

Date: October 25, 2012

To: Department of Commerce, National Institute for Standards and Technology
Sent by email to: nnmi_comments@nist.gov

From: Michael Langley, CEO, GREATER MSP
Jaime Nolan, Executive Director, Minnesota Precision Manufacturing Association
Dale Wahlstrom, Executive Director, LifeScience Alley
Margaret Anderson Kelliher, Executive Director, Minnesota High Tech Association
Nena Street, CEO, Global Robotics Innovation Park

Re: Comments to Request for Information on Proposed New Program: National Network of Manufacturing Innovation (NNMI), RIN: 0693-XC001

Introduction

Thank you for affording us the opportunity to submit comments on the proposed new National Network of Manufacturing Innovation program (NNMI or Network). The following comments are the product of a collaborative effort between educational institutions, economic development organizations, industry representatives and industry associations in Minnesota. To assist the NIST-hosted AMNPO in the development of the Network, our comments first propose an institute technology focus area that will accomplish the goals of NNMI by serving national needs and improving the competitiveness of a broad base of domestic manufacturers. We then propose criteria for use in selecting technology focus areas, and we demonstrate that our proposed focus area satisfies each criterion. Finally, we provide a brief introduction to the unique resources available in Minnesota to support the proposed institute.

Comments

I. Medical Technology Manufacturing Institute

We propose establishment of a medical technology manufacturing institute. With a primary focus on advanced manufacturing of medical technology, the institute will develop enabling technologies and refine manufacturing processes that can be broadly applied to other industry sectors, including robotics and automation, agriculture, energy, security and defense. Advancements in medical technology manufacturing require collaboration across multiple disciplines and involve:

(a) Developing advanced modeling and simulation tools (i) for design, verification, validation, and manufacture of medical technologies, including simulation-based medical device engineering; (ii) to revolutionize the regulatory evaluation pathway for medical technologies and their development, by enabling virtual clinical trials and personalized medicine; and (iii) for training of all professionals involved in the manufacture and use of medical technology, from engineering technicians to doctors, including linking simulations with visualization and interactive design;

(b) Creating and integrating technologies capable of efficiently handling the volume, velocity, and variability of big data generated: (i) during the design, verification, validation, and manufacture of medical technology, (ii) by medical devices and other technologies themselves once in use, including incorporation of the data into patient medical records, and (iii) during classroom and on-the-job training programs;

(c) Incorporating robotics, process automation and machine learning into medical technology, including the use of embedded sensors, which will enable, among other things, sensor-based diagnostics, as well as, compact and fluid power, cultivation of energy harvesting, weight optimization and optimization of energy allocation;

(d) Improving manufacturing processes for rapid manufacture of modular, customized and adaptable medical technologies, including medical devices, particularly through the use of micromachining and nanotechnology;

(e) Improving materials used in manufactured medical technology, including, nanotech coatings, green plastics, biological materials and other biocompatible agents;

(f) Developing facilities and controls technology that enable controlled environment areas in which conditions can be maintained, monitored, and corrected with high reliability and minimal cost impact; and

(g) Enabling interoperability in manufactured medical technology to allow for standards-based connectivity and streamlined equipment management and deployment, which will promote the rapid development and deployment of new medical sensors and actuators that can be integrated with the existing infrastructure as they become available.

II. Proposed Technology Focus Area Criteria and Justifications for Medical Technology Manufacturing Institute

We propose the following criteria for selection of technology focus areas. An institute focused on medical technology manufacturing satisfies each proposed criterion, as noted below.

- 1. No single company has the technical expertise or financial incentive to catalyze the advancements necessary to keep domestic manufacturers competitive in the technology focus area. And no single institution, academic or otherwise, has the ability to promote rapid dissemination of key technological advancements throughout the nation. Advancements in the technology focus area must occur at the intersection of multiple disciplines and require collaboration and coordination that is unlikely to occur without the opportunity created through federal funding.*

Advancements in medical technology manufacturing will occur most efficiently through collaboration between multiple industry sectors and through interdisciplinary collaboration within and between research institutions. For instance, development and deployment of advancements in medical

technology manufacturing require collaboration between myriad industries and disciplines, including, for example, the medical device industry, precision manufacturers, software firms, engineering firms, robotics and process automation companies, hardware/software integrators, regulators, technical colleges, medical schools, and hospitals and clinics, among many others.

- 2. Advancements in the technology focus area will improve the competitiveness of broad base of domestic manufacturers.*

Advancements in medical technology manufacturing require development and deployment of enabling technologies that will improve the competitiveness of all firms directly involved in the manufacture of medical technology, as outlined in Section I of these comments. Further, improvements in those enabling technologies will have broad application to other key manufacturing sectors including robotics, agriculture, security and defense, and energy, among many others.

- 3. Advancements in the technology focus area can be spurred through cost sharing; for instance through the provision of shared assets to help companies gain access to cutting edge capabilities and equipment.*

Advancements in medical technology manufacturing require access to a wide variety of expensive, highly specialized equipment that would be prohibitively expensive for any one firm or academic institution to acquire. For instance, immersive virtual reality environments are essential to effective use of modeling and simulation tools, but extremely expensive. Similarly, access to the array of manufacturing equipment necessary for research, development, testing and evaluation of new technologies is prohibitively expensive for nearly all entrepreneurs, small and mid-size manufacturers, and even for many large firms. Further, access to such equipment is essential for proper workforce development and educational programming, and yet most community and technical colleges cannot afford to purchase the equipment.

- 4. Advancements in the technology focus area will serve national needs.*

A Medical Technology Manufacturing Institute will serve a variety of national needs. Advancements in medical technology will equip the Departments of Defense, Veterans Affairs, and the National Institutes for Health with new tools to provide effective, affordable and efficient care for military and civilian personnel at home and abroad. The Department of Energy will benefit through advancements in enabling technologies related to energy harvesting, weight optimization and optimization of energy allocation. The National Institute for Standards and Technology will benefit through development of standards in medical technology, including advancements in interoperability capabilities and facilities and controls. The National Science Foundation will benefit through transferrable enabling technologies related to big data. And the Federal Drug Administration will benefit through innovations in the regulatory approval process for human and animal medical devices and related regulated medical technology.

5. *Advancements in the technology focus area will reduce the risk and cost of commercialization, by bridging the gap between applied research and product development and by addressing production-level challenges.*

A Medical Technology Manufacturing Institute satisfies this criterion by enabling cost-sharing among all participants in the medical technology ecosystem, which will spread the burden of pre-commercialization costs among several firms and create a bridge between applied research and production-level manufacturing. Advancements in the areas detailed in Section I will further reduce the risk of commercialization by lowering manufacturing costs through better materials, more efficient manufacturing processes, and an increased ability to manufacture modular and customized equipment.

6. *The technology focus area will create opportunities to continuously educate and train students and workers in advanced manufacturing skills.*

Advancements in medical technology manufacturing will fundamentally redefine manufacturing careers for the foreseeable future through profound changes in the technology areas detailed in Section I. A Medical Technology Manufacturing Institute will accelerate innovation and technology transfer, thereby increasing national demand for workers trained in relevant advanced manufacturing skills. Moreover, the work of the institute would benefit from the participation of students and workers, and could provide relevant hands-on experience for learners, resulting in an experienced workforce for employers.

III. Minnesota Resources to Support a Medical Technology Manufacturing Institute

Minnesota is one of the world's most respected ecosystems for medical technology development and manufacturing. With the largest concentration of medtech manufacturers in the U.S., the state is home not only to global giants like 3M, Medtronic, St. Jude Medical and Boston Scientific's cardiovascular business, but also to an active start-up community, solid mid-sized device firms, world class research institutions – such as the University of Minnesota and Mayo Clinic – hospitals, payers, contract design and manufacturing firms, highly specialized medtech consultants and investors, and the nation's largest and most active regional life science industry association. A functioning ecosystem is not just the constituent parts, it is also the trusted relationships among them that accelerate the development of new ventures – and Minnesota's medtech cluster is highly interconnected. While many communities possess ideas to improve medical care, few possess the experience and commitment to transform ideas to reality through the long, complex and expensive process necessary to demonstrate safety and efficacy for novel medical devices. Minnesota's strengths in related industries will enable the effective development and deployment of the advancements identified in Section I.

Minnesota's manufacturing sector is likewise robust. It represents one in seven Minnesota jobs and has the largest total payroll of any business sector. Minnesota has 300,200 manufacturing jobs statewide, which accounts for 14 percent of all private-sector jobs in the state. In addition, each manufacturing job supports another 1.3 jobs elsewhere in the economy through supplier purchases and employee spending. In all, manufacturing accounts for nearly 800,000 jobs or about 29 percent of all

jobs in Minnesota in the state. Minnesota is a national leader in manufactured medical devices, producing everything from catheters and pacemakers to dental instruments, eyeglass lenses and hearing aids.

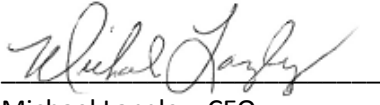
Minnesota's academic institutions also offer a wealth of resources for basic and applied research, as well as access to a diverse array of students and workers. For instance, the institute could draw from and leverage the resources and expertise at the University of Minnesota, including, the Minnesota Supercomputing Institute, the Institute for Engineering in Medicine, the Medical Devices Center, and the Center for Distributed Robotics, among others. The Minnesota State Colleges and University System offers a network of 31 institutions, including 24 two-year colleges and seven state universities located throughout the state. The colleges and universities operate 54 campuses in 47 Minnesota communities and serve about 250,000 students in credit-based courses. Overall, the system produces about 33,500 graduates each year, many of whom join Minnesota's manufacturing and medtech workforces. In addition to credit-based courses, the system offers customized training programs that serve about 153,200 employees from 6,000 Minnesota businesses each year. Minnesota also has a robust network of private colleges and universities, which also educate and train the region's manufacturing and medical technology workforces.

Conclusion

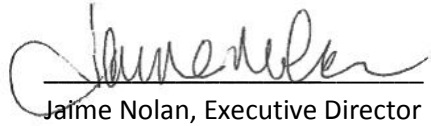
A core purpose of the Network is to foster industry, academic and government collaboration around domestic manufacturing. As demonstrated above, our region has a long history of public-private partnerships around the medical technology industry. We welcome the opportunity to leverage and expand that existing network to enable advanced medical technology manufacturing throughout our nation. The foregoing comments are the result of a collaborative effort from a wide-ranging group of industry-led organizations, and their academic, government, and economic development partners. We look forward to further opportunities to share our vision for a Medical Technology Manufacturing Institute with NIST and the nation.

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Respectfully submitted by,



Michael Langley, CEO
GREATER MSP



Jaime Nolan, Executive Director
Minnesota Precision Manufacturing Association



Dale Wahlstrom, President and CEO
LifeScience Alley



Margaret Anderson Kelliher, Executive Director
Minnesota High Tech Association



Nena Street, CEO
Global Robotics Innovation Park

United States Senate

WASHINGTON, DC 20510

October 25, 2012

Mr. Michael F. Molnar
Director, Advanced Manufacturing National Program Office
Chief Manufacturing Officer, National Institute for Standards and Technology
100 Bureau Drive, Stop 1000
Gaithersburg, MD 20899-1000

RE: Minnesota-Based Medical Technology Manufacturing Institute

To Mr. Molnar,

We are pleased to express our support for establishment of a Medical Technology Manufacturing Institute within the National Network of Manufacturing Innovation program, and for locating the Institute in Minnesota. With a primary focus on advanced manufacturing of medical technology, their vision is that the Institute will develop enabling technologies and refine manufacturing processes that can be broadly applied to other Minnesota high-technology industry sectors, including robotics and automation, agriculture, energy, security and defense.

A core purpose of the Network is to foster industry, academic and government collaboration around domestic manufacturing. Increased collaboration has already occurred in our region in response to the RFI opportunity. To prepare a collaborative response for the RFI, a diverse team of Minnesota leaders from industry, economic development and academic institutions examined the unique manufacturing strengths of our region and prepared a joint response to the RFI. In their response, they propose the establishment of a Medical Technology Manufacturing Institute. With a primary focus on advanced manufacturing of medical technology, their vision is that the Institute will also develop enabling technologies and refine manufacturing processes that can be broadly applied to other Minnesota industry sectors, including robotics and automation, agriculture, energy, security and defense.

For the reasons above, we encourage your strong consideration of this proposal. If you have any questions or need additional information, please contact Katherine Blauvelt at 651-221-1016 or by email at Katherine_Blauvelt@franken.senate.gov or Adam Schiff at 612-727-5228 or by email Adam_Schiff@klobuchar.senate.gov.

Amy Klobuchar
United States Senator

Sincerely,

Al Franken
United States Senator

October 25, 2012

Michael F. Molnar
Director, Advanced Manufacturing National Program Office
Chief Manufacturing Officer, National Institute for Standards and Technology
100 Bureau Drive, Stop 1000
Gaithersburg, Maryland 20899-1000

RE: Letter of support for Minnesota-Based Medical Technology Manufacturing
Institute

Dear Director Molnar:

I am pleased to express my support for establishment of a Medical Technology Manufacturing Institute within the National Network of Manufacturing Innovation program, and for locating the Institute in Minnesota.

A core purpose of the Network is to foster industry, academic and government collaboration around domestic manufacturing. Increased collaboration has already occurred in our region in response to the RFI opportunity. To prepare a collaborative response for the RFI, a diverse team of Minnesota leaders from industry, economic development and academic institutions examined the unique manufacturing strengths of our region and prepared a joint response to the RFI. In their response, they propose the establishment of a Medical Technology Manufacturing Institute. With a primary focus on advanced manufacturing of medical technology, their vision is that the Institute will also develop enabling technologies and refine manufacturing processes that can be broadly applied to other Minnesota industry sectors, including robotics and automation, agriculture, energy, security and defense.

I am proud to write in support of their vision for a Minnesota-based Medical Technology Manufacturing Institute.

Sincerely,



Eric W. Kaler
President

EWK:tl

cc: Steven Crouch, dean, College of Science and Engineering



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October 25, 2012

Mr. Michael F. Molnar
Director, Advanced Manufacturing National Program Office
Chief Manufacturing Officer, National Institute for Standards and Technology
100 Bureau Drive, Stop 1000
Gaithersburg, MD 20899-1000

Dear Mr. Molnar:

I am pleased to express my support for the establishment of a Minnesota-based Medical Technology Manufacturing Institute as part of the National Network of Manufacturing Innovation program. While the Medical Technology Manufacturing Institute would focus primarily on advanced manufacturing of medical technology, the Institute would also develop enabling technologies and refine manufacturing processes for broad application to other high-technology industry sectors important to Minnesota and its regional economies, including robotics and automation, agriculture, energy, security and defense.

In Minnesota, we have outstanding collaboration among leaders from business and industry, state and local governments and K-12 and higher education. These leaders are working together to enhance Minnesota's highly-skilled workforce and ensure a flourishing manufacturing economy.

On behalf of the seven state universities and 24 technical and community colleges that comprise the Minnesota State Colleges and Universities system, I am pleased to offer our support for a Minnesota-based Medical Technology Manufacturing Institute.

Best wishes,

Steven J. Rosenstone

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Michael F. Molnar
Director, Advanced Manufacturing National Program Office
Chief Manufacturing Officer, National Institute for Standards and Technology
100 Bureau Drive, Stop 1000
Gaithersburg, MD 20899-1000

RE: Letter of Support for Minnesota-Based Medical Technology Manufacturing Institute

Dear Mr. Molnar,

On behalf of the Minnesota High Tech Association, I am writing to express my support for the establishment of a Medical Technology Manufacturing Institute within the National Network of Manufacturing Innovation program, and for locating the Institute in Minnesota.

With a primary focus on advanced manufacturing of medical technology, our vision is that the Institute will develop enabling technologies and refine manufacturing processes that can be broadly applied to other Minnesota high-technology industry sectors, including robotics and automation, software, agriculture, energy, security and defense. Minnesota's long-time leadership in the medical device industry – anchored by major corporations such as Medtronic, Boston Scientific and St. Jude Medical – makes us well positioned to leverage our medical device expertise and strengths in other technology sectors to further refine manufacturing technologies.

In addition, a core purpose of the Network is to foster industry, academic and government collaboration around domestic manufacturing. Minnesota has a long history of collaboration among these sectors and has assembled a diverse team of Minnesota leaders from industry, economic development and academic institutions to examine the unique manufacturing strengths of our region and prepare a joint response to the RFI.

MHTA's goal is to keep Minnesota as a center of innovation and grow high-skilled, high-wage jobs and believe not only is Minnesota the ideal location for a Medical Technology Manufacturing Institute, it is an important factor to achieving that goal.

Sincerely,

Margaret Anderson Kelliher
President and CEO
Minnesota High Tech Association

MHTA represents more than 350 technology companies and organizations from across the state. Our members include some of the world's leading corporations, mid-sized companies and startups and represent industries ranging from IT, bio-sciences and advanced manufacturing to clean, green, edtech and health care tech. Together, we fuel Minnesota's prosperity through innovation and technology.