INDUSTRY NEWS

NOVEMBER 2008 EDITION

San Jose Contract Manufacturer Receives ISO 13485:2003 Certification for Medical Devices and Implants

SAN Jose, Calif.—MASS Precision, Inc., an ISO 9001:2000 certified provider of precision sheet metal design, fabrication, and assembly services, is ratcheting up its services for the medical industry. Reported to be the first design and manufacturing company on the West Coast to be ISO 9001:200 certified, Mass understands the value of process control, real time data, accurate records, and effective reporting—all essential in an industry that has little tolerance for defects in design and manufacturing. The company recently upgraded to ISO 13485:2003, an effort that took only 105 days, according to James R. Johnson, director of the ISO 13485 certification effort.

"This is largely due to the foundation laid down in 1993 (when the company achieved ISO 9001:2000 certification) and the management team's commitment toward doing it right the first time," says Johnson, who now focuses on medical manufacturing after formerly serving as Mass Precision's Director of Quality of Assurance. "Mass was ahead of the curve and used its processes to organize a massive document control, records, and traceability program that is typically required for the FDA's Quality Systems Requirements. This is Mass's greatest strength—the training of its people!"

According to Johnson, the company's work for the medical industry includes the production of precision electro-mechanical assemblies and sub-assemblies composed of sheet metal. In addition, the company manufactures welded frames and machined components for small-to-large assemblies, such as patient-positioning tables and surgical equipment that work interactively with a small linear accelerator. Patient-positioning tables require movement along x, y, and z axes, along with pitch and roll, and movement needs to be accurate to sub-millimeter positioning while operating within a surgical environment. Applications for the company's components also include electrical power controllers; console assemblies; laser positioning alignment and calibration tools; and robotics for positioning of medical instruments or beams.

To manufacture these components, the company uses a variety of numerically-controlled vertical and horizontal CNC machining equipment, high-speed laser cutting machines, turret punch presses, and punch/laser combo machines. Mass also employs a robotic welder and a water-jet cutting system that's particularly suited for titanium orthopedic implants because it reduces heat from friction and holds the tight tolerances required. Turnkey assemblies are completed in a 12,000-square-foot ESD assembly area and in multiple clean or environmentally controlled rooms. Mass also performs testing (hi-pot, ground, functional and software).

"We've been serving the most stringent requirements for over 20 years, and the lessons learned from a rapidly globalizing marketplace taught us controlled, accelerated product turnaround, near-zero defect quality ratings, and an almost unheard-of degree of product complexity," says Al Stucky, CEO. "I'm certain as the medical industry seeks to outsource more and more, they will benefit from our learning over the last 20 years."

In one case, an OEM needed to find a replacement supplier for its patient-positioning table. After working with the previous supplier, who could no longer produce the table and had little documentation that could be distributed, Mass produced a full turn-key package that included manufacturing process instructions, inspection checklists, photographs, tests, and verification and validation programs. "In some instances, Mass needed to reverse engineer or design new components because nobody had the specs," said Matt Stucky, program engineer. The resulting package of CAD files, manufacturing drawings, bills of material, and assembly instructions became the foundation for the launch of the new product.

Designing for manufacturing, test, reliability, and maintainability proved particularly important. As Mass finalized the product development and manufacturing process, its staff viewed the build from a final assembly perspective and broke down the entire build/assembly tree into easy-to-assemble sub-components. By combining components and designing the assembly process, the company was able to reduce cost and improve process integrity.

In field trials, several difficulties were encountered in producing a consistent movement of the patient-positioning table over its range of travel. Mass worked with the suppliers of the slide and railing components to understand their capabilities and process control; it then initiated a change that reduced variance in the edging of the railing that was causing the problem. The result, according to Mass, was a drastic decrease of variation in the slide movement along the y axis.

Medical device makers are most concerned about the issues of patient care and product reliability, according to Johnson. He mentions four key areas that are essential to reliability: process control that adheres to designs; change control; traceability of materials through plating and painting; and monitoring of processes that cannot be verified except after delivery. Accurate recording and dissemination of data keeps the customer's team and Mass's team on the same page and ensures reliability throughout the new product introduction and product life cycle process.

Mass takes full advantage of 3D modeling and is able to import the customer's software and produce manufacturing drawings that are linked to its ERP program for a complete paperless environment. Operators can pull up prints, specs, process instructions, procedures, and, where applicable, changes or new engineering links that are occurring real time in any one of the company's four buildings. In addition, the company's enterprise resource planning (ERP) program is particularly suitable for ISO 13485 medical device requirements because of traceability and process control.

"We can tell you what day a particular sheet of metal was ordered, which work order it was used in, and what final assembly it went to," says Len Bushnell, director of operations. "This is necessary for traceability, records retention, and risk mitigation."

Mass's turnkey capability allows the company to peer into operations via the MRP database and see inventory, build status, and production schedules. As market conditions change, it's often not easy for customers—especially a new start-up or a company launching a new product—to predict deliveries. But with the aid of real time information, Mass is able to react quickly.

"Knowing what to look for during our Failure Mode and Effects Analysis (FMEA) from a manufacturability perspective gives a customer and engineering an opportunity to prevent defects by designing for assembly," says Dan Heiman, quality manager. "Seeing the data collected by our on-line SPC and placing it on the web helps customers become more involved when changes are requested."

Johnson says that Mass has been doing contract design since the early '90s and has a "unique approach to rapid prototyping." The company can use its CNC equipment to conduct "use" testing for product life cycle testing; it can also reverse engineer older products and can often redesign components to improve manufacturability. Mass also employs a New Product Introduction methodology that provides real time feedback during the build in order to refine the manufacturing process.

"As a contract manufacturer, our proprietary service comes from our focus on technology and customer service," Johnson says. "This provides the overall details for manufacturing, inventory, packaging, shipment, and installation. These choices are often secondary choices, but are significant issues to consider."

For more on Mass Precision, visit www.massprecision.com or **enter E25.**

New Division Creates Overnight Prototypes

VALENCIA, Calif.—Solid Concepts, a supplier of rapid prototyping, direct digital manufacturing, tooling, and injection molding services, has expanded its outsourcing services to meet the growing needs of design engineers in a broad spectrum of industries, ranging from aerospace to automotive, medical, and electronics assembly, among others. The expansion is centered on a rapid prototyping service and its corresponding website, www.ZoomRP.com, which provides a three-step process for designers to acquire fast access to prototypes.

If an order is placed by 5:00 p.m. EST, the finished part can be built and shipped for morning delivery the following day. The company expects to expand from its use of the standard, rigid white prototype material into "whole other spectrums of fast, available prototypes, using a variety of materials and colors" in the following months.

Solid Concepts uses high-speed PolyJet™ technology to provide prototypes quickly and reliably, the company reports. The PolyJet system builds parts in 16-micron layers with exceptional detail and edge visualization, and is suitable for high-quality prototypes and master patterns. PolyJet prototypes are best-suited for applications in which accuracy, detail, and surface finish are critical and the part fits within a 5-inch x 5-inch x 5-inch build volume. The maximum PolyJet build volume is said to be 19.3 inches x 15.4 inches x 7.9 inches.

For more information, visit www.ZoomRP.com or **enter E26.**

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