

\$238.7 million in new and retained sales  
\$13.5 million in new investments  
858 jobs created or retained

The **Montana Manufacturing Extension Center** (MMEC) is the state's representative of the National Institute of Standards and Technology's (NIST) Hollings Manufacturing Extension Partnership. The mission of MMEC is to work with Montana manufacturers to create and retain jobs, increase profits, and save time and money. It provides a variety of services – from innovation strategies to process improvements – and works with manufacturers to develop new customers, create new products, and expand into new markets.

The core strength of MMEC is its employees. They are experienced, committed to Montana, and knowledgeable about all aspects of manufacturing. MMEC field engineers interact directly with manufacturing clients and bring a wealth of expertise, tools, and techniques to help solve the production, technical, and management issues facing companies today. MMEC specialists travel to the manufacturing workplace to observe and evaluate the problems and then collaborate with management and staff to develop workable, cost-effective solutions consistent with company goals.

MMEC has provided worthwhile assistance to over 750 clients across Montana from Alzada to Eureka and Corvallis to Opheim (in 54 of Montana's 56 counties!).

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\* Impacts are based on clients receiving service in FY2010



# CLIENT SUCCESS: NEURALYNX INC

*“MMEC’s help allows us to continue to expand the business and keep growing. The Center did a really good job of showing the importance of a Quality System to all our employees and fired up upper management to convey it at every turn.”*

Casey Stengel, CEO, Neuralynx Inc.

## Innovation Meets Standardization: Neuralynx Pursuing the Medical Device Market

Neuralynx, a high tech firm in Bozeman, Mont., manufactures “state of the art” high density data acquisition and experiment control solutions for the study of electrical activity in the central nervous system (electrophysiology and neuroscience). The company currently employs 20 people.

### *Situation:*

Neuralynx is on a journey to become a medical device manufacturer where its signature products may provide information that will lead to effective future treatments for debilitating ailments. New research has proven that the products manufactured by Neuralynx could play a role in future patient assistance. Assistance from the Montana Manufacturing Extension Center (MMEC), a NIST MEP network affiliate, was sought to help the company achieve the quality system and certification for medical devices needed as the foundation to comply with U.S. Food and Drug Administration (FDA), CE Medical Device Directive Mark and other regulatory requirements for safety. These requirements must be met to sell its products into the medical device market here and abroad. After several false starts on its own, the company called MMEC (Montana Manufacturing Extension Center), a NIST MEP network affiliate, for help with ISO 9001 and ISO 13485 Standards.

### *Solution:*

MMEC built a clearly defined plan with timelines to define and achieve tasks as the company worked toward implementation of a QMS (Quality Management System). MMEC conducted a gap assessment and reviewed with the management team. Kickoff meetings were scheduled to teach the ISO 13485 objectives, assign teams and develop tasks and reviews for each business operation. Many of the staff participated in the effort to adopt and document procedures and processes for a fully documented quality system. Close attention was paid to risk management, an important part of ISO 13485.

Verification of the effectiveness of corrective and preventive actions, inspection, traceability, and validation of processes were also scrutinized. The MMEC field engineer provided guidance in defining the role of a Quality Manager in preparation for hiring for that position. He also helped with criteria for selecting a Registrar and participated in initial audits with Neuralynx and the Registrar Agent from the certifying body selected for the full audit.

### *Results:*

- \* 15% increase in output.
- \* ISO 13485 certification.
- \* Improved production consistency.
- \* Complete documentation of all processes.
- \* Neuralynx positioned for growth in new markets.

15% increase in output

Feb 2012