add to the price you pay for the product. If a component is defective and is not discovered until functional test, then it may require disassembly, repair, reassembly, and retest. The costs associated with these extra activities are part of the TAC. And of course, if the problems are significant enough to affect your customer relationships, then the costs could include the loss of future revenue. The bottom line is anything that forces diversion from your critical path can potentially increase TAC.

Best-practice OEMs have systems that can measure TAC and use it for EMS supplier evaluation. These systems assign value to intangibles, such as the ease of working with a vendor and their ability to expedite. An OEM assessing a CM must be able to capture the additional elements of the relationship that add cost—not just unit price.

Here's an example. An OEM has a system that measures TAC by weighting supplier attributes. Two suppliers are on the preferred list. Supplier A is approved at a higher level than Supplier B because of performance. They both quote the same job. Supplier A comes in at $10 per unit, Supplier B bids $9. But the OEM adds $2 per unit to Supplier B's price because he doesn't deliver on time, quality isn't as high,

and flexibility isn't as good. So now Supplier B's landed cost is $11 per unit. Based upon that comparison, Supplier A will probably win the job. Even though Supplier B's selling price is $9, the TAC ($9 plus all of the pain and aggravation that goes with it) will actually cost the OEM more.

Avoid the knee-jerk reaction of deciding exclusively on quoted selling price. While it is important, make sure you know what you're getting for that price. Calculate the TAC and avoid the pain of choosing the wrong partner.

Summary

Selecting an EMS partner for medical devices is a strategic process. A successful long-term relationship will pay lasting dividends in lower costs, higher productivity, greater creativity, and increased velocity to market. But the stakes are high. Virtually every decision is a minefield. Don't take anything for granted. Use these guidelines as a checklist in your supplier evaluation and selection process.

Bouncing from supplier to supplier is a painful, expensive, time-consuming process. Choose wisely and your CM becomes an integral link in your supply chain that generates competitive advantage for years to come.

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About Federal Electronics

Founded in 1948, Federal Electronics, Inc. is a leading electronics manufacturing services provider. Based in Cranston, Rhode Island, the company serves the needs of original equipment manufacturers and government contractors by providing comprehensive production solutions that lower cycle times, control and reduce costs, and create flexible supply chains that are responsive to volume variability. For more information, visit www.federalelec.com.

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