



Devicix

Engineering the Future of Medicine

Fall 2009

The Outsourcing

2009 Highlights

- Achieved ISO 13485 & 14971 certification
- Hired six additional engineers for a total of 32 employees
- Occupied additional 5,000 sq. ft. for a total of 15,000 sq. ft.
- Invested in an environmental chamber for humidity and temperature testing



ISO 13485
FM 546200

ISO 14971
RM 546203

Inside this Issue:

- Upcoming Events 2
- Have You Heard? 2
- Employee News 2
- ISO Certifications 3
- New! Environmental Chamber 4
- Spotlight on: Software Development 4
- About Devicix 4

An exciting time

New projects, new employees, new certifications

Hello again!

One of my favorite aspects of putting this newsletter together is that it gives me the opportunity to publicly thank our customers who put their projects and their trust in our hands, and our employees, who put 100 percent (and more!) into their work to make sure we continue to deliver the premier level of service that Devicix is known for.

ISO CERTIFICATIONS

Bob Parsons joined us last October and has worked diligently with the Devicix team over the last 11 months in pursuit of our ISO 13485 and 14971 certifications. We received final approval at the end of September!

The ISO certifications focus on requirements for firms designing medical devices, as well as risk management procedures, and the implementation of these processes illustrate how important it is to us to simultaneously ensure our clients' continued success as well as our own. (More about this on page 3).

RECENT PROJECTS

Since last year, we successfully completed a project with Dr. Ramon Gustilo. His revolutionary "Bone Drill" system is a set

of technologies that helps surgeons fix long bone fractures in a fraction of the time that it takes today. The project culminated in a strategic deal with DGIMed Ortho, Inc., a new player in the orthopedic trauma market. One exciting aspect of this project is that DGIMed Ortho was able to raise \$3 million in the midst of a difficult economy and highly selective funding environment. This is a testament not only to the novel technology, but also to the founders and management team of DGIMed Ortho!

Additionally, we completed Dr. Puno's spinal implant, which represents a new model for how surgeons can turn their ideas into products.

AND GROWING ...

In January, we expanded our space by an additional 5,000 square feet, bringing our total to 15,000 square feet. We also completed the expansion and the addition of our production capabilities. This gives us the space to quickly build clinically-usable products under strict manufacturing processes. Additionally, this space offers the ability to complete early builds of products, which allows Devicix and our customers to develop and optimize the



Peter DeLange
President and CEO

manufacturing processes of their products. The best part: we can now do all of this internally.

OUR EMPLOYEES

I mention our employees last, but believe me, they are at the top of my list when it comes to the day-to-day operations and success of Devicix. Since last fall, we have added another six individuals to our team, bringing our total to 32 employees!

This growth is important to Devicix, as it is our desire to remain strong and steadfast even in this tough economy. That being said, and I can't stress this enough, we have our clients and employees to thank for our continued success!

Have you heard?

Mithun Gundi (Project Engineer) is volunteering his expertise to “The Phoenix Project,” a study group of the Twin Cities IEEE that is developing an ambulatory blood pressure monitor for the Halberg Chronobiology Center at the University of Minnesota. Specifically, Gundi is working on the Data Acquisition Prototype.

Raymond Lei (Software Engineer) recently learned that his H-1B visa, sponsored by Devicix, was approved effective Oct. 1, 2009.

Anil Asrani (Manager of Business Development) joined the management team at Devicix on June 29, 2009. He brings 10+ years of academic biomedical research experience and a recent MBA in marketing with a medical industry specialization from the Carlson School of Management. Anil was recognized as Student of the Year for his efforts at Carlson, which included leadership roles on two student groups, being a recipient of a Carlson Family Foundation scholarship and the founding of the Medtronic Interdisciplinary Healthcare Case Competition.



Wow! Devicix employees have been busy!

- Chris Thorp and his family welcomed a baby boy, Alexander, on April 23, 2009.
- Anil Asrani and his wife, Laura, welcomed a baby girl, Arabella on May 27, 2009.
- Jeremy Ling and his family welcomed a baby girl, Mairi, on July 5, 2009.
- Alice Spurrier married Young Cho on July 3, 2009, and they are expecting a baby girl Feb. 5, 2010. Todd Moucha married Esther M. on Sept. 26, 2009.

2009

Upcoming Events

2010

Oct. 21-22, 2009 — MD&M Minneapolis

Minneapolis Convention Center
Minneapolis, MN
www.devicelink.com/expo/minn09



Oct. 27-28, 2009 — CIMIT Innovation Congress

CIMIT INNOVATION CONGRESS 2009 October 27-28, 2009 Back Bay Events Center
Boston, MA

www.cimit.org/innovationcongress.html

Nov. 5-7, 2009 — Orthopedic & Trauma Seminar

Minneapolis Convention Center
Minneapolis, MN
www.orthotrauma.us/index.html

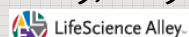
Nov. 11-12, 2009 — MidAmerica Healthcare

Monona Terrace
Madison, WI
www.midamericahealthcareforum.com



Dec. 9, 2009 — LifeScience Alley

LifeScience Alley. Minneapolis Convention Center
Coming together to collaborate, innovate, succeed. Minneapolis, MN
www.lifesciencealleyconference.org



Feb. 9-11, 2010 — MD&M West

Anaheim Convention Center
Anaheim, CA
www.MDMwest.com



March 9-13, 2010 — AAOS Annual Meeting

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS



Morial Convention Center
New Orleans, LA
www.aaos.org

April 13-15, 2010 — DMD Conference

Radisson University Hotel
Minneapolis, MN
www.dmd.umn.edu



May 12-13, 2010 — OrthoTec

Grace College
Warsaw, IN
www.orthotec.com



For an updated list of events visit www.devicix.com/events.htm

ISO certifications bring quality systems to the forefront

In an effort to better serve its clients and remain competitive in the marketplace, Devicix applied for and received ISO 13485 and 14971 certifications in September of this year.

ISO 13485 instructs firms who are designing and manufacturing medical devices on the requirements that must be adopted into their comprehensive management systems in order to be compliant. A key component of that is risk management, which must be conducted and documented throughout a product's lifecycle. Concurrently, ISO 14971 takes the specifics of risk management one step further by defining a list of action items to identify hazards and evaluate risks.

"The certifications go hand-in-hand," says Bob Parsons, Devicix's director of quality and regulatory issues. "Because risk management is a key element of ISO 13485, it just makes sense for Devicix to get certified in ISO 14971 as well."

It makes sense for clients, too.

"More and more, our larger clients are requiring their suppliers to be ISO 13485 certified because they are certified and want their suppliers to be playing by the same rules," says CEO and President of Devicix, Pete DeLange.

SMOOTH RIDE TO MARKET

Smaller companies can benefit by having products engineered under ISO 13485 because its requirements are very close to not only the FDA's 21CFR820 requirements, but also to other foreign regulations as well.

"Using an ISO-certified company provides high assurance that the devices

will meet FDA requirements, making it easier to get the product approved and to market," says Parsons.

While it is true that ISO 13485 does not fulfill all of the stringent requirements of each of the global regulatory bodies, it does provide a foundation upon which compliance can be built.

"It helps ensure that our services and goals can meet all of our clients' quality standards and provides them with the assurance that we can get their device into the market quickly, regardless of the markets they are pursuing," says DeLange.

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BUILDING A QUALITY SYSTEM

Devicix weighed the pros and cons of hiring a consultant versus an employee to pursue certification, and ultimately brought Parsons on board Oct. 31, 2008, as Devicix's full-time director of quality and regulatory issues.

Parsons previously managed ISO 13485 certification processes through Technical Compliance during his work as a consultant for Abbott Laboratories, Eli Lilly, Ethicon, Cardinal Healthy and St. Jude Medical.

"To implement our quality systems, we mapped out the business processes then built a quality system to support those processes," says Parsons. "We needed to develop a system that didn't hinder our well-known efficiency."

One of Parsons' goals was to debunk the common misperception that having quality systems in place slows down the process. The opposite is actually true.

"We've been able to create procedures that comply with ISO 13485 requirements while still working with, not against, the way Devicix employees already do their jobs," says Parsons.

"Because Devicix team members helped create the system that incorporates their specific needs, they're more likely to follow its procedures and feel invested in the outcome."

CONSULTING SERVICES

As an added resource for clients, Devicix will offer consulting services on quality systems, as well.

"We can help smaller customers, who have a marketable device, to implement their quality management systems," says Parsons. "They can leverage Devicix's experience and rely on us to maintain an accurate and complete design history file."

The ISO 13485 certification follow-up maintenance includes internal and external audits by the regulating body, BSI. Additionally, Parsons is responsible for inspecting and releasing all components that come to Devicix.

Published in 2003, ISO 13485 supersedes the earlier 1996 version EN 46001, EN 46002 and ISO 13488.

Humidity/temperature testing available in environmental chamber

Devicix recently acquired an environmental chamber, also known as a temperature/humidity chamber, to expose medical devices to a range of temperatures and humidity levels, similar to those that might be experienced during shipping and end use.

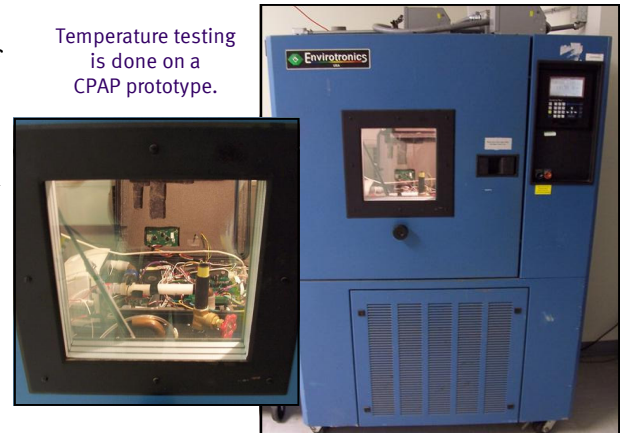
One benefit of the environmental chamber is that Devicix has the ability to test devices quickly in-house rather than contracting out for testing. The testing can be done earlier in the prototyping phase and can help to troubleshoot system malfunctions that have a thermal component.

Temperature range: -68C to 177C

Humidity range: 20% to 95% relative humidity

Capacity: 16 cubic feet

Temperature testing is done on a CPAP prototype.



About Devicix

Devicix is an engineering firm dedicated exclusively to designing and developing medical devices.

Each of our electrical, mechanical, biomedical and software engineers has earned a Bachelor's, Master's and/or Doctorate degree in his or her engineering specialty.

Medical backgrounds include experience in cardiovascular, orthopedics, critical care, monitoring devices, exercise physiology and nutrition. The average experience level is 15+ years.

- Electrical Design
- Mechanical Design
- Software Design
- Product Development
- Regulatory Support
- Quality Assurance
- Intellectual Property



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Spotlight on ...

Software Development

The software development profession continually generates new ideas for more efficient and more robust methods of creating safe and reliable software. Devicix closely monitors those efforts to ensure that its processes are as efficient, up-to-date and as safe as possible.

IEC 62304

Quality management standard, IEC 62304, defines the life cycle requirements for medical device software and, according to Devicix's Director of Software Engineering, Glenn Toews, fills in the gaps in other standards like 60601-1-4, which are intended as general software engineering standards.

"The IEC 62304 standard has seen significant involvement from the FDA from the start and is a standard recognized by the FDA," said Toews. "IEC 62304 contains risk safety management requirements essential for medical devices."

IEC 62304 is intended to be used in conjunction with the ISO 14971 risk management standard, and requires the risk management process to be performed at various stages of software development.

"This is a natural fit for Devicix since

we have received our ISO 14971 certification," said Toews.

By using the interdependence between IEC 62304 and ISO 14971, Devicix has tailored its development process based on the risk classification of the target device.

"Using industry best practices, FDA guidance documents, and technical reports from AAMI and IEC, we have created efficient processes that meet the requirements of the software development standard and the risk management standard for devices of all safety classifications," said Toews.

VALUE-ADDED SERVICE

The high level of expertise customers receive from Devicix engineers allows companies to plan better, to identify the most critical or riskiest parts of applications, and ensures that, at the end of the day, all steps are taken to create the safest product.

"Customers benefit from having access to a software development team that is highly trained in developing medical device software and knowledgeable about risk management, the development process and regulatory documentation requirements," said Toews.