

ISO CERTIFICATION REASSURES AND OPENS DOORS

BACKGROUND:

Sigma Design Company provides creative design and advanced engineering analysis for the development of new products, complex electro/mechanical machinery & specialty filtration equipment. The company's new 20,000 sq. ft. Technology Commercialization and Manufacturing Research Center is located in Middlesex New Jersey. Sigma Design, a Made in New Jersey Company, was founded in 1962 and today the company has 10 employees servicing its target markets that includes: Aerospace, Automotive, Biotech, Consumer Products, Electronics, Environmental, Food & Beverage, Industrial Machinery, Marine & Shipbuilding, Medical Devices, and Pharmaceutical.

CHALLENGE:

The markets that Sigma Design services are highly competitive. Certifications or lack of can make the difference as to whether a company thrives or struggles. Gerard Lynch, President of Sigma Design explained, "In 2011, the international company Northrop Grumman came to Sigma to audit the company for a \$100K+ design/build development program. Sigma was one of three firms visited out of the initial twenty firms Northrop reviewed. To make the short list of qualified suppliers was a great achievement however, in the end Sigma was eliminated as the other firm had ISO 13485 certification." Sigma needed ISO 13485 certification not just for Aerospace but for other industries as well.

The company needed training to reorganize with a focus to obtain ISO 13485 certification that would qualify them to get more international business which was extremely important to the survival and growth of the company. Mr. Lynch had visited the NJMEP website and contacted the company to request information on possible New Jersey programs that help small manufacturers in green technology and bio science. When the need for ISO training arose he contacted NJMEP.

SOLUTION:

As a small company the costs associated with gaining certification could be prohibitive. NJMEP pointed out that the State of New Jersey invested in companies through Skills4Jersey. The program offered matching grants to qualified companies to cover workforce training. NJMEP immediately began the application process on behalf of Sigma with the intent of training its team in preparation for ISO 13485 certification. A training plan, which was required, was developed and the NJMEP trainer that was most appropriate for this particular ISO training was secured.

Funding was approved and training began. Two classes were needed, Intro to ISO 13485 which explains the basic requirements for ISO 13485-the international quality management system for medical devices. The requirements of the standard apply to the methods used in the facilities and controls used in the design, development, production, installation, and servicing of medical devices. In addition, Employee Understanding & Involvement Training to provide employee awareness of the management system was included. This was an important course because having employee understanding and involvement in the company's system provides more value to an organization. A set of ISO Employee Training Materials to convey the fundamental information was created so that everyone in the company would understand the ISO system, especially the company's Quality Policy, document control system, corrective and preventive action process, etc. All members of the Sigma organization were trained.

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RESULTS:

The training enabled Sigma to become more competitive. They were able to fine tune their business processes which resulted in reduced lead times, improved productivity, reduced the cost of manufacturing and improved quality.

When completing the NIST survey on the work that was done with NJMEP, Mr. Lynch reported:

- Cost savings: \$15,000
- Investment in workforce practices: \$20,720.00 (\$10,720 invested through the Skills4Jersey grant and \$10,720 matched by Sigma)
- Investment in Equipment: \$10,000
- Investment in Information Systems: \$15,000
- New Products and Processes Amt: \$25,000

“NJMEP proved to be a great partner on this and without them we would not have achieved all we did,” said Mr. Lynch and then added “I believe that the training and preparation for new manufacturing activities and the jobs they will create will be paramount for us to participate in the current USA manufacturing revival.”

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