

# ForwardFocus

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Winter 2011

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## Plus

4-5 **Special Report:**  
Montana Manufacturing  
Industry

Montana Manufacturing Center

University Technical Assistance Program

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

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.

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 cur-



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

rent 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 sig-

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## Going Global – Are You Ready!

The reputation for American-made quality and service is strong. The Montana brand embodies pride-of-workmanship and an unmatched mystique. These are qualities we should be capitalizing on in the global marketplace today. Of the quarter million U.S. firms selling internationally, 97

**Steve Holland**

percent are small and medium-sized companies. They account for 30 percent of U.S. export totals with greater possibilities ahead.

Why? Because more than 95 percent of consumers live outside the USA, and nearly two-thirds of small and medium-sized exporters only sell to one foreign market. Many of these firms could reach new customers, grow their bottom lines and add employees by expanding the number of countries to which they sell. With the global economy up 3.9 percent in 2010, now is the time for your company to get involved and improve your stake in the international market.

But where do you start?

If you have seriously considered entering the export market or expanding where your export program is now but feel that you lack the tools and strategy to move forward, I'd like to invite you to consider participating in a unique and customized export training program that begins this month. The program, *ExporTech Montana*, is designed to radically accelerate a company's ability to grow in the global marketplace. A collaboration of the Montana World Trade Center and the

Montana Manufacturing Extension Center, it will bring together the state's best experts and export resources in one location to help build individual export plans with committed company decision makers, those at the CEO/owner/executive level, where strategic change and growth is driven.

Working with a limited number of non-competing companies, experts will help each develop a strategic international plan that is immediately implementable [actionable] at the end of a three month period. In three one-day working sessions over the period, participants will not only learn about the mechanics of exporting, including financing, export licensing, protecting intellectual property, documentation, and logistics but also receive expert guidance on how to create a successful plan, including market entry and distribution strategies. Each company will work side-by-side with an export

coach to conduct market research and identify target markets.

ExporTech Montana is effective because it uses focused, customized content based on a company's particular needs, not a canned approach. As each company's growth plan devel-

ops, an expert panel will review it and provide feedback. Currently two series are scheduled to begin in mid-March, one to meet in Bozeman and one in Missoula. You may enroll more than one person from your company, but enrollment is limited to between six and eight firms at each location, guaranteeing a high caliber of training and resources suited to individual company needs.

ExporTech is a proven advanced learning technique, and we are pleased to offer an introductory rate for each participating person that is signifi-



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## Neuralynx (cont. from cover)

nals 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.”

### 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



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

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.”

### 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

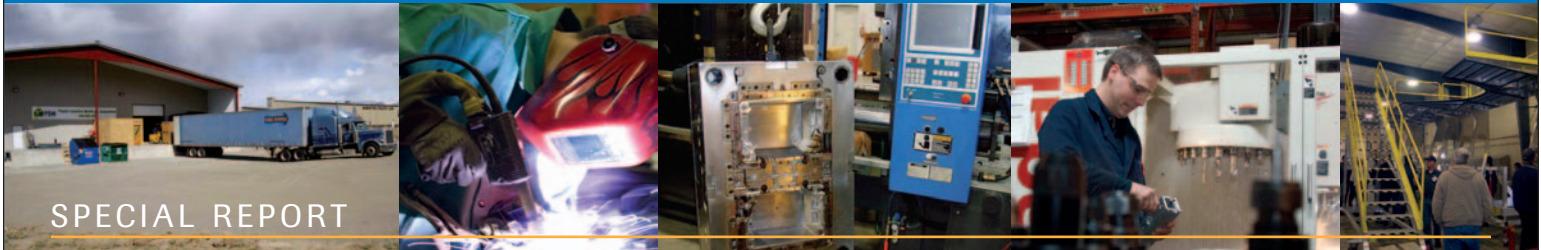
The path to becoming a medical device required that the innovative nature of Neuralynx be documented, setting up controls in the work environment to maintain processes in a consistent way with procedures that ensure product safety during design, manufacture and distribution. Traceability and risk analysis are key procedures for documentation. Two years ago, the company attempted to set up a quality management system on its 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

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SPECIAL REPORT

# Montana's Manufacturing Industry

by Todd A. Morgan, Charles E. Keegan III, and Colin B. Sorenson, Bureau of Business & Economic Research

Despite the recent recession and extensive declines in wood products, manufacturing remains a substantial component of Montana's economy, with sales of \$10 billion during 2010. The state's manufacturers employed 21,000 workers in 2010 (Figure 1), earning more than \$1 billion in labor income (Figure 2).

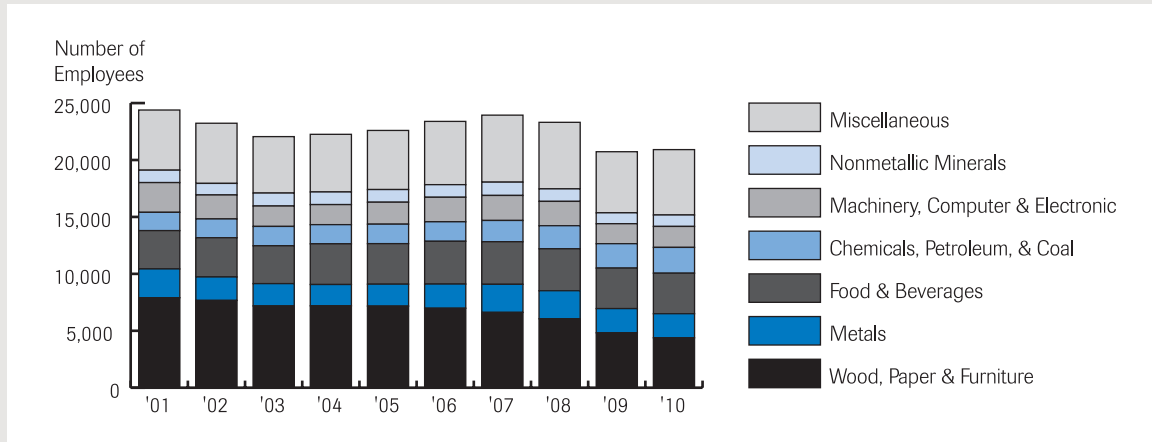
The manufacturing sectors account for more than 20 percent of Montana's economic base, and prior to the recent downturn, four Montana counties each had more than 2,400 manufacturing employees and more than \$135 million in labor income from manufacturing (Table 1). Recent declines primarily in the wood and paper products, primary metals, and machinery industries have dropped Flathead County below 3,000 manufacturing workers and Missoula County

below 2,000.

The value of production rose in 2010 by an estimated \$1.7 billion to approximately \$10 billion. The increase was due to generally higher product prices and output across most sectors, with Montana's petroleum refineries accounting for the bulk of the increased sales value compared to 2009.

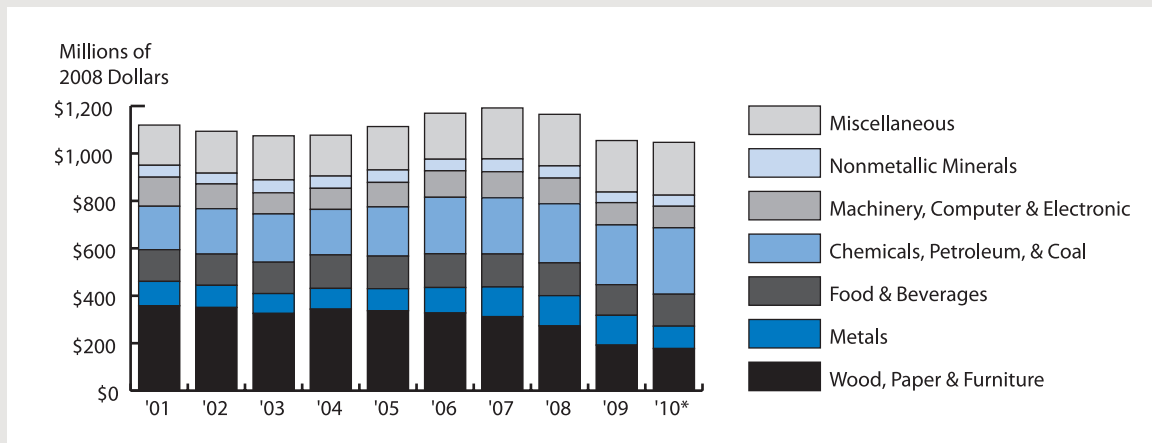
After substantial declines in employment during 2009, Montana manufacturing employment turned upward as 2010 progressed, with a net increase of an estimated 200 workers. Estimated workers' earnings in 2010 were approximately equal to the \$1 billion reported for 2009. This is in contrast with the U.S. manufacturing sector, which had lower employment in 2010 versus 2009. The largest single loss in

**Figure 1** Montana Manufacturing Employment, 2001-2010



\* 2010 estimated by BBER. Source: Bureau of Economic Analysis, U.S. Department of Commerce.

**Figure 2** Labor Income in Montana Manufacturing, 2001-2010



\* 2010 estimated by BBER. Source: Bureau of Economic Analysis, U.S. Department of Commerce.

2010 was the closure of the Smurfit-Stone Container pulp and paper mill in Frenchtown, dropping overall manufacturing employment by 400 workers. All other manufacturers combined added an estimated 600 workers.

Looking at the past decade and comparing 2001 to 2010, total employment and labor income for 2010 are estimated to be lower than 2001 levels for manufacturing as a whole in Montana (Table 2). However, a number of sectors have shown growth over that period including chemicals, petroleum and coal, food and beverage, and a mix of manufacturers in the miscellaneous category, including high-tech and light manufacturing. Declines since 2001 were largest in Montana's wood and paper products industry (see Table 2) with segments of Montana's metals, machinery, and nonmetallic minerals manufacturers also suffering declines.

## Outlook: 2011 and Beyond

The 2011 outlook is for modest improvement in Montana manufacturing activity, with expectations that the United States and other major economies will continue the slow recovery that began in the last half of 2009. Montana manufacturers should continue to benefit from improved export activities. The weakness of the dollar has spurred sharp increases in U.S. exports as the global economy improved in 2010; emerging economies such as Latin America and China showed rapid growth. Exports are projected to continue to increase by 8 percent in 2011 and 10 percent in 2012. In part due to strong global markets, the high-tech related sectors have shown recent growth, which will continue through 2011. Also benefitting U.S. and Montana manufacturers in 2011 and 2012 is an expected reduction in the rate of imports of manufactured goods, which increased during 2010.

Montana manufacturers who responded to the BBER's annual manufacturers survey continue to express optimism in their outlook for the coming year. Nearly 50 percent expected improved conditions for 2010, and about 45 percent expect better conditions for 2011. About 15 percent expect worsening conditions in 2011, very similar to the 15 percent that expected worsening conditions for 2010. Nearly 64 percent of manufacturing respondents expect to keep their workforce at the same level in 2011, while 29 percent foresee an increase in employment.

More than 60 percent of responding firms indicated the recession has caused their firm to fundamentally change the way they plan to operate in the future. Most of the major changes involved reducing costs and operating more efficiently. Other major changes included diversification into new products and markets, or focusing on key products and projects.

*“Montana manufacturers should continue to benefit from improved export activities.”*

**Table 1** Montana Manufacturing Employment and Labor Income, by County, 2008

County	2008 Manufacturing Employment	Percent of Total	2008 Manufacturing Labor Income (Millions of 2008 \$)	Percent of Total
Yellowstone	3,543	15%	287	25%
Flathead	3,501	15%	196	17%
Gallatin	2,577	11%	151	13%
Missoula	2,434	10%	138	12%
Ravalli	976	4%	45	4%
Cascade	963	4%	55	5%
Lake	750	3%	33	3%
Lewis and Clark	703	3%	43	4%
Silver Bow	597	3%	38	3%
Park	303	1%	18	2%
Lincoln	290	1%	12	1%
Other counties	6,672	29%	138	12%

Source: Bureau of Economic Analysis, U.S. Department of Commerce.

**Table 2** Employment and Labor Income in Montana Manufacturing Sectors, 2001 and 2010

	Labor Income (Millions of 2008 \$)		Employment	
	2001	2010*	2001	2010*
Wood, paper & furniture	358	178	7,907	4,385
Metals	103	94	2,526	2,116
Food & beverage	134	135	3,365	3,558
Chemicals, petroleum & coal	183	280	1,607	2,266
Machinery, computers & electronics	123	91	2,612	1,842
Nonmetallic minerals	50	47	1,090	1,005
Miscellaneous	169	223	5,283	5,742

\* 2010 estimated by BBER.

Source: Bureau of Economic Analysis, U.S. Department of Commerce.

## Manufacturing News Across Montana

### Wind Turbine Tools Inc. of Lincoln, Montana purchased by Transcat Inc.

**Transcat Inc.** <http://www.transcat.com> has completed the acquisition of substantially all of the assets of Wind Turbine Tools Inc. <http://www.windturbinetools.com/> and affiliated entities, the Ogden-based distributor of test and measurement instruments announced. Wind Turbine Tools is recognized within the wind energy industry as a premier provider of product tool kits, technical assistance, torque calibration and hydraulic services, Transcat officials said. Wind Turbine Tools founder, Jim Daugherty, will remain with Transcat as director of wind energy sales. Full Story by Nate Dougherty: <http://www.rbj.net/article.asp?aID=186295>

### Ravalli Firm Acquired; Reopening

**Specified Fittings** owners Greg and Kathy Gundel of Bellingham, Wash., <http://www.specfit.com> have acquired all the assets of Poly Warehouse - a Stevensville firm that had closed - doubling the company's production capabilities of HDPE fittings. Many of the new jobs being created at the plant require specialized skills. Bitterroot Job Service is working with Specified Fittings to help retrain workers who lost jobs to layoffs or business closures. Good news for a region that in December had unemployment at 10.4 percent. Full story by Peter Backus, Ravalli Republic at [http://www.ravallirepublic.com/news/local/article\\_0de464aa-3335-11e0-84d4-001cc4c03286.html](http://www.ravallirepublic.com/news/local/article_0de464aa-3335-11e0-84d4-001cc4c03286.html)

### Two Lumber Mills Win Awards

**Pyramid Mountain Lumber Co.'s** <http://www.pyramidlumber.com/> commitment to reforestation and best management practices has won the Seeley Lake mill top honors from the industry's Sustainable Forestry Initiative. Other Montana firms that won SFI certification are F.A. Stoltze Lumber Co. of Columbia Falls and The Nature Conservancy in Helena. Full story by Rob Chaney, Missoulian [http://missoulian.com/news/state-and-regional/article\\_7b3ab4cc-2846-11e0-a98b-001cc4c03286.html](http://missoulian.com/news/state-and-regional/article_7b3ab4cc-2846-11e0-a98b-001cc4c03286.html)

### Red Ants Pants Featured in Magazine

The story of **Red Ants Pants** in White Sulphur Springs was featured in a recent edition of Country Woman magazine with owner Sarah Calhoun featured on the cover. Calhoun made a conscious decision to have her product sewn in the USA right up front in order to control quality, delivery and minimums. To read more about the ingenuity and strong work ethic behind this company, go to <http://www.countrywomanmagazine.com/2011/FM11/article1.asp?RefURL=&KeyCode=&tdate=&PMCode=&OrgURL>



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## Going Global (cont. from page 2)

cantly below the typical fee for this type of personalized learning and outcome. Sticking with the program can increase sales, accelerate time to market, reduce export risks, and gain effective connections to export resources.

I urge you to think strategically. Step out and lead as you diversify your markets on an international scale.

### Session Dates & Registration:

(Bozeman)

March 14th, April 18th, and June 13th

<http://www.eiseverywhere.com/ehome/index.php?eventid=20422>

(Missoula)

March 15th, April 19th, and June 14th

<http://www.eiseverywhere.com/ehome/index.php?eventid=20515>



Steve Holland, MMEC Director

## New Face at MMEC



Bryant Higgs

MMEC has a new Business Manager, Bryant Higgs, who joined the center in December. His expertise includes 13 years of restaurant management, most recently as area supervisor for Restaurant

Management Company, a franchisee of Pizza Hut, Inc., based in Miles City for its eastern Montana operations. He has previous university experience as an accountant for the MSU Animal and Range Science Department and holds a Masters in Public Administration and Bachelor of Science in Business Management from Montana State University.

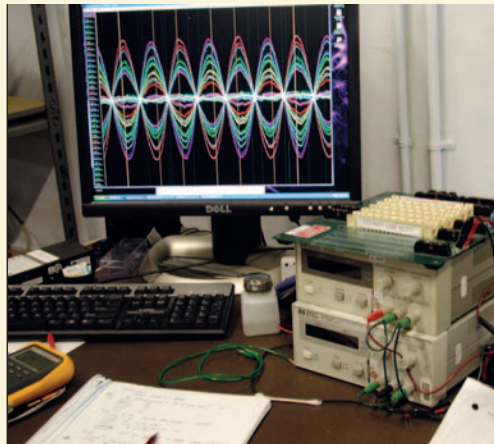
## Neuralynx (cont. from page 3)

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 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



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

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.

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.



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**Deborah Nash**  
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**Bryant Higgs**  
Business Manager

**G. August Uhl**  
Program Assistant

## UTAP Staff

**Adam Bacon, Ind. Engineer**

**Rhea Poole, Ind. Engineer**

**Casey Chumrau, Marketing**

## MMEC Mission

To Help Manufacturers  
Be More Successful

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## EVENTS...

March 8-10, Wingate Inn, Missoula

### AS 9100C Basic Internal Quality Auditor Training

Use the skills in this 3-day workshop, 8 a.m. to 5 p.m., to drive continuous improvement; includes live audit practice at a real aerospace company and report building skills. For more information or to register

<http://www.eiseverywhere.com/ehome/index.php?eventid=20203>

March 14th, April 18th, and June 13th

### Expotech Montana – Bozeman Group

Customized export training program designed to radically accelerate a company's ability to grow in the global marketplace. Meets at MMEC Conference Room. Must attend all three sessions. For more information or to register go to

<http://www.eiseverywhere.com/ehome/index.php?eventid=20422>

March 15th, April 19th, and June 14th

### Expotech Montana – Missoula Group

Customized export training program designed to radically accelerate a company's ability to grow in the global marketplace. Meets at MonTEC. Must attend all three sessions. For more information or to register go to

<http://www.eiseverywhere.com/ehome/index.php?eventid=20515>

Tuesday, March 15, noon-1 p.m.

### Trademark Fundamentals, free webinar by Trade.gov

New to the China market or interested in defensive measures to protect Trademark, a first step should be to consult with a China IP lawyer to update IP portfolios. Join webinar in Beijing as Rachel Tan, Head of Rouse China's Trade Marks Group walks newcomers to the China market through brand clearance, protection and enforcement in China. To register send your contact information to [Janice.wingo@trade.gov](mailto:Janice.wingo@trade.gov). A registration confirmation, and dial-in/log-in instructions will be sent to you before the program. To learn more go to Stop Fakes:

[http://www.stopfakes.gov/events/china\\_webinar\\_series.asp](http://www.stopfakes.gov/events/china_webinar_series.asp)

March 25-26 Great Falls, Mansfield Convention Center at the Civic Center

### Made in Montana Marketplace

The trade show boasts 111 booths and is strategically timed to connect exhibitors juried in the show with wholesale buyers looking to purchase Made in Montana products for the spring and summer seasons. The second day of the show is open to the public.

<http://www.greatfallsmt.net/events/madeinmontana/>