

LAKESIDE LIFE SCIENCE BUILDS CONFIDENCE WITH ITS CUSTOMERS AND THEIR EMPLOYEES THROUGH ISO CERTIFICATION

ABOUT LAKESIDE LIFE SCIENCE. For the past 30 years Jeffrey Allard, PhD has been involved in the IVD (In Vitro Diagnostics) industry working for large companies and as a consultant. In 2015 he decided to form his own company, and with his son Paul Allard, they started Lakeside Life Science out of Jeffrey's house in New Durham, NH. Since 2015 Lakeside Life Science has grown to 11 employees now working out of a 3,000 square foot facility in Belmont, NH.

Lakeside Life Science is an industry leader and full-service clinical research organization that offers integrated services during every stage of diagnostics product development. They provide the scientific and clinical expertise to help their clients complete the journey through the seasons of product development of laboratory tests from concept to FDA clearance and commercialization. Lakeside has designed and implemented the protocols to support more than 100 Analytical and Clinical Validation Studies. These studies have led to successful implementation of Laboratory Developed Tests (LDTs) and 54 successful FDA submissions.

THE CHALLENGE. "We were a small company looking to grow but at that time our growth was primarily from word of mouth," said Gabriela Cook-DiDomenico, Senior Vice President of Quality and Regulatory Affairs for Lakeside Life Science. Leadership realized growth meant having to compete with other IVD companies and most of them had some kind of certification. "We needed a way to show potential clients that we have processes in place and could compete at the highest level."

MEP CENTER'S ROLE. A colleague who had worked with NH MEP, part of the MEP National Network™, recommended their services to Gabriela. President Zenagui Brahim assigned an NH MEP project manager who, along with DeNovo, LLC, NH MEP's 3rd party partner and trainer, developed an on-site ISO 9001:2015 certification training program for Lakeside Life Science. ISO 9001:2015 training for Lakeside Life Science would formalize its processes, create ways to effectively manage its people and resources, and be better able to meet customer requirements. Top management would be provided support in designing and implementing a QMS (quality management system) tailored to meet the needs of the company's operations and customers. The ISO 9001:2015 training and coaching would span Lakeside's service offerings in areas such as diagnostic research services, clinical trials, product development, analytical validation, and FDA submissions. This training and coaching took place over 6 months.

"NHMEP, its support staff, project management and subject matter experts were very helpful in helping us achieve ISO 9001:2015 certification in less than 6 months. It has made a very noticeable difference in the services we provide to our customers, including how we present our service offerings, execute our agreements, and provide the final product to our clients. I can't thank NHMEP enough in helping us achieve this goal."

-Paul Allard, CEO

RESULTS



10 created or retained jobs



\$1,303,000 in new or retained sales



\$125,000 in plant and equipment



\$50,000 in new software investment



\$10,000 in training

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