

ISO 9001 REGISTRATION OPENS DOORS TO NEW BUSINESS OPPORTUNITIES.

ABOUT BEACON ANALYTICAL SYSTEMS INC. Beacon Analytical Systems, Inc. is a 10 person, minority-owned biotechnology company incorporated in 1996. Their 10,000 sq. foot facility, located near the seacoast in Saco, Maine, houses operations for research and development, as well as kit manufacturing.

Beacon focuses on providing development and manufacture of immunodiagnostic kits for environmental and food/feed testing markets. Over the past 20 years, Beacon has provided contract method development and manufacturing for companies requiring custom methods specific to their testing needs, as well as offering over 75 different test kits for food, feed, agricultural and environmental analysis.

THE CHALLENGE. As a result of strategic planning, the company wants to expand into new product markets and increase its market share domestically and overseas. In order to support these strategic goals, leadership identified the need for a formal ISO 9001 based Quality Management System (QMS). Beacon approached Maine MEP, part of the MEP National Network™, to obtain training and guidance for the implementation of an ISO 9001 based QMS.

MEP CENTER'S ROLE. Maine MEP worked closely with key employees assisting with the clause interpretation and creating QMS documents that comply with the ISO 9001:2015 version of the standard. Care was taken to identify non-value added practices in an effort to keep the documentation and processes simple, while complying with the new requirements. In addition to the documentation implementation efforts, a team of four employees completed 16 hours of QMS Internal Auditor training provided by Maine MEP.

Beacon successfully passed their Stage 1 and 2 audits and was issued an ISO 9001 Certificate in December of 2016. They plan to use their certificate as a marketing tool to stimulate revenue growth in new products as well as in an effort to increase market share in South America, Asia, and the EU. This certification and training is an investment that increases the overall value of the company and its potential for growth.

"We enlisted the help of Maine MEP to document the processes used in our operations to establish a Quality Management System compliant to the ISO 9001:2015 standard. Maine MEP is an exceptional resource - providing training, understanding, and focus to our team - leading to certification in under one year. As we move forward in 2017, these credentials will help us to be more competitive in the global marketplace."

-Dr. Titan Fan, President & CEO

RESULTS



\$7500 cost savings from Make It In America Grant



\$41,000 in man hours invested into implementation



Invested **\$2000** in training



\$4500 in other new investments

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