

AERODYNAMICS TAKES ON ISO 13485:2016 TO COMPETE IN THE MEDICAL MARKETPLACE

ABOUT AERO DYNAMICS. With decades of metal finishing experience and a deep technical knowledge of the trade, in 1989 Gregg Burzynski started AeroDynamics, LLC, a premier metal finishing business. After many years Gregg brought on his wife Cara Burzynski in 2007 to join the company as President. Today AeroDynamics is located in a 40,000-square-foot facility in Seabrook, New Hampshire, with 40 employees. The company specializes in metal finishing for the aerospace, military, and defense industries, and also serve a customer base in the commercial, industrial, and medical device fields.

THE CHALLENGE. As of 2024, AeroDynamics had doubled its employee base. They also doubled their customer base earning work from customers like Raytheon, Gillette and SpaceX. "After the pandemic manufacturing slowed down. So we were looking for ways to diversify and appeal to different industries," said Director of Quality and Engineering Emerson Bilodeau. "We were already in the aerospace market, but it dipped like everything else. So we decided to go after the medical market thinking it would be a good fit for us." AeroDynamics realized, however, that they first needed to go after ISO 13485:2016 certification.

MEP CENTER'S ROLE. Emerson had worked with NH MEP, part of the MEP National Network™, in the past with various training opportunities they offered. In this case he reached out to an NH MEP representative for help with ISO 13485:2016 certification training. NH MEP then brought in Exolytic, NHMEP's third-party provider partner, to deliver the ISO 13485:2016 certification training to AeroDynamics.

AeroDynamics pursued ISO 13485:2016 certification to establish a quality management system based on ISO 13485:2016, which included a process improvement component. AeroDynamics' pursuit for ISO 13485:2016 certification was based on the company's strategy to train its employees on best quality management practices and position the company to compete globally, while satisfying the requirements of the medical device industry. AeroDynamics trained nine employees to create a documented system with ISO 13485:2016 as the basis for registration at their facility. Existing quality system documentation was used where possible in the training for the creation of the new system. Upon creation of the documentation, AeroDynamics was assisted in implementing ISO 13485:2016.

"NHMEP was instrumental in helping us implement the ISO 13485 quality management system. They connected us with Exolytic, whose expertise guided us through the process, identifying gaps, optimizing documentation, and training our team. Thanks to their support, we achieved ISO 13485 certification efficiently, improved our processes, and enhanced product quality and customer satisfaction. NHMEP has been a vital resource in supporting our ongoing continuous improvement efforts, helping us maintain high standards and drive long-term success."

-Emerson Bilodeau, Director of Quality & Engineering

RESULTS



\$100,00 in retained sales



\$25,000 invested in plant equipment



\$7,000 in training



\$5,000 invested in software



\$5,000 in new markets

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