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Brent Bollong
President



Michael R. Lolli
Chief Financial Officer

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Pushing the Boundaries in High Precision Medical Device Manufacturing

\$15



COVER STORY



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By Laura Davis

Taking a medical device from concept to the commercial market is no walk in the park. It requires clarity of vision, focus, and the right manufacturing partner who, in addition to sharing the creator's passion, holds the technical capability to bring their vision to life. Auer Medical/Precision is one such partner.

"We had produced and co-engineered components for medical devices for over two decades and in 2014, we decided to leverage our strength to achieve the goal of becoming a contract manufacturing organization (CMO) for medical devices," states Brent Bollong, President of Auer Precision. Subsequently, the company attained its ISO-13485 accreditation and hired skilled professionals to complement their organization. Soon, they established their position in the market and were servicing some of the world's top diagnostic device companies. The experience helped fortify Auer's strategy of focusing on point-of-care in-vitro diagnostics as a subset of the broader medical device market. The company later added an applications lab that provides near-production quality prototypes via a multitude of manufacturing techniques, helping customers develop and refine their product—with the correct tolerances—for high volume production.

Auer's capabilities include 3-D modelling, digital manufacturing and extensive metrology that ensures quality and process optimization at both the tooling and end-product level. Auer's engineering and quality documents are made available via their web-based secure content management system, providing clients

PUSHING THE BOUNDARIES IN HIGH PRECISION MEDICAL DEVICE MANUFACTURING



“Our long-term vision is to really be a true tier one, turnkey contract manufacturer and we are on the path to achieving that goal”

access to their critical data from anywhere in the world, 24/7. The company’s client engagement thereby entails total and uncompromising transparency.

The systematic approach to high precision manufacturing

Auer’s approach to delivering services can be broadly broken down into three distinct phases, the first of which involves Auer thoroughly examining the feasibility of manufacturing the product in question, including material characterization, production methods and unique equipment/facility requirements. Secondly, the company deploys its engineering resources to assess the progression of manufacturing requirements, from low volume to fully automated high-volume manufacturing, to achieve the throughput, budgetary and unit cost requirements of the client. Finally, Auer’s regulatory and Quality Assurance team provides full validation services on the production lines upon launch of a commercial product with Auer capable of providing full Tier 1 supply chain management

for the ongoing support of the client.

Auer’s extensive manufacturing experience and breadth of engineering, automation and validation resources provides its clients a unique collaborative effort to bring their medical device from prototype to a high volume commercial state. Auer believes this provides a competitive advantage as compared to other companies in the space.

Exemplary success stories

Becoming a trusted supplier leading medical device companies is built on proven success. One such success story was Auer’s work with Accelerate Diagnostics, an in vitro diagnostics company providing solutions to drug-resistant diseases and hospital-acquired infections. Auer was selected as a result of its work in the development of challenging stamping and assembly solutions for the production of consumable cassettes for Accelerate’s ID/AST system. “Auer Precision is a professional, quality-conscious and solutions-oriented organization,” said Kurt Reinhardt, Head of Operations for

Accelerate, “They understood our needs and worked diligently to meet our goals.” Darin McDaniel, Head of Manufacturing for Accelerate added, “Our supply chain is steadily improving, and the time to consolidate is this year.” We selected Auer Precision based on their performance and ability to support our expected future growth.” Auer was later awarded Accelerate’s Tier 1 Supplier of the Year.

In yet another instance, a major diagnostics company facing design issues approached Auer for support. Auer first designed a high precision stamping line with high-speed vision capability to measure intricate stamped features in line at a 100 percent sampling rate. When Auer was later awarded the assembly of the finished product, Auer’s Automation Group expanded the vision and data gathering capabilities of the production line to verify all components were in place and present before sealing the cartridge to ensure the highest level of quality and accuracy. The company also validated a Zeiss coordinate measuring machine (CMM) to

measure the client's products directly – a first for the customer.

Another example include Auer Precision's capabilities in high precision grinding for fabricating the core components for mass spectrometers. Measured in the sub-micron scale, this was ultra-high precision work, with very tight tolerances; something that Auer Precision could deliver for the client on a macro scale. Since inception of the program, Auer has been a sole source provider of these critical components.



“ We really do feel like an extension of the companies we serve and we know how much our customers appreciate the dedicated resources we commit to their project from the very start ”

These capabilities all boil down to Auer's constant attention to quality, accuracy and service; the pillars of what the Company refers to as “Auer Excellence”. Auer's desire to be a premier provider of close tolerance assemblies involves the continued modernization of their equipment to deliver tools and product with absolute capabilities. In addition, they are strong believers in a highly specialized and well-trained team of technical

professionals. These two, the tools and the team, combined with nearly 50 years of high precision manufacturing experience, ensures Auer shall continue to expand its presence in the specialized manufacturing space.

Pursuing Innovation

Anticipating client needs is second nature to Auer Precision, which recently added another 100,000 ft² to their manufacturing footprint. Facility improvements, technology, and human resources are being added as well, all

in the pursuit of delivering high-quality contract manufacturing capabilities to their clients. With the success that Auer Medical/Precision has enjoyed in this field, they are currently experiencing accelerated new business activity; onboarding customers as a much more rapid pace and establishing a robust pipeline of projects at all states of commercialization. Michael Lolli, Auer's Chief Financial Officer stated, “From an organizational perspective,

Auer will continue to expand our medical manufacturing footprint given the largely dedicated space and specialized equipment needs of our medical customers. While we just added a sizable amount of new clean room facilities, we already have new projects slotted for a large portion of that area”. Lolli added, “With the industry moving to a more CMO model and Auer's continued investment in the Automation Group and Tier 1 capabilities, we expect our growth trajectory to remain strong”. Looking to the future, the company will explore growth capital and, in the long-term, address the need to add additional competencies via investment or acquisition.

To Auer, collaborating with their customers is a critical attribute of what makes them unique. Lolli states, “We really do feel like an extension of the companies we serve and we know how much our customers appreciate the dedicated resources we commit to their project from the very start.” While the medical diagnostics market is driving much of Auer's recent growth, the Company's other business lines, ranging from the design and manufacture of custom transport media products for automated assembly and manufacturing of semiconductor devices and other electronic sub-assemblies, to critical components for low-emission microturbines (green technology applications), are also experiencing robust activity.

“We think our core competencies are very unique. We have worked on many platforms products: electro-chemical, optical, opto-enzymatic and molecular diagnostics. We are developing a strong partnership ecosystem and are seeking complementary technologies. Our long-term vision is to really be a true tier one, turnkey contract manufacturer and we are on the path to achieving that goal.” Bollong concludes. 



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The annual listing of 10 companies that are at the forefront of providing Precision Manufacturing services and impacting the industry