

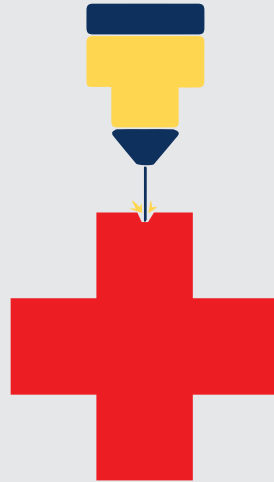
What to look for in a Medical CNC Machine Shop



PROTOMATIC

Life-saving precision.

What to look for in a Medical CNC Machine Shop



When it comes to machining parts for the medical industry, all CNC machine shops aren't the same. The demands of the medical field are well-documented, and rightly so. Not only are the parts often highly complex, they also require extreme precision. Indeed, lives are at stake and close enough just won't cut it.

That's why it is so vital that you work with the right precision CNC machine shop. You need someone who has the equipment, the engineers and machinists trained in the latest techniques and technology, and a steadfast commitment to life-saving precision that runs throughout the company.

With a variety of shops to choose from, with most touting the same skills and services, how do you know which one to choose? That's the purpose of this eBook: to give you tips on finding a partner who will earn your confidence from design through manufacture.

What to look for in a Medical CNC Machine Shop



Is the shop well organized and clean?

Extraordinary cleanliness is vital in your medical CNC machine shop. Protomatic, located in Dexter, Michigan — minutes from Ann Arbor — is housed in a modern, bright facility that is nearly hospital-clean from the reception area to the plant floor. Before you choose a CNC shop, take a trip to their place and take a tour. If anything seems not quite right, it's probably not quite right for you. First impressions really do count.

If you are conducting a tour, look for a great HVAC system, since controlling temperatures in the summer is typically the most difficult. Ask to see temperature recorders in manufacturing and inspection areas and ask how well the building regulates temperature. This is critical for high tolerance work.

Other environmental observations include air filtration, which not only creates a comfortable work space, but also a cleaner work space. The levels of noise and lighting are critical too, as communication and sufficient light is required simply to “see” product differences.

Watch glasses and microscopes are a plus and required for detailed precision deburring of metal and plastic parts.

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Does the shop have modern multi-axis, multifunction equipment?

The medical field is increasingly demanding parts of more complexity and tighter tolerances. This is why it is so important that the medical CNC shop you choose has the latest multi-axis, multifunction equipment.

Here is why multi-axis, multifunction equipment is important.

CNC machines are very precise, but the overall accuracy of manufacturing a part is related to the machine and the way a part is processed. Errors in the machining process can occur in many areas, from building temperature to cutter deflection.

One of the most significant is related to errors than can happen every time a part is clamped, unclamped and reclamped. The act of clamping on the most precise machine with precision collets is typically 0.001" (25 microns). So the order of operations is critical, and multi-axis machines have an advantage in minimizing error from multiple operation clamping.

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Simply, they do more work without a clamp/reclamp. For instance, an operation that manufactures on a 3-axis CNC, first conducting work on the top, then sides, then the end, and finally the bottom, is four operations.

These four could be replaced with a 5-axis machine, performing the first operation machining the top, sides and end work, and a second operation with finishing the bottom. Wow, only two operations! This 5-axis two-operation process will provide more accurate parts than the 3-axis four-operation process simply due to reduced clamping error.

Regarding multi-axis equipment capability, Protomatic has a well-balanced list of equipment including CNC 5-Axis Machining Centers, CNC Turning Centers, and CNC Multi(8)-Axis Machining Centers. It also has a number of conventional 2-, 3-, and 4-axis CNC machines for simpler work. Equipment for vertical integration for the manufacturing process of your specific part should be observed, such as wire and sinker EDM machines or special finishing equipment.

However, it is the multifunction equipment that is front and center for machining medical parts.

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One example of a part produced on these machines is a component for a medical device for a femoral procedure. Many shops may run the part across up to seven machines such as a saw, lathe, gun drill and mill. Protomatic completes the process in one setup on one of its multifunction turn-mills.

Instead of taking 25 hours of total setup time per 100-piece lot and over three hours of machining time, the use of much more modern equipment has reduced the 25 hours to 4, and the 3 hours of machining to 90 minutes per batch.

In an era of the Affordable Care Act and its taxes on medical devices, the resulting cost savings take on added significance.

Protomatic also utilizes CNC lathes to produce relatively short parts that require multiple turning, milling and drilling operations. Machining prototype and production with the same style of equipment helps ensure accuracy and product consistency, while minimizing setup time, work-in-process and how often a part must be touched.

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What special capabilities does the shop have?

Protomatic also has very specialized equipment not typically found at a job shop – specialized finishing equipment such as micro-blast deburring, vibratory, and magnetic tumbling. Microscopes enable the machinists at Protomatic to “see and address” and provide the attention to detail required in critical parts. Other processes include manufacturing rubber molded parts, welding, forming and bending to accent the customer’s special needs.

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What processes does the shop outsource?

While you want your CNC machine shop to have the capabilities to handle most projects themselves, there are occasions when outsourcing is simply a better solution. You will want to know what processes your shop outsources.

For instance, some shops have added processes such as laser welding and laser marking to their in-house capabilities to reduce delivery time of medical components to customers. Whenever a process can be completed in hours instead of days by moving it in house, it is certainly worth consideration.

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However, other processes are best left trusted to outside partners. Rather than dealing with nitric acid (controlled substance) and other chemicals, many shops outsource anodizing, passivation, heat treating and electro-polishing. By not bringing these secondary processes in house, the shop can focus on its primary job of precisely machining medical components and devices.

These are just some of the processes a precision CNC machine shop might outsource. It is important that you know exactly what they will and won't be doing. And if a process is outsourced, it is wise to keep asking questions about that outside supplier and its capabilities until you feel totally comfortable.

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Does the shop meet regulatory compliance?

Because of the complexity and precision required of CNC-machined medical devices, many CNC shops have added another level of quality assurance to existing standards of safety and efficiency. Make sure the shop you choose has taken that extra step.

Protomatic is not only ISO 9001:2008 registered, but also ISO 13485:2003 registered.

ISO 13485 is the medical version of ISO 9001; and adapts the ISO 9001 process-based mode for a regulated medical-device manufacturing environment. However, there are some important differences.

While ISO 13485:2003 is based on the ISO 9001:2000 concept of Plan-Do-Check-Act, it is particularly designed for regulatory compliance. A better way of thinking is to look for companies that embrace traits such as:

- Customer-driven attitude
- Leadership commitment
- Engagement of employees
- A process approach
- Improvement-based operations
- Evidence-based decisions
- Relationship management (suppliers, internal)

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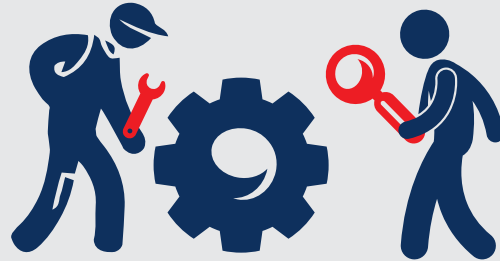
ISO 13485 was, in fact, written to help medical device manufacturers design quality management systems that better establish and maintain the effectiveness of their processes. It ensures consistent design, development, production, installation and delivery of medical devices, making them safe for their intended purpose.

Risk management is a key requirement for ISO 13485 certification. That's where ISO 14971 comes in. It helps manufacturers meet the increasing global requirements to implement not only quality, but also full risk-management systems throughout the life cycle of the medical devices they produce. ISO 14971 also satisfies the risk management requirement for IEC 60601-1, pertaining to medical electrical equipment and systems.

ISO 13485 is significantly more difficult to achieve for a CNC machine shop. When a shop becomes certified, here's what it means to you:

- An effective quality management system is established
- The efficiency of processes and reducing waste is increased
- A focus on risk management is enhanced
- Responsiveness to issues and nonconformities is increased
- Safe, quality medical devices are ensured

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Does the shop have the capacity to manufacture and inspect?

If you ask engineers, machinists and inspectors, “What is the largest technical problem that will be experienced in the next 5-10 years?” many would say speed and accuracy of inspection. Inspection instruments are expensive and all have limitations.

While CMM inspection machines are very capable, the demand for flawless parts requires even better and faster inspection technology. In most applications, critical features have to be inspected at 100% sampling size. This creates cost, especially when more time is spent inspecting parts than manufacturing them.

To be as efficient as possible, Protomatic uses many types of inspection devices including XRF to confirm raw material alloys, and tally surf to measure surface roughness. Also, to measure part quality, optical comparators, vision systems, laser micrometers, optical/3D microscopes and CMMs are all utilized.

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Is the shop process-validation capable?

For medical products, a formal validation process must occur. This process has specific defined steps. The basic validation plan is designated by letters and a description: IQ-Installation Qualification, OQ-Operational Qualification, and PQ-Performance Qualification.

Even the above-average ISO-9001 job shop simply does not understand the process. This process involves setup of equipment, monitoring of equipment, as well as controlling the process with advanced control plans and PFEMA. This is supported by Gage R&R for critical measurement devices. This needs to be performed for every medical part.

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What does the shop do in the way of training?

An employer that invests in training for their employees and educates their customer is another key attribute when selecting any contract manufacture.

Employee programs should include quality management system training, safety training, and procedural training. Additional skills training and cross training are essential.

Customer programs may be more subtle. These can be newsletters, blogs or on-site events such as capability tours. The message here is that both supplier and customer have to work on the relationship and a common understanding through mutual education.

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Bottom line

Choosing the right medical CNC machine shop is critically vital. Capabilities, capacity and dedication to excellence are extremely important when making the choice. With our ongoing commitment to “Life-Saving Precision,” Protomatic has the tools, talent and processes in place to provide orthopedic, cardiovascular, dental and optical medical components of the highest quality.

We would be glad to answer any questions you might have about CNC precision medical machining. Please contact our Managing Director, Doug Wetzel.



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About the author: Doug Wetzel is Managing Director of Protomatic. Protomatic is a CNC precision machining shop specializing in prototype and short-run-production components for the medical, aerospace and other technical industries. Because of the critical nature of the parts they design and manufacture, the emphasis is always on Life-Saving Precision.