THE SUMMIT

Innovations in Bioengineering

Worcester, Massachusetts

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MassMEP

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Bioengineering Institute

MANUFACTURING ADVANCEMENT CENTER

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"The purpose of this Summit is to call attention to the fact that the primary manufacturing sector in Massachusetts is medical manufacturing, an exciting and innovative industry that continues to evolve through bioengineering research and development."

Paul Kennedy, President of Kennedy Die Casting and Chair of the MassMEP

The focus of the **2003 Manufacturing Our Future Summit** was Gateway Park and the Bioengineering Institute. New efforts at WPI, the Bioengineering Institute, and the new one million square foot Gateway Park have allowed the local area to build on an already strong base in bioengineering, biomechanical devices, manufacturing, and related research.

With the creation of extended industry clusters in this region, a wealth of new capabilities have unfolded, including new metal processing techniques, brownfield development, and workforce education. In combination with the state's high velocity of capital utilization, Central Massachusetts is outperforming other sectors around the world.

According to MassMEP Chairman Paul Kennedy, Massachusetts ranks among the top states for production and exportation of medical instruments. The highly specialized components and stringent quality control processes required to develop these devices have made it unlikely that the medical instrument sector will outsource jobs and manufacturing operations overseas. But Massachusetts faces a number of challenges, both in terms of economics and jobs.

The State of the State

"We must deal with a number of key issues as we face our future as a Commonwealth and as a nation," stated Governor Mitt Romney. "Fortunately, the principals that have led us to our position of worldwide strength are the ones we must espouse and live by. We have good people, the basis for our competitive advantage, and we believe in individual responsibility. Our citizens must come first. They need our support. We as a state must invest in our people, provide more education, offer more training, keep taxes in check, and learn how to do our jobs better."

Governor Mitt Romney

According to Governor Romney, Massachusetts has the highest concentration of biotechnology firms in the nation. Greater Boston through Central Massachusetts is the leading biotech cluster in the US, followed by San Francisco and San Diego. But as the industry transitions from a research focus to production operations, many biotech firms have moved elsewhere.

Governor Romney reported that in a recent survey of business leaders, the primary reason they had not considered expanding in Massachusetts was because of the high cost of housing for employees. To remain competitive, the state infrastructure must support competitive wages and affordable housing. As a result, the state has turned its attention to affordable

housing venues and reforming the unemployment insurance system.

Governor Romney also discussed a new series of incentives to encourage employment growth; these take the form of investment tax credits, bridge loans, and manufacturing incentives. For example, for any manufacturing company with 10 or more employees in the biotech field, whether devices, instrumentation, or biopharmaceuticals, the state takes half the taxes the employees pay and gives it back to the company for three years. This has produced an immediate positive impact on key measures of financial success, including IRR and NPV.

A practical example of the benefits of reinvestment was recently seen at Ocean Spray. The company had planned to close the manufacturing facility and move to Wisconsin. The CFO said their numbers changed, through, when the state of Massachusetts gave them a job training grant. The grant paid for the training of an entire new production line and made Massachusetts a more attractive place to stay. In other words, a $250,000 grant kept 200 jobs here.

Congressman James McGovern

"I am very committed to the principal that government service is about public service," stated Governor Romney. "We have a responsibility to serve the people who elected us. We must be efficient with the resources that are given to us so we can provide an economy and environment that will allow businesses to grow. As a result, our tax base will grow and we can build more schools and provide more elderly services. Our goal is to have the kind of competitive environment that makes Massachusetts the place to be. Manufacturing jobs will be alive and well. To do that we must link research and education, as well as manufacturers and employees. We must encourage businesses to stay here by keeping the costs of doing business down."

A new Jobs First Bill has been proposed to put additional monies into UMass and encourage all 120 colleges and universities in the state to provide a renewed emphasis on technology development, patent creation, VC funding, and new business launches. The goal is to strengthen the entire state and ensure it remains a competitive area where manufacturing companies can grow and thrive.

Leveraging our Educational Resources

Congressman James P. McGovern also addressed the Summit. "At the local level, we have a can't fail opportunity with the WPI Bioengineering Institute. This is a research engine with limitless potential and a unique ability to transform our city and our regional economy. We have the infrastructure and some of the finest colleges and universities in the world. In Worcester alone, we have over 36,000 students, a tremendous amount of brainpower that's crying out to be harnessed. Our challenge is to strategically leverage this intellectual capital in such a way that it complements our rich tradition of manufacturing and innovation, and pays dividends for the entire region."

Congressman McGovern continued, "WPI's Bioengineering Institute is the embodiment of this strategy in motion. It is a marketplace for ideas where the next generation of cutting edge research will meet the emerging technologies of today. Never imagined advances in untethered healthcare, molecular engineering, and comparative neuroimaging have already begun to attract biomedical industry giants as well as

fledgling startups. These companies will continue to attract the attention of our region's top-notch graduates and will provide careers that will change the course of healthcare and improve the lives of people around the world."

According to Congressman McGovern, the Federal government earmarked $3.5 million from the Department of Defense for the Center of Untethered Healthcare. This money is designed to bring advanced technologies to combat soldiers, such as tracking health conditions from remote locations. The application of such advances to the civilian world, such as using home monitoring devices to reduce required hospital stays, lowers overall healthcare costs.

The Medical Device Industry

According to Tom Sommer, President of MassMedic, the medical device industry in Massachusetts is an excellent example of successful collaboration. Massachusetts houses the second largest concentration of device manufacturers in the US. The industry encompasses 21,000 jobs in 264 manufacturing companies, accounts for more than $4 billion in annual sales, and shows an annual growth rate of 6-9%. An additional 17,000 jobs in related industries such as injection molding, component manufacturing, marketing, and legal services, have produced a supercluster of nearly 40,000 jobs.

Employment in this industry covers a wide range of instrumentation, with Philips Medical in Andover and Boston Scientific in Natick among the largest:

- Surgical and medical instrument: 37%
- Electromedical and electrotherapeutic apparatus: 23%
- Surgical appliances and supplies: 11%
- Irradiation apparatus: 9%
- Opthalmic goods: 9%
- Lab apparatus: 7%

The bulk of the industry, 75%, is companies with fewer than 50 employees.

"Our early stage community is innovative and active," stated Mr. Sommer. "This is vital for the continued growth of any technology based industry cluster. This is where we see major breakthroughs. In fact, Massachusetts is in the top tier of states filing medical device patents. And we are second only to California in attracting and securing venture capital money for medical device companies."

"The challenge is that this industry doesn't enjoy the same level of patent protection that's seen in biotechnology or pharmaceuticals," continued Mr. Sommer. "So we must constantly innovate and continuously improve medical healthcare delivery. That makes it a tumultuous industry with lots of activity and R&D. Product life cycles are fast, one to two years, with an overall life cycle of 3-4 years, at best."

Currently, Massachusetts ranks second or third in premarket approval products, the more innovative devices that are reviewed by the FDA. The state ranks third behind Connecticut and California in generating value in the production process for medical devices. The bulk of the state's industry is highly complex technical devices as opposed to commodities like tongue depressors and bedpans.

The medical device industry has enjoyed strong expansion. Smith & Nephew added two facilities in Mansfield and Andover. Philips Medical purchased HP's medical products group and kept it here in Massachusetts. Zole Medical produces the new automatic external defibrillators found in bus terminals and municipal buildings. Nova Biomedical added 90 jobs in Bedford to undertake a new partnership with Becton Dickinson for glucose monitoring devices.

Even related industries are finding strong connections in medical devices. Kennedy Die Castings recently worked with scientists to develop a better way to catch mosquitoes. The company's expertise in thermal management led to the development of a mosquito catcher that uses a biochemical process to attract insects. It has since become their largest product line.

Our Pursuit of Outer Space

NASA has become a central player in the area of technology innovation. Interested in the effects of space flight on human physiology, their research partnerships with academia and industry have produced in a wide range of biomedical instruments and applications.

According to astronaut Dan Barry, PhD, MD, "Space has a dramatic effect on the human body. Bone loses strength, muscles atrophy, the immune system doesn't function as well, and radiation directly damages cells. NASA began with such basic systems as telemetry to monitor heart rate and rhythm, and has since progressed to telemedicine where we now remotely monitor people in space. We can even look at changes that occur in body tissue as it undergoes damage." NASA collaborations have resulted in a variety of advanced technologies that have direct application in our lives. For instance, initially the Shuttle's fuel lines had a hard time pumping the amount of fuel that was needed in the amount of space provided. The technology that solved this problem is now being used in Houston to develop a ventricular device that assists weak hearts. Similarly, colloid experiments in space have proved invaluable for detecting and monitoring cataracts. A new NASA device, the bioreactor, allows examination of three-dimensional cell cultures, allowing us to look at more organ type cells and see how things truly operate inside living structures.

For more information, visit:

- National Space Biomedical Research Institute, http://www.nsbri.org
- Space Product Development, http://spd.nasa.gov
- Commercial Applications, http://commercial.hq.nasa.gov

"All these technologies are important, but they don't explain why we risk lives to fly in space," said Dr. Barry. "When we talk about the benefits of space flight, from food safety to medical monitoring to microelectronics, that's only part of the payback. The reason we risk lives is because life forms that have too much success become complacent and stop adapting. As soon as that happens, the species time is limited. They will become extinct. This is true in biology and it's true in business. If you lose your vision and stop expanding, your business will suffer. For individuals and nations, as well; if we stagnate, we dissolve."

"Expansion is part of man's nature," Dr. Barry continued. "The 1400's will be remembered for Christopher Columbus. The 1900's will be remembered for 1969, the day we first stepped on the moon. Next stop is Mars. If we can find out if there ever was or is life on Mars, even the smallest microbe, we will know that we are not alone. If life evolves in two places independently, then it is everywhere in this galaxy. Reaching Mars may also help us discover another way to create life. On Earth, we use nucleic acid. If we find there's another way, it can help us discover whole new concepts. Space is not about technology, it's about destiny."

Partnerships Between Government, Industry, and Academia

State Representative Vincent Pedone, Senior Member of the House Ways and Means Committee and Vice Chair of the Science and Technology Committee, stated, "Government, industry, and academic need to work together in public-private partnerships. A great example is in the area of biomedicine. In early 1980, the Massachusetts Department of Mental Health turned over a large portion of land to be developed into biotech clusters. It has since turned into one of the leading biotech centers, Mass Biomedical Research Park. Currently, over a dozen new biotech companies reside there and contribute tens of millions of dollars in revenue to the local economy. Massachusetts also invested in MBI, the Massachusetts Biomedical Initiatives, a collaboration designed to incubate and grow small biotech companies."

Most recently, the House of Representatives recognized the need for involvement in the rapidly developing cross section of science, technology, and economic development. They created the Science and Technology Committee and charged it with consider-

ing all matters related to science, technology, economic development, and the retention of science and technology intensive industries.

To continue to support public and private partnerships, on July 15, 2003, the Massachusetts House of Representatives enacted An Act Relative to Economic Development Stimulus package. This bill permanently extends the 3% tax investment credit and an investment of $55 million in the Emerging Technologies Fund. In addition, a $20 million investment in the Massachusetts Development Corporation provides long term capital for technology companies, bridge loan programs, brownfields development projects, and strengthens the research bonds between industry and academia.

Technology Transfer

The Association of University Technology Managers has developed a successful program that aligns university research with technology transfer opportunities in the commercial sector. The program started in 1974 with 7 participants. Today, there are 3200 members representing 1500 institutions around the world. 50% are universities and colleges, and 50% are industry/government/investors/attorneys in the technology transfer field.

According to Anne Hammersla, PhD, President Elect of the Association of University Technology Managers and Senior Counsel for Intellectual Property at MIT, "The most recent survey of technology transfer and its results has shown impressive growth. In FY2001, 190 US institutions reported $31.7 billion in sales and 13,569 disclosures of technology. That's essentially one disclosure for each $2.3 million. In addition, 6800 new patent applications were filed by universities with industry sponsors. 4058 licenses and options were entered into by universities across the country and there were 494 new company starts, clearly demonstrating the high success rates being achieved in technology transfer."

Over the last 10 years, $235.5 billion in research has resulted in 110,751 disclosures, 49,815 US patent applications, and 24,420 US patents issued.

Paul Kennedy, MassMEP Chair and President, Kennedy Die Casting

Commercialization has been successful as well. Over the same time period, there were 32,417 licenses (22,937 of which are still active) and 3970 commercialized platforms (2514 of which are still operational).

On the Outside Looking In

"The local area is looking strong, but it's often easier for someone on the outside to peak in and see what's going on," said Michael Wacholder, Director of the Rennselaer Technology Park at RPI in New York. "When I looked at the Bioengineering Institute and Central Massachusetts, it didn't take long for me to see that you're doing all the right things. In fact, our journey was very similar to yours and we've seen tremendous success. I'm confident you will, too."

There are 14 colleges/universities in the region surrounding RPI and about 1 million people in the area. The original idea was to build a technology park, but it evolved into a series of economic and business development opportunities. This led to the creation of the Capital Region Technology Council and several venture forums where entrepreneurs connect with RPI and the community and obtain financing.

"RPI is not a huge university, therefore the park had to be a business," Mr. Wacholder continued. "To enrich the intellectual environment of the university, we had to create a place that would attract and grow

industry, as well as foster economic development in the community. The results have been tremendous."

In the Rennselaer Technology Park, 160 tenants reside on 1250 acres. One third of the companies were founded by students or alumni, one third by faculty, and one third from the community. The Park has created over 2000 jobs and generated annual sales of over $200 million. 2400 employees work in 23 buildings. The survival rate of the participating companies is over 80%.

One of the notable successes is MapInfo. The company started with three students in a course at RPI. In 1986, they developed a business plan for onboard mapping for trucks and delivery vehicles. They quickly evolved that concept into desktop mapping and databases. The company went public in the 1990's, owns 210,000 square feet in the Park, and employs nearly 700 people.

Dr. Tim Gerrity, Director, Bioengineering Institute

"Overall, eight out of ten companies will fail," said Mr. Wacholder. "In an incubator environment, 8 out of 10 will survive. With the assistance of resources like the Rennselaer Technology Park and the Bioengineering Institute, there is now a formula for accelerating success."

WPI Bioengineering Institute

First launched in 2002, the WPI Bioengineering Institute (BEI) is an interdisciplinary research and development organization dedicated to taking academic discoveries and turning them into useful biomedical devices.

According to Tim Gerrity, PhD, Director of the Bioengineering Institute, "We are here to support and expand the Central Mass medical device cluster. Nurturing this industry requires a community of partners including government, industry, and academia. Our goal is to get new technologies into the market quickly by feeding existing companies and by creating new ones. But the competition is fierce. We need to make manufacturing easy, develop new manufacturing technologies, and train the workforce."

BEI's mission is to commercialize research discoveries, and create beneficial life science products through industry, university, and government alliances. The organization fosters relationship creation, provides commercialization education and guidance, and conducts cutting edge research.

BEI's programs include MedTech Grand Rounds, a regular event where clinical problems and engineering solutions are brought together to catalyze commercialization and provide links to a variety of support services.

Worcester needs to remember its manufacturing heritage. 150 years ago, Ichabod Washburn brought together a core technology (wire manufacturing), innovated with the help of WTI (now WPI), created a strong supply chain from raw materials to finished goods, and took advantage of the room to build and easy access to transportation to create a vertically integrated industry.

The same resources that have driven this industry are driving new developments in biotechnology, medical technology, and biopharmaceuticals. All the ingredients are in place for a thriving bioengineering industry at the forefront of a new economy.

Speakers

Welcome and Overview
Paul Kennedy, President, Kennedy Die Casting, Inc.

Creating New Jobs in Massachusetts
The Honorable Mitt Romney, Governor of Massachusetts

How Will Massachusetts Compete in a Knowledge Economy
The Honorable James McGovern, Member of Congress, 3rd District

The Medical Technology Industry: The Merging of Technical Innovation and Manufacturing
Tom Sommer, President, MassMEDIC

The Government, University, Industry Partnership: Creating New Ways to Move from Science to Application
Dan Barry, Ph.D., M.D., Astronaut, NASA

Regional Socio-Political Forces Affecting New Industrial Growth
Representative Vincent Pedone

Creating New Technologies from Academic Research
Ann Hammersla, Ph.D., President-elect Association of University Managers of Technology, Office of Intellectural Property Counsel, MIT

The University as a Driver of Regional Economic Development
Michael Wacholder, Director, Rensselaer Technology Park, RPI

Putting it All Together: A Roadmap for Success
Timothy Gerrity, Ph.D., Director, WPI Bioengineering Institute

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