

Innovation Meets Standardization: Neuralynx Pursuing the Medical Device Market

Key Points

- Different market segments may have different regulatory requirements.
- A sound Quality Management System (QMS) is foundational not only to good management practices but also to meeting regulatory requirements for health and safety.
- When the whole company embraces QSM from management on down, its benefits have a huge impact on the company.

By Deborah Nash, MMEC

[Neuralynx](#), a high tech firm in Bozeman, is on a journey to becoming a medical device manufacturer where its signature products may provide information that will lead to effective future treatments for debilitating ailments. Assistance from the Montana Manufacturing Extension Center (MMEC) has helped 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.



The modular Digital Lynx SX undergoes testing prior to heading to an MSU research laboratory.

Neuralynx 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). It has been providing single-unit, multi-channel electrophysiology recording equipment to researchers since 1993 using microwire electrodes (thinner than a human hair) to detect neuron spikes in the brain. The company also builds proprietary software to record, observe and manipulate the data in experiments. Its customizable systems are used in more than 500 laboratories worldwide. A variety of accessories are also produced to meet varied researchers' needs. Ninety percent of its products are used in animal research; ten percent in clinical human recording.

"The difference between our current systems and the more familiar EEG system is that EEG records from 100,000 neurons [macro-contact]; ours enables the investigation of individual neurons," Neuralynx CEO Casey Stengel explained. A company brochure explains the difference between macro-contact and microwire recording with a football stadium analogy: macro-contact equated to "trying to determine the events at a football game as listened to from a flying blimp above the stadium – overall activity can be determined from the roar of the crowd but little detail about scores and penalties..." while microwire electrodes discern data as if "in the seats, following close conversations simultaneously."

High Performance Systems May Lead to New Treatments

"Research is more effective with our systems," Stengel said, "and could have a far reaching effect on diseases and afflictions like stroke, birth defects, Parkinson's Disease, Alzheimer's, and epilepsy that are so devastating to patients." Five hospitals currently use the equipment but as a research, not medical, device. He envisions that the Digital Lynx® and Cheetah® Data Acquisition and Experiment Control software will be used to study such ailments in human subjects and lead to new treatments.

Neuralynx does approximately \$6 million in sales annually with an average growth rate of about 30 percent per year. In addition to sales in the U.S. and Europe, the company has a strong presence in Japan, and sales in Korea. Becoming certified as a medical device manufacturer will open up a huge market for the company which currently employs 24 people and plans to hire four additional people in

each of the next two years. Brain research draws good funding, Stengel said, and will continue as baby boomers age.

Stengel is proud of the Neuralynx accomplishments over the years and said it sets high goals, invests lots of time in R&D [research & development] and has a system no one else is able to match. Its Digital Lynx products digitize the signals from neurons in the brain to process with a high performance PC using its Cheetah data acquisition software. "The data rate is 500 times what we get on a typical home Internet connection," Stengel explained. "Very fast." The Digital Lynx system is modular so additional circuit boards increase the amount of data that can be recorded and systems can be connected together for unlimited capability. "The quality of design in the electronics is so good, no competitor can match its performance; the specs are 10 times better. Our software has 20-30 man years in the research of our business – very efficient."



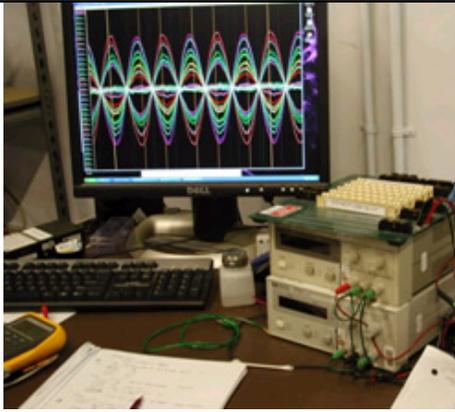
Casey Stengel is pleased with improvements to inventory control throughout the firm.

A Lifetime of Innovation

Stengel has been inventing solutions for brain researchers since an ah-hah moment in 1985. At that time he met leading neuroscientists at the University of Colorado in Boulder and observed that they were recording from one electrode with a room full of equipment. "I visualized that software would enable recording and processing on a PC" (keep in mind this was the era of the 5.25" floppy disk). He and several others launched a company called Brainwave Systems and invented a process of neuron spike discrimination in software instead of electronics. "It put the competition out of business," he said. It also launched a series of events that may now lead to developing new treatments for complex and devastating illness.

Stengel's innovations in the field of data acquisition continued, and in the early 1990s he applied for an SBIR grant, incorporating Neuralynx in 1993. He worked with a laboratory at the University of Arizona to create a new data recording system for experiments in space. The science challenge for a Shuttle space mission, of course, was no size, no weight and little power consumption. The Cheetah was the heart of the University of Arizona E100 experiment for the NASA NeuraLab Space Shuttle Mission which flew on Columbia in April, 1998. It performed flawlessly, Stengel said. By 1998 he had a 160 channel unit that could be carried under a person's arm (about the size of two boot boxes).

In 2006 Neuralynx moved from Tucson to Bozeman, attracted by the talent at the Montana State University, the quality of life and strong work ethic here. Three Neuralynx engineers are MSU graduates from the Electrical Engineering Department. Stengel confirms that it's a classic story of a high tech firm being able to come to Bozeman and operate successfully. He and his family vacationed here with an eye on places to retire. The University presence was a draw, and the high work ethic, he said. "The people here are really excellent; honest, with high personal values."



An automated incoming-product test setup for data acquisition boards.

Promising Research in the Study of Epilepsy

Neuralynx products are well known among research neurologists and research labs. When Stengel realized epilepsy patients were undergoing a surgical procedure where macro-contact electrodes were attached to the brain and required hospitalization for weeks in order to gather needed data, he developed schemes to support a microwire system for use in humans that would enable faster, more specific data recording. Researchers at the Rochester Mayo Clinic made a significant discovery using microwires, finding that in the epilepsy "focus," the area of the brain that affects seizures, many micro-seizures are going on which lead to full seizures. Those were never observed using macro-contact. Researchers are now better able to study affected areas and how they react to stimulus on the individual neuron level. It became clear that the data recording system has value as a medical device.

Innovation Meets Standardization

The path to becoming a medical device required that the innovative nature of Neuralynx be documented, setting up controls in the work environment to maintain processes in a consistent way with procedures that ensure product safety during design, manufacture and distribution. Traceability and risk analysis are key procedures for documentation. Two years ago, the company attempted to set up a quality management system on their own to document its processes. "False starts," Stengel called them. What the team found was "a huge raft of regulations. We had no idea the number of regulations," he said. FDA rules in the U.S. for safety compliance and CE Medical Device Directive marks for selling in Europe are examples. "During the design process, you have to prove your product is safe. The toughest problem we had was not knowing what much of it meant or what was required."

A documented Quality Management System (QMS) under the ISO 13485 Standard is foundational to meeting regulatory requirements for medical devices. So last year, the company called on Mark Shyne, MMEC's local Field Engineer, for help with ISO 9001 and ISO 13485 Standards. Stengel considers Mark an expert on the regulations and the systems to be compliant to quality standards, especially for ISO 13485 where the scope is much larger.

Well Defined Plan Adds Structure

Mark built a clearly defined five- phase, 144 step plan with timelines to define and achieve tasks as the company worked toward implementation of a QMS. Early on, a gap assessment was conducted and reviewed with the management team. The MMEC gap assessment showed that the company was about 70% there, Shyne said. "The whole company embraced the process; and the benefits have had a huge impact on the company."

Kickoff meetings were scheduled to teach about ISO 13485 objectives, assign teams and develop tasks and reviews for each business operation. From Management to Sales, Shipping and Receiving, Purchasing, Design, and Production, staff participated in the effort to adopt and/or document procedures and processes for a fully documented quality system. Close attention was paid to risk management as ISO 13485 dictates that risk management must be thoroughly documented and conducted throughout a product's entire lifecycle, from initial concept to delivery and post-delivery. These foundational procedures align it well with requirements of various regulating agencies. Verification of the effectiveness of corrective and preventive actions, inspection, traceability, and validation of processes were also scrutinized.

Mark provided guidance in defining the role of a Quality Manager in preparation for a hiring for that position, which removed shared responsibility from the sales department. He also helped with criteria for selecting a Registrar and participated in both Stage 1 and Stage 2 Audits with Neuralynx and the Registrar Agent from TÜV Rheinland, the certifying body selected for the full audit. Within a year, the company passed the final audit and was certified in December 2010 to ISO 13485 for design and development, production, installation and servicing of electrophysiology data recording systems.

"The important thing is that we got it done. Mark's help allows us to continue to expand the business and keep growing," Stengel said. "He did a really good job of showing the importance of a Quality System to all our employees. He fired up upper management to

convey it at every turn, and everyone really embraced the whole system.”

Shyne also introduced the company to additional experts on quality. He arranged meetings about ITAR export control rules with Montana’s US Commercial Service representative Carey Hester. He put them in touch with a regulatory specialist Michael Johnson, MD, to assist them with the more detailed CE Mark and FDA requirements, “which we are tackling now,” Stengel said. “Mark has been great; he is very professional and efficient. He helped us meet our schedule for implementation.”

Positive Impacts of a QMS

Today all job functions are documented, and procedures like recall and updates are efficiently executed. Inventory control is in place with electronic parts stored in a humidity controlled storage space where every part, bin and shelf is labeled and stored in consistent manner.



Clear instructions aid assembly technician working with tiny components.

Each member of the assembly team has a computer screen where instructions are displayed for viewing clear, concise steps. “Consistency of production is greatly improved; we don’t measure that but customer calls or returns are now almost nil,” he said. Management gets fewer questions about job duties because they are documented and consistent. Because Stengel travels extensively to meet with customers, knowing his staff can move forward in his absence is extremely valuable.

Now new products in development go into production 100 percent complete on documentation: users manuals, assembly/test documents, bill of materials, and risk analysis. “The quality of designs is better because of additional review processes that are part of the quality system,” Stengel reported. “All of this has led to better products, higher user satisfaction, quicker order fulfillment, better customer training and lower costs for us.” Some of those gains are

- Inventory control up over 99 percent
- 10-15% increase in output just on the production side
- Clear instruction enables faster training for new staff
- New quality manager hired
- Shipping in one-third less time
- Higher customer satisfaction

Innovation Continues

Customer satisfaction has always been a strong goal for Neuralynx. Having a recognized quality certification is a major milestone in achieving that. Providing innovations that extend its product lines is another way it delights customers. In 2008, Neuralynx created its first wireless digital acquisition system, the Digital Falcon®. In the past year, the company took another step toward the ultimate in customer service adding a Web-based remote troubleshooting and training capability that allows its engineers to pull up a customer’s Cheetah system right in the Bozeman office, debugging, looking at data and providing online training on how to use the software. This is not only a convenience to the customer, but a significant reduction in travel time and expense and the related lost productivity.

Certification to ISO 13485 tells the world the company is complying with internationally recognized quality standards. It positions Neuralynx to move into a new market segment with huge growth potential.

MMEC Forward Focus has been prepared solely for the purpose of providing helpful information to users of this service. The information has been compiled by Tech Resources, a contractor to Montana Manufacturing Extension Center; however, no representation is made by either Tech Resources or Montana Manufacturing Extension Center as to the completeness or accuracy of the information contained therein. In particular, some information may be incomplete, may contain errors or may be out of date. In addition, neither Tech Resources nor Montana Manufacturing Extension Center endorses any product or service mentioned therein.

