Precision MicroFab Benefits from BSI's Diversity in ISO Certification.

"Big companies who won't look at a company without a quality certificate [from an accredited registrar] can now consider us as a vendor. That was the whole purpose – not just to show that we're reliable, but to get us in the door."

Chris Selley
President

Customer needs

- Dual certification in ISO 9001: 2008 and ISO 13485: 2003
- Procedures and policies that adapt to the structure of a small business
- Demonstrable reliability to global customer base
- Uphold best practices for procedures and policies
- Continuity with external auditor

Customer benefits

- Opens the door to industry leading customers
- Proof of compliance with quality standards
- Allow for company expansion and growth into device development
- Access to management training programs

Customer Background

Founded in 2002, Precision MicroFab LLC, based in Severna Park, MD, designs and manufactures microscopic parts and devices to fit customer-specific requirements. The team of experts at Precision MicroFab takes the time to understand client challenges and use their collective micro-manufacturing knowledge and experience to provide unique solutions. Services extend from designing and generating 3-D CAD models and complete engineering drawing packages, right through to fabrication and validation of the micro-devices from prototype to production. Additionally, Precision MicroFab specializes in just-in-time micro-manufacturing of parts. Their impressing list of clients includes NASA, Northrop Grumman, Abbott Laboratories, Boston Scientific, Zimmer, Goodrich, Honeywell, KLA Tencor, Johns Hopkins, Cornell and MIT.

Currently a small operation with a full-time staff of five, the company's goal is to attract larger clients, to expand its engineering and design services. Precision MicroFab serves the medical device, life sciences, microelectronics, and aerospace industries.

Precision MicroFab is a newcomer to the ISO quality certification world. According to Chris Selley, President at Precision MicroFab and the company's owner, the primary decision to become ISO 9001: 2008 and ISO 13485: 2003 certified was to comply with major medical device companies' requirements for quality and regulatory certification.

A medical device manufacturer's quality management system is the foundation for maintaining regulatory compliance, driving improvements, effectiveness, efficiency, and achieving stakeholder confidence in the manufacturer and

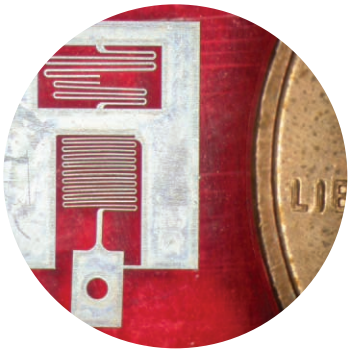
"Big medical device companies won't even consider a company without a [ISO 13485] certificate, can now consider us as vendors," notes Selley.

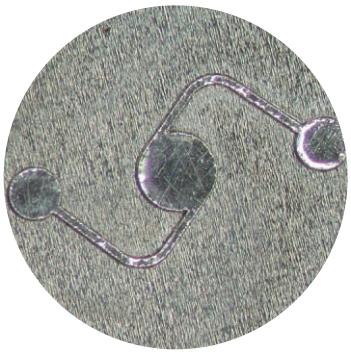
their products. The requirements of ISO 13485 provide the model for quality management system building blocks of success. Whether a medical device manufacturer is a single-site start-up, like Precision MicroFab, or a multinational corporation, an ISO 13485 certification indicates to all stakeholders that a medical device manufacturer is dedicated to bringing the highest quality products to market and that they are a manufacturer fully committed to quality and compliance with regulatory requirements.

The company embarked on its certification mission in April 2011 and successfully achieved both ISO 9001 and ISO 13485 certifications in December 2011.

Customer needs

ISO 13485 is based on the ISO 9001 process model approach, but has had some elements removed that are not appropriate as regulatory requirements and other elements added to better address the quality requirements of the medical device industry. As a globally harmonized standard, certification to ISO 13485 will meet most regulatory requirements in a host of countries including the EU. Additionally, certification to ISO 9001 may bring further business benefits as it reflects a much stronger commitment to customer service and continuous process improvement. Manufacturers who serve both the medical device market as well as non-medical technologies markets will find it very useful to consider certification to ISO 9001; or at the very least become compliant with its requirements. As this is the case with Precision MicroFab, they decided to seek certification under both standards.





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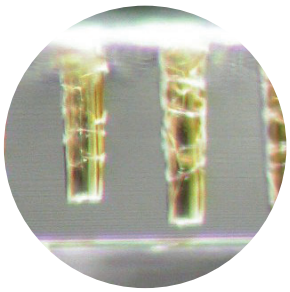
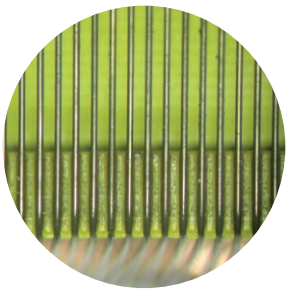
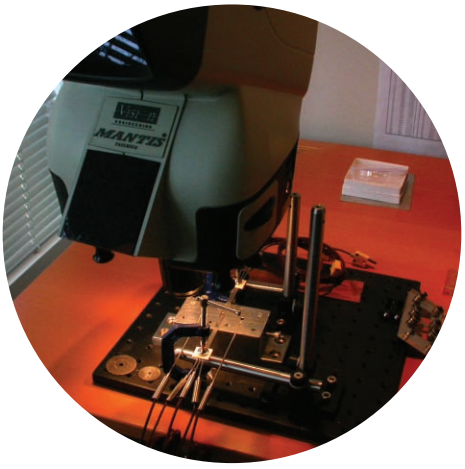




Selley explained that if a company is ISO 13485 certified, then it is relatively easy to qualify for ISO 9001. "As long as we had ISO 13485 we were on the path for ISO 9001," explained Selley. "ISO 9001 makes sure everyone worldwide is working under the same (quality) guidelines. When you have that certification, you're letting everyone (know) that you're following the same guidelines as everyone else." Selley says ISO 13485 is a very challenging certification because manufacturing medical devices requires compliance with a host of regulations. "Since we don't design and put devices onto the market, but rather manufacture devices based on our customers' drawings, we don't currently fall under those guidelines. But we wanted to have procedures in place so we can work with clients to design medical devices, micro-manufacture them and bring them to market, we'll be able to do that," he explained.

Becoming ISO certified is a daunting task for a company of any size. But for a company as small as Precision MicroFab, there were additional challenges that required specific attention. For example, procedures are typically assigned to certain roles or job titles. This works fine when the company being certified is large enough to accommodate all of the defined positions. However, it gets a bit confusing when one individual performs an assortment of functions. In searching for the right certification body, Precision MicroFab was looking for one that was flexible enough in its processes to work with a small company and could provide a high level of service at reasonable cost. Also, since Precision MicroFab was new to the certification process, they needed to feel confident that their external auditor would have a lot of patience, understanding and would provide adequate guidance while avoiding any conflict of interest.

According to Selley, the process took eight months from start to finish. In April, armed with instruction manuals on certification procedures, they engineered a production flow that worked for the company and complied with the certification standard. They signed on with BSI in June, and by the time of their stage 1 internal audit in early August, they had drafted a manual that contained all the procedures and forms, each one designed in-house. They met with the BSI auditor for the first time in August, who reviewed their progress and identified opportunities for improvement. The most important part of the process was making sure Precision MicroFab was found to be compliant with the requirements, policies, and objectives as outlined in ISO 13485. This required a lot of information gathering and hard work.

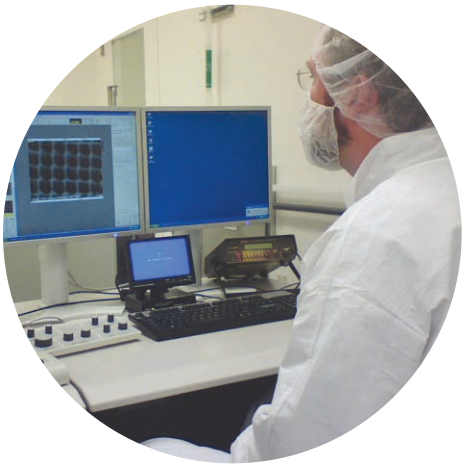


Benefits

The knowledge he and the rest of the team gained through learning about necessary procedures, combined with producing a procedure manual that contains all the procedures and forms that were all designed in house, has helped streamline the company's manufacturing processes. With two members of the team now certified as lead auditors, checks and balances are in place to maintain compliance. Being able to post the certification on the company website was a proud moment. Selley says the company has created a brochure showcasing the certifications to effectively market this achievement. One marketing benefit specific to BSI was the opportunity to participate in a case study. No other certification bodies Selley researched offered that opportunity.

As Precision MicroFab just received its certifications in December, the financial benefits have yet to be fully realized, notes Selley. However, he anticipates the certification to boost revenues as soon as Q2 2012. "We're hoping to be able to get in more clientele. When people visit our website and see our BSI certification, that lets them know we have a conforming management system," he explained. "Big companies who won't look at a company without a quality certificate [from an accredited registrar] can now consider us as a vendor. That was the whole purpose – not just to show that we're reliable, but to get us in the door."

"Just the process of becoming certified was beneficial to Precision MicroFab's growth," notes Selley.



"BSI's responsiveness was terrific. Whenever I had a question, they were right on top of it," said Selley.

Why BSI?

Regardless of a company's size, BSI stands ready to help navigate the challenging waters of certification. That's because for over 100 years, BSI has led the way in developing the concept of standards and making them relevant to your business. No other certification body can offer the expertise, knowledge and recognition that come with a BSI certificate. Additionally, the BSI auditing process delivers the outputs that manufacturers require of an effective audit, an experience that is predictable, transparent and responsive with consistent local and global resources, reliable office back-up, and accessible support.

BSI's flexibility when working with a small company was paramount to Precision MicroFab's decision to hire them as a certification body. Selley said the company's responsiveness to initial inquiries was another deciding factor. "They provided better responses to my questions, and I could get a hold of someone right away," he said, adding that they were also more efficient and more cost-effective of the companies we considered. Other companies also had more add-on expenses, such as airfare, hotel and gas, which BSI didn't have.

"Our auditor was great with the learning curve; when we didn't understand something he provided interpretation so we could get a picture of how it should look. He was also hard on us when he needed to be, while understanding that the whole process was something different for us."

Selley says he expects BSI will be on hand to perform annual surveillance audits to ensure the company is maintaining compliance. BSI's surveillance audits cover both standards simultaneously, and assessors are kept informed and trained on the latest developments in the industry.

As Precision MicroFab continues to grow, they will continue to take advantage of BSI management training programs. Overall, Selley foresees a lasting relationship with BSI.

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Your business could benefit from ISO 9001 and ISO 13485, just like Precision MicroFab LLC. To find out more, visit www.bsiamerica.com/quality

BSI Group America Inc.
12110 Sunset Hills Road, Suite 200
Reston, VA 20190-5902
USA

Tel: +1 888 429 6178
Fax: 1 703 437 9001
Email: inquiry.msamericas@bsigroup.com
Web: www.bsi-entropy.com

BSI Group Canada Inc.
6205B Airport Road, Suite 414
Mississauga, ON
L4V 1E3
Canada

Tel: 1 800 862 6752
Fax: 1 416 620 9911
Email: Inquiry.canada@bsigroup.com
Web: www.bsi-entropy.com

BSI Brasil Sistemas de Gestão Ltda
Rua Gomes de Carvalho, 1.306 – 11° andar – Vila Olímpia
São Paulo - SP
CEP: 04547-005

Tel: +55 11 2148 9600
Fax: +55 11 2148 9601
Email: bsibrasil@bsibrasil.com.br
Web: www.bsi-entropy.com

BSI Group México, S. de R.L. de C.V.
Torre Mayor
Av. Paseo de la Reforma No. 505
Piso 41 -Suite C-
Col. Cuauhtémoc, C.P. 06500
México, D.F.

Tel: +52 55 5241 1370
Fax: +52 55 5241 1371
Email: informacion.msmexico@bsigroup.com
Web: www.bsi-entropy.com

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The mark shall never be applied directly on the product or service.