

CONSIDERATIONS FOR SELECTING COMPONENT MANUFACTURERS

Surgical Robotics Product Development

When it comes to advising and supporting surgical robotics teams who are working on new products, we find they get frustrated because for one of two reasons:



Their current supplier can't scale beyond prototypes into production



They only want production volumes and don't support prototype

Our customers describe themselves as innovative, and they value dialogue around innovation throughout the product lifecycle.

That's why Hirsh continuously builds capabilities to provide <u>DFM</u> consulting, prototypes, AND production to support leaders and engineers.

Consider the following criteria when considering component manufacturers to support surgical robotics product development.

Considerations for Prospective Suppliers

- General
- Prototype Stage
- Production Stage
- Long-term



General Considerations

Aim for High-Precision Capabilities

Surgical robots require components that meet extremely tight tolerances to ensure accuracy during surgeries.

It is safe to assume that, of the entire population of manufacturers who appear capable of producing components like what you need, based on your requirements, you are looking for a supplier in the top quartile of its peers.

Look for Materials Expertise

Suppliers should know and understand how to work with biocompatible and durable materials (e.g., medical-grade metals and plastics), necessary for components that interact with human tissue.

Prior Experience with Medical or Robotic Components

Suppliers should have experience producing similar components, especially in industries like robotics, aerospace, or medical devices.

Surgical robots frequently need custom components, and suppliers should also be able to help design and manufacture tailored parts when COTS options are unavailable.

Plan for your Company's Long-term Success

The decision criteria for selecting a prototype supplier differ from those of a production supplier, but you should recognize the savings and synergy you can realize if you find a company that can support both.

Selecting a prototype supplier at the outset that you know you'll move away from when you're ready for production can cause problems at a critical phase when you need to impress customers with delivery and capture market share quickly.



General Considerations

Meet the Owners

Almost without exception, your supply chain will include a component manufacturer(s) who is a small business (<\$5m in annual revenue) or a lower-middle market company (<\$150m). Most of the ~6 million small businesses in the US (unfortunately) don't get passed on to a second generation. Owners are often motivated to create a lifestyle company and have unlimited liability and limited access to capital.

You want to grow and minimize long-term costs, so look for suppliers who wish to build equity rather than take it out of the company. It's easy to tell - they will be the owners who reinvest to build their business for the long term and will be the right companies to help you succeed. Understand your supplier's ownership structure, growth strategy, and succession or continuity planning perspective.

If you anticipate your company may be bought by a large or public medical device company in the coming years, consider how your relationship with your strategic supply partners may play a role in valuation. The scalability, logistic simplicity, and innovation partnerships you develop early on can help drive valuation and be a differentiator for a buyer.

Train your Procurement Team

Today, you probably don't want to quantify the cost of poor quality and supply chain risk very well. You also don't want to be in a position where quantifying the cost of poor quality is clearly necessary since that means a problem has existed for some time; you may be "treating the symptom". To help avoid this, build your procurement team's operational and business acumen.

Procurement teams need to understand your products well enough to find and select the right strategic suppliers who can produce the work and look for ways to add value, rather than assuming that the supplier with the lowest price represents the highest value offer.



Prototype Stage Considerations

Learn about prior R&D Efforts

Component suppliers generally have smaller R&D budgets than OEMs but it's preferable to work with teams who have demonstrated strong R&D partnerships with customers in the past – they can help you develop the next-generation components and subassemblies you need.

A strong supplier will provide engineering collaboration, helping solve technical challenges and improving robot performance. If you want a supplier to develop new manufacturing technology for your robot or achieve something that hasn't been done before, the supplier may be challenged to meet lead times and OTD targets due to technical uncertainty.

Dialogue across stakeholders and functions to align expectations at this stage is healthy since unexpected challenges can (and do) arise. As a rule of thumb, plan around the idea that proactive design for manufacturability work on the front end will pay off 10x while fixing design issues in production will drive costs up by 10x.

Evaluate NPI Resources

If a component supplier operates in a high-mix environment, your prototype project may compete for capacity with the supplier's current production work on shared resources. Determine if your prospective supplier has dedicated resources available for your project or – at a minimum – has strong tendencies to escalate and resolve issues promptly during NPI.

In addition to technical skills, try to find suppliers with a sense of urgency and good communication practices so your team can make timely decisions with you as progress unfolds. While periodic face-to-face visits are smart and conventional, these days make sure you find a team that's fluently using digital collaboration tools with customers.

There's a limit to how much engineering talent exists in the country, and talented team members are an important factor in achieving milestones for high-end product development and testing. You'll be more successful during product development and testing stages if you select the right team than by achieving the lowest price.



Prototype Stage Considerations

Confirm Cutting-Edge Technology

If you're pioneering work in surgical robotics, you should seek suppliers with the latest manufacturing technologies. Suppliers should confirm that the necessary component tolerances fall within the equipment's specifications for accuracy and repeatability.

Suppliers should know and understand emerging techniques, such as automated inprocess quality controls, high-mix automation, a set-up reduction program, and/or software that controls and mitigates variability in production support activities. When a supplier has these in place, it validates the company has a deeper bench of highly trained team members and has made a consistent, broader commitment to technical excellence.

There is always a shortage of highly trained personnel, but manufacturing PE groups with short holding periods (~3 years) are especially susceptible to neglecting talent development; this is a slow-release poison for performance. It is ultimately bad for customers when it's identified and costly to fix in skills-based roles where the industry struggles to scale training.



Production Stage Considerations

Plan Production

Talk with your prospective supplier about your likely volumes to check if they can scale production as your deployment ramps up – particularly if your robotic solution is considered relatively portable, affordable, and user-friendly for staff and healthcare providers.

If they can't, you should know expanding capacity may not be possible due to facility constraints or cost. If expanding capacity is possible for the supplier, lead times may be long and the costs of doing so may not have been carefully evaluated by the supplier during initial DFM conversations.

In tandem, evaluate the age and utilization of existing equipment and estimate the ratio of a supplier's sales growth to capital investment in recent years.

Align on Adaptability and Communication

Suppliers should be flexible enough to modify designs efficiently or produce different volumes based on demand fluctuations. Accept that expectations need to be maintained and aligned across the supply chain.

Proactive, concise, and regular exchanges about forecasts, lead times, and Economic Order Quantities (EOQs) can keep supply chain teams on track throughout a product's lifecycle and avoid costly delays.

Ask about Delivery Times

Manufacturing can present unique execution challenges. High-performing suppliers have a culture of continuous improvement and consistently work to enhance their culture, systems, and technology.

High on-time delivery is not easy, but consistent results are easier to obtain with production work than with product development.

You should expect a strong supplier to be happy to discuss their performance and related improvement initiatives with you (if appropriate).



Production Stage Considerations

Confirm Repeatability

Verify if a prospective supplier can consistently reproduce components with exact specifications, avoiding variations between batches. Suppliers should demonstrate SPC capabilities at larger volumes, but at smaller volumes, look for documented processes and inspections, training programs, and a culture that fosters teamwork and low turnover.

Determine their Approach to Quality Assurance

Consider companies whose investments in metrology equipment are as impressive as the production equipment. Look for suppliers who build quality into everything they do rather than bolt on a sluggish "paper tiger" Quality Management System (QMS) that can drive costs up and slow innovation. Once the design is stable, great suppliers can enable you to adopt Dock-to-Stock (DTS) for savings.

Avoid Regulatory Risk Upfront

You should select suppliers who adhere to medical device regulatory standards such as FDA regulations or CE marking. Complete traceability, validation, and regulatory documentation for the materials and processes used in component manufacturing are essential.

Outline Future Options for Supply Chain Integration

As late-stage prototypes ramp into production, you may enter an awkward procurement phase with a mix of prototype and production-capable suppliers. Once a product is on the market, engineers need to be redeployed to the next project. If you want to invest more into design than building an assembly and test capability within your team, selecting a contract manufacturer to oversee product delivery may be the right decision.

Selecting a contract manufacturer is a separate topic from this discussion, but you might first ask a proven component and subassembly manufacturer if they have the capability to take on more responsibility for supply chain integration and initial box builds.



Long-Term Considerations

Align on Long-Term Cost Optimization

While quality is critical, cost competitiveness is also important once production ramps up. You should convey an expectation that a supplier balance precision and quality with affordability.

Work with teams who are profitable enough to reinvest on your behalf but also value your sustainability enough to optimize processes and share verified cost savings.

Test the Customer Service Early

Expect suppliers to provide technical support, promptly handle issues, and communicate well. Great suppliers know your business, anticipate your operational needs, and run their business profitably.

Conversely, your procurement team's demeanor and communication with suppliers in production can impact your supply chain risk. The best suppliers can – and do – select their customers as carefully as you try to select them.

Consider Maintenance and Replacement Support

If applicable, a supplier who provides ongoing support for maintenance, repairs, or component replacements can simplify your business and allow your engineering team to remain focused on broadening your robot's procedural range, helping providers integrate your solution, and designing the next generation of your solution.