

Guide to Outsourcing: Medical Machining

Stricter quality standards, increasingly complex designs, difficult materials, and shrinking budgets can make choosing the right contract machinist a daunting task. But before you resign yourself to tired out legacy relationships and heaps of old school directory listings, take a few minutes to review these few practical guidelines to help you make the right decision. (Besides, it's not really procrastinating if it's work related.)

As budgets get tighter, OEM's are looking for more value-added services from their machining partners: expanded capabilities, a broader materials knowledge base, and increased technical acumen.

Material World

Contract machinists should possess a comprehensive knowledge of the mechanical properties and machinability of commonly used medtech materials, such as the full range of titanium alloys and the behavior of various stainless steel series. Look for suppliers who have an extensive inventory of these and other appropriately graded materials, as well an experienced network of

sourcing partners.

Checklist for Success

- o Raw materials knowledge
- Versatile and advanced tooling capabilities
- Innovative, experienced machinists who can make smart tool selections
- o Tool-wear monitoring
- Established quality system
- Multitasking machines
- Adaptable software

Cool Tools

However, raw material alone doesn't make a device. Most machinists will tell you their work is as much an art as it is a science; the right combination of material knowledge and tooling proficiency ensures a collaborative relationship early on in a device's development phase that can lead to long-term profitability. Your machining partners should be able to efficiently produce prototype parts *and* their subsequent iterations in order to shorten a device's time-to-market. Practically, this translates to versatile CNC capability, including multi-axis and live tooling centers to reduce delivery times and set-up costs.

Remember, medical device machining requires suppliers to produce complex geometries from difficult metals, while holding close tolerances. Thus machining small-batch, complex parts requires not only material and machining expertise, but also innovative and experienced tool selection. The best suppliers offer creative solutions and a transparent view of their limits.

Quality Time

Notably, the metallurgical properties such as durability and corrosion resistance that make for ideal use in medical devices, also make for high tool-wear rates that can drive up costs and affect part accuracy. OEM's look for machining suppliers that produce exact dimension, burr and particulate free parts throughout any number of processes with consistent results.

That means in addition to continuous, automated tool-wear monitoring, machining partners need to have up-to-date quality systems (specifically ISO 9001:2008 or higher) to monitor process variables and provide custom statistical reports.

Many components require specific surface finishes and treatments. OEMs are particularly interested in making partnerships with machining suppliers who can offer inhouse secondary services such as sandblasting, lapping, electropolishing and passivation.

Small Stuff

As medical device applications such as guide wires, stents and drug delivery systems strive to go smaller, so too must their suppliers. Multi-tasking tooling capabilities and bar-fed milling machines (like those showcased at last September's IMTS) could be a promising answer to the ever-growing demand for smaller parts in larger volume.

Tech Talk

Machining increasingly complex materials with tougher tolerances and specifications will require suppliers to not only maintain up-to-date materials competency, but may also involve investing in automation or advanced CAD/CAM technologies. Already, software has developed to learn based on the ways machinists customize and order processes. Suppliers should be able effectively leverage their technology to adapt to your evolving needs.

Because life sciences devices require time and testing, you and your contract machinist will likely be spending quite a bit of "time" together, which is why it's especially critical to choose a supplier you can envision yourself working with for the long haul. And now that you've read this, get out there and pick a good one!



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