

National Institute of Standards and Technology Manufacturing Extension Partnership Advisory Board Minutes of the October 22, 2008 Meeting

Background

The National Institute of Standards and Technology (NIST) Manufacturing Extension Partnership (MEP) Advisory Board met in an open session from 11:30 a.m. to 5:30 p.m. on October 22, 2008, at the University of Maryland Inn and Conference Center in Adelphi, Maryland. Approximately 37 attendees, composed of Board members, MEP staff, and observers, attended the meeting.

Attendees

Board Members

Edward W. "Ned" Hill, Ph.D., Chair, MEP Advisory Board, and Vice President for Economic Development, Cleveland State University

Mark S. Rice, Vice Chair, MEP Advisory Board, and President, Maritime Applied Physics Corporation

Lydia Carson, President and Chief Executive Officer, Balm Innovations, LLC

Cheryl Hill, Owner and Chief Executive Officer, Hill Manufacturing, Inc., and Chairwoman, Board of Directors, Oklahoma Manufacturing Alliance

James Jacobs, Ph.D., President, Macomb Community College, Michigan

Fred Keller, Chairman and Chief Executive Officer, Cascade Engineering

Merritt Marquardt, JD, Office of General Counsel, 3M (retired), and Chairman, Board of Directors, Enterprise Minnesota

Capers McDonald, Executive in Residence, Carey Business School, Johns Hopkins University

MEP Staff Presenters

Roger Kilmer, Director, NIST MEP

Aimee Dobrzeniecki, Deputy Director, NIST MEP

Ken Voytek, Chief Economist, NIST MEP

Karen Lellock, Senior Policy Advisor, NIST MEP

Guest Presenter

Martha Connolly, Director, Maryland Industrial Partnerships, Maryland Technology Enterprise Institute

Observers

Samantha (Samm) Bowman, Conference Project Manager, NIST MEP

Ron Burke, Interim Director, New Mexico MEP

Bill Burwell, Director, Department of Commerce, U.S. Export Assistance Center - Baltimore

Mike Coast, President, Michigan Manufacturing Technology Center

John Connelly, Center Director, Enterprise Minnesota
Doug Devereaux, Technology Analyst, NIST MEP
Ronald Gan, Administrative and Financial Management Officer, NIST MEP
Amy Garcia, Legislative Assistant, Motor and Equipment Manufacturers Association
Anthony Gomez, Business Liaison Specialist, NIST MEP
Paul Hernandez, Information Technology Assistant, NIST MEP
Autumn Houser, Administrative Assistant, NIST MEP
Michael Johnston, Senior Business Advisor, Chicago Manufacturing Center
Tom Mahoney, Director, West Virginia MEP
Keith Mayeaux, President, A+ Corporation, and Member, Industrial Advisory Board,
Manufacturing Extension Partnership of Louisiana
Petra Mitchell, Vice President for Operations, Catalyst Connection
Glenn Pence, Director of Sales, Enterprise Minnesota
Jennifer Sinsabaugh, Program Manager, New Mexico MEP
Gerald Snell, Sales and Marketing Director, Oregon MEP
Dave Snow, Director, Indiana MEP - Purdue Technical Assistance Program
Bruce Vaillancourt, Director, NIST MEP Program, Ohio MEP
Phillip Wadsworth, Account Manager, NIST MEP
Bob Weinstein, President, Illinois Manufacturing Extension Center
Ruth Wilcox, Interim Program Manager, Iowa Center for Industrial Research and Service
Lynn Witten, President, Kentucky Manufacturing Assistance Center
Bob Zider, Director, Vermont Manufacturing Extension Center

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Welcome and Agenda Review

Speaker: Ned Hill, Chair, MEP Advisory Board, and Vice President for Economic Development, Cleveland State University

Mr. Hill, Chair of the MEP Advisory Board, called the meeting to order. The Board members and NIST MEP presenters introduced themselves. The meeting's agenda was outlined as follows:

- Biomanufacturing: A Primer
- MEP System and Center Performance
- MEP Next-Generation Strategy
- Update on MEP Strategic Initiatives,
- NIST Manufacturing Trends 2020 Study
- Board Feedback Session

Speaker: Roger Kilmer, Director, NIST MEP

Mr. Kilmer welcomed the attendees to the Advisory Board Meeting and introduced Mr. Keith Mayeaux, President, A+ Corporation, and member of the Industrial Advisory Board of the Manufacturing Extension Partnership of Louisiana. Mr. Mayeaux has been nominated to serve on the Advisory Board. Guest presenter Dr. Martha Connolly was then introduced. Dr. Connolly is a

biomedical engineer and the Director of the Maryland Industrial Partnerships (MIPS), a program of the Maryland Technology Enterprise Institute (MTech). The MIPS program accelerates the commercialization of technology in Maryland by providing matching funds for collaborative research and development (R&D) projects between companies and University of Maryland faculty.

Presentations

Biomanufacturing: A Primer

Speaker: Dr. Martha Connolly, Director, Maryland Industrial Partnerships, Maryland Technology Enterprise Institute

Biotechnology product development is a high-risk and high-reward business. In biomanufacturing, the costs are very high, the process is very long, and the chances of success are only 1 in 10,000. However, successful new products generate large revenues.

There is a strong nationwide interest in biotechnology. *BIO 2008*, a national biotechnology conference, has grown dramatically in recent years. Every State had representatives at *BIO 2008*, including many high-ranking officials, such as the Governors of Maryland and California. Biotechnology has wide interest because of its national and global impacts.

There are currently only nine competitive biotechnology centers located in the U.S. that have demonstrated the entrepreneurial and financial capacity to sustain biotechnology-related businesses. The centers generally develop near the coast and around research and commercialization-funding opportunities.

The commercialization of a new drug typically goes through three phases. During the discovery/pre-clinical-testing phase, the drug is assessed for its safety, biological activity, and formulations using laboratory and animal studies. In the clinical-study phase, the safety and dosage of the drug is first tested in healthy volunteers; then to evaluate effectiveness and side effects, the drug is tested in patient volunteers; and, finally, to confirm the drug's effectiveness and to monitor any adverse reactions from long-term use, the drug is further tested in patient volunteers. In the New-Drug-Application review/phase, the drug is put through the Food and Drug Administration's (FDA's) review and approval process. FDA sets requirements for biotechnology with two major goals in mind: safety and efficacy.

The cost to bring a new drug to market is approximately \$200 million, about 29% of which is spent on FDA-required clinical trials.

Some of the local bioscience firms in Maryland that have obtained national success include MedImmune, Digene, Human Genome Sciences, and Martek. Maryland's bioscience sector is among the country's largest, with around 350 companies.

Biomanufacturing is complicated because biomanufacturing requires very special facilities. For regulatory reasons, these facilities are rarely altered or retrofitted after production begins. These facilities require:

- Good Manufacturing Practices (GMP) as developed by FDA,
- Clean rooms and special air handling, and
- Highly trained and specialized staff.

Many bioscience firms are small (averaging 15 employees) and are not in a good position to manage the biomanufacturing process on their own. This is because small biotechnology firms:

- Lack expertise in manufacturing; focus is more on R&D and clinical programs,
- Do not understand GMP as required by FDA,
- Are not prepared to make timely decisions on the manufacturing process,
- Do not understand intellectual property and patents,
- Are not prepared to make outsource versus in-house decisions, and
- Do not have access to large manufacturing facilities.

There are opportunities for the MEP Centers to assist biomanufacturing firms. Specifically, MEP Centers can:

- Assist firms in the manufacturing decision-making process,
- Provide expertise in manufacturing best practices for emerging R&D companies,
- Educate biotechnology companies on manufacturing, and
- Assist in plant layout, Lean, supply chain opportunities, lot tracking, inventory control, and staff training programs.

MTech and NIST MEP's Maryland Technology Extension Service are assisting many small Maryland bioscience firms in such areas as product packaging, Lean training, automation of processes, manufacturing facility improvements, workforce training, manufacturing scale-up analysis/strategy, and radio-frequency-identification-interface development.

Comments from the Advisory Board:

- If the business model of large biopharmaceutical companies is to purchase their innovation from start-up companies, and those local or state public funding, is there not a danger that the company may move without any return being generated for the community that provided the funding? States need to understand the risks associated with pharmaceutical investments.
- A few Contract Research Organizations (CROs) exist around the country that offer a wide range of pharmaceutical drug biologic- and device-development services. Quality is very important in the pharmaceutical industry. Partnering with a CRO may be a good idea.
- The R&D arm of a company must work closely with the manufacturing-process group. FDA may close a manufacturer down if the manufacturer changes the formula or facility.
- MEP should think more broadly about biomanufacturing. There is a large industry outside of the innovators of new products.

MEP System and Center Performance

Speaker: Ken Voytek, Chief Economist, NIST MEP

The purpose of the MEP evaluation system is to determine how well the National MEP System is performing. MEP's evaluation system is composed of inputs, processes, outcomes, feedbacks, and controls to derive program results and measure the performance of the National MEP System, the Centers, and the clients.

Overtime MEP has modified its approach to its system evaluation. MEP now measures 1) economic impacts rather than client impacts and 2) client-level results rather than project-level results. The changes have led to outcome improvements.

After capturing survey results from quarterly client-impact studies over the last 10 years, MEP's evaluation process suggests that:

- Program impacts (new sales, investment, and cost savings) have increased while Federal funding has remained fairly constant,
- Client interactions have increased,
- Clients served have increased,
- Client bottom-line impacts have increased, and
- Client investment-leverage ratio has increased.

Reasons for these increases are that the National MEP System is a maturing program, MEP Centers are working on a new set of priorities, and the MEP System and the MEP Centers are currently focused on growth services.

MEP understands that the MEP survey process is complicated. In an effort to reduce the burden on the clients, the survey is being updated and streamlined.

MEP has developed a Center performance chart that maps out variations in Center performance in terms of impact dollars/impacted clients versus impacted clients/Federal dollar investment, allowing MEP to look at its Federal investment and the impact of the Federal funding. MEP can then determine Centers that have high impact/low penetration, low impact/low penetration, high impact/high penetration, and low impact/high penetration.

Comments from the Advisory Board:

- Should data be adjusted for inflation?
- It appears that some MEP survey questions contradict each other.
- What if an impact is not measurable? For example, if you improve safety, a facility can avoid Occupational Safety and Health Administration (OSHA) fines; a facility cannot always put a dollar figure on this kind of savings
- Clarify whether the number of clients served is a unique set of clients.
- Surveying large manufacturing clients may have long-term impacts.
- With a large number of responses to the survey, idiosyncratic issues typically average out.
- On the survey process, MEP Centers should be able to help clients quantify impact.
- Regional patterns should be examined.

Federal Budget Update - Fiscal Year 2009

Speaker: Roger Kilmer, Director, NIST MEP

The Federal government is currently operating under a Continuing Resolution (CR) based on FY2008 funding levels. The current CR, which provides a funding level of \$38 M for MEP, runs until March 6, 2009, and the Centers will be funded through January 2009. If the CR is extended for the full year, the MEP program will be reduced by 15% for FY2009.

MEP enjoys strong support from Congress. MEP was reauthorized in August 2007 with for increasing funding levels - \$122M in FY2009 and \$131.8M in FY2010. However, MEP is competing with other national priorities, such as defense, entitlement programs, and financial bailouts, and at this point, it is still uncertain if MEP will see any funding increases in the near future.

MEP will continue to move forward with its strategy, identifying the highest-priority initiatives and leveraging partnerships to the maximum extent possible.

Comments from the Advisory Board:

- MEP needs to identify sustainable issues that are important to the decision makers. MEP needs to offer solutions on sustainable issues such as job retention and exporting.
- MEP needs to define its budget in terms of problems facing the manufacturing industry, such as workforce development and training.
- MEP needs to better define why it should exist; data will help sell the program.
- MEP is a relatively small program; it is a challenge to get Congressional and the Administration's attention.
- Taxes are a big concern to small businesses. Will the government tax manufacturers out of existence? MEP cannot ignore the issue of taxes. With increasing taxes, the manufacturing base may further decline.
- Is there a way to better demonstrate partnerships and cooperative efforts between MEP with other Federal agencies, such as the Department of Labor or the Department of Energy?

MEP Next-Generation Strategy

Speaker: Roger Kilmer, Director, NIST MEP

Building on feedback from the Advisory Board and Center staff, NIST MEP has drafted a new Strategic Plan, which will be tailored for specific audiences, such as Congress, NIST, other government agencies, States, and manufacturers. The Plan takes into account that manufacturing has and continues to change, especially in such areas as globalization, innovation, supply chains, technology advances, and sustainability. Sustainability is rapidly becoming the overarching business driver for industry – sustainability is a struggle to balance economic, environmental, and societal challenges and opportunities.

NIST MEP has developed a new vision statement and a new mission statement. The vision is that MEP be the focal point of American manufacturing, accelerating the ongoing transformation of manufacturing into a more efficient and powerful engine of innovation driving economic growth and

job creation. MEP's mission is to be the voice of manufacturing within the federal government, as an expert advisor for manufacturing growth and as the key connector of manufacturers, Federal and State governments, private-sector resources, research laboratories, and educational communities.

The basis for MEP's next-generation strategies include:

- Business growth is the overarching strategy for the next-generation MEP,
- The approach is to provide a framework of cost-reduction savings – historically MEP's core services – to enhance productivity and business growth,
- Business growth should focus on new sales, markets, and/or products, leading to greater profitability, and
- Key MEP initiatives for accelerating manufacturing business growth include technology acceleration, supplier development, and sustainability.

NIST MEP continues to promote a 20/20+ vision for manufacturers – take 20% off bottom-line expenses through Lean and other programs targeting plant efficiencies and add 20% to top-line sales through growth services by increasing new sales, new markets, and new products.

Elements of the tactical approach for MEP to meet its new Strategic Plan include:

- Staying true to MEP's public mission of helping U.S.-based manufacturers,
- Establishing partnerships at the National, regional, State, and local levels,
- Focusing on leveraging resources that provide solutions to manufacturing's business and production challenges,
- Being proactive and adapting to National, State, and local needs, strategies, and opportunities,
- Allowing flexible implementation to take into account such elements as resources, economic environment, and new approaches,
- Looking at all possible financial resources, including Congress, other Federal agencies, State programs, and industry,
- Continuing to play an advisory role at the national level on such cross-cutting manufacturing needs as workforce development and financing, and
- Continuing to assess the evaluation of MEP program and Center performance with the central focus on MEP's public mission.

Comments from the Advisory Board:

- A strategic approach is very important. When working with other Federal agencies, many issues, like training, overlap. Need to define role when establishing alliances and partnerships.
- Need to connect the power of the numerator-and-denominator strategy in terms of sustainability.
- The economic landscape has changed for small manufacturers. The nation could see a large loss of small manufacturers. Does MEP want to overtly address loss of small and medium-sized enterprises? Does MEP know the impact yet?
- If job creation is a part of the vision, job creation should be included in the evaluation criteria.
- Business growth versus growth services must be better defined.

- To say that MEP serves as the voice for manufacturers sounds like MEP is more of an advocacy organization versus a public-private partnership.
- The voice of industry should be emphasized.

MEP Strategic Initiatives

Speaker: Aimee Dobrzeniecki, Deputy Director, NIST MEP

As NIST MEP continues to help small and medium-sized manufacturers build strong foundations through process improvements, MEP sees expanding their potential through business growth opportunities. Four key MEP initiatives to accelerate manufacturing business growth are growth services, technology acceleration, supplier development, and sustainability.

Growth Services

The objective of Growth Services is to increase financial profits through a structured approach to create new sales, markets, and products. Currently, MEP is focusing on two tools to assist in growth services: Eureka!Winning Ways (E!WW) and ExporTech.

E!WW is a partnership between MEP and Eureka! Ranch. E!WW helps organizations reduce barriers to success, develop new products/markets/services, and increase capacity. Over the past 18 months, 23 MEP clients, which utilized E!WW realized \$40.6M in new and retained sales, \$13.5M in cost savings, and \$11.3M in new investments. To help promote E!WW, MEP is focusing on training more staff to provide Center to Center support.

ExporTech is a partnership between MEP and the Department of Commerce's U.S. Export Assistance Centers (USEACs). ExporTech helps organizations develop a strategic exporting plan to reduce barriers to exporting products and services. The approach of ExporTech is to have six to eight companies work together with MEP facilitators and USEAC staff in the development of an international growth plan customized for each company.

Technology Acceleration

The objective of Technology Acceleration is to identify opportunities to leverage technology into the processes, products, and services of manufacturers. MEP is developing and testing methodologies for translating "raw" laboratory technologies into business-friendly product concepts and business-simulation tools to determine the market value of a translated product concept. These studies incorporate E!WW and involve MEP Centers and research laboratories from universities, Federal agencies, and private companies and inventors.

MEP's approach for technology acceleration is to act as the liaison between the sources of technology and the manufacturers through technology scouting, supplier scouting, and commercialization support.

In the area of technology scouting, MEP is researching processes and tools to help manufacturers access technologies, evaluate technology needs, and build scouting networks to access technology sources.

In the area of supplier scouting, MEP is examining how the system can help large manufacturers: 1) identify small manufacturers to co-develop new innovations or provide technology solution business opportunities, and 2) identify small manufacturers that can supply especially hard-to-source items or produce a specialized component.

In the area of commercialization support, MEP is partnering with the U.S. Patent and Trademark Office to help MEP manufacturing clients understand intellectual property and their "knowledge assets" and strategies for protecting them.

Supplier Development

The objective of Supplier Development is to help manufacturers understand, maintain, and expand their position in the supply chain. MEP is focused on the big picture and can foster the relationship between the small business and the Original Equipment Manufacturers (OEMs). MEP's approach is to develop "bottom-up" relationships with suppliers and "top-down" relationships with OEMs.

MEP works with small and medium-sized suppliers to help make their operations more efficient and flexible to better meet the needs of their OEMs. And, MEP works with OEMs to better understand their process and technology needs/requirements and future plans in order to better make that connection between the OEM and small and medium-sized suppliers.

Sustainability

The objective of Sustainability is to help manufacturers gain a competitive edge, maintain profitability, and create jobs while increasing energy efficiency and reducing negative environmental impacts. MEP's goal is to assist companies (1) to reduce environmental costs and impacts while remaining profitable and (2) to develop new environmentally focused materials, products, and processes to gain access to and grow new markets.

To reach these objectives and goals, MEP's approach is to establish and expand partnerships with other environmentally driven partners at the Federal, State, and local levels. Two examples of these partnerships are the Green Suppliers Network (GSN) and the Waste to Profit (WTP) Network.

GSN represents a multi-year, co-funded collaboration between MEP and the Environmental Protection Agency. GSN works with large manufacturers to engage small and medium-sized suppliers to invest in their companies and utilize LEAN and CLEAN on-site reviews that focus on process improvement and waste minimization, which can lead to substantial environmental benefits and reductions in labor and capital costs. GSN also allows for members of the supply chain to work together to identify opportunities for change, such as product-specification changes that are environmentally focused.

MEP estimates that potential cost savings from environmental-impact opportunities through 76 GSN projects to be \$13.5M/year. Through these same projects, potential cost savings from LEAN opportunities total close to \$26M/year.

WTP, a partnership between the U.S. Business Council for Sustainable Development and NIST MEP's

Chicago Manufacturing Center, brings companies together so that one company's waste becomes another company's raw material. For example, Curb Appeal, a manufacturer of plastic composite lumber and car stops, uses plastic waste from the Chicago Department of Fleet Management as raw material in its production process. This program has brought together 25 companies that are learning from each other, helping each other, and offering a replicable program for other MEP Centers to implement.

Comments from the Advisory Board:

- The concept of sustaining yourself by innovating your future should be part of defining sustainability.
- The slide depicting interrelationships between U.S. manufacturers, MEP making the connection, and technology sources through gears should be re-vamped to better show that all three components drive each other equally.
- There is concern for the Center's ability to absorb all of MEP products and offer the entire suite of products; MEP's goal is for a Center to understand its region and use the products and services that make sense.
- It is import to leverage those Centers and partners that may excel in a particular service.
- If MEP is facilitating a small company/suppliers in meeting the product-development needs of a larger company, it is important that the small company's "knowledge asset" is protected. It is important that MEP be cognizant that critics on the outside may see MEP becoming too involved in "owning" new technology or directing who is developing that technology.
- MEP sees its role as scouting/scanning for a new set of tools to offer to manufacturers, but not developing those tools. MEP can help define the next generation of tools for manufacturers.
- MEP talks about a resource database, a national innovation marketplace; are such databases not available commercially, such as those offered by the Kauffman Foundation or the American Society of Mechanical Engineers, Institute of Electrical and Electronics Engineers, or American Society for Testing and Materials?

SRI Consulting - Manufacturing Trends 2020

Speaker: Mark Rice, Co-Chair, MEP Advisory Board, and President, Maritime Applied Physics Corporation

NIST is sponsoring a study - Manufacturing Trends 2020 - to better understand trends in the technology-based manufacturing sector and the opportunities these trends will have on future U.S. economic growth. The first manufacturing-trends workshop will be held in early November. Mr. Rice will be participating and asked the Board to share their ideas and suggestions for the meeting. Mr. Rice will report the results of the meeting with the MEP Advisory Board.

Comments from the Advisory Board:

- Important to emphasize that "technology push" has supply-chain implications.
- Workforce/skills development is key; need to look at education linkages/STEM (Science, Technology, Engineering, and Mathematics) program.
- Sources of innovation involve partnerships between small and large innovators; must understand the importance of the value chain.

- Regarding additional technology elements, like bioscience and material science – what are the evolving opportunities? Answer is not to generate new manufacturers, but translating technology into existing manufacturers to better compete globally.

Board Feedback

Moderator: Ned Hill, Chair, MEP Advisory Board and Vice President for Economic Development, Cleveland State University

During the Board-Feedback session, the Board discussed the draft MEP Strategic Plan. Their comments, divided into clusters, follow:

Tone

- The tone should be upbeat. Manufacturing is key to economic success and MEP can promote American manufacturing.

Objective/Goal

- MEP needs to decide what is important.
- MEP's objective is to develop one document that can be modified for various audiences.
- MEP needs to fully describe why MEP is relevant.
- MEP needs to fully describe MEP's impact for the transition team.
- This document needs to define the program. Emphasis of networks, sharing of best practices; not mechanistic, but viral.

Audience

- MEP needs to decide who is its audience. Is the audience Congress or other Federal agencies or MEP Centers or partner organizations? One document cannot serve different audiences (i.e., Congress, other Federal agencies, MEP Centers, Web site).
- If MEP is seeking funding, Congress is the audience. MEP does not need to convince the Centers or other Federal agencies of MEP's importance.
- MEP needs to decide how to best handle the different audiences.

Format

- The current document seems to be a "tweener" document. It is too big for a short document and too small for a big document.
- There are many redundancies in the document. When one brings up a thought, one should complete that thought. It appears that this document is a "cut-and-paste document."
- The document needs to better differentiate growth services from growth.
- The document needs to be more coherent.
- The document could be a one-page executive summary.
- The document needs shorter, crisper paragraphs and better transition from one thought to another.

Content/Theme

- First paragraph is critical, sets the tone. Need to bring up the importance of MEP in the current

economic crisis.

- Emphasize that MEP is stimulating change.
- The document needs to better describe where MEP wants to go.
- The document needs to discuss MEP capabilities, not what MEP does.
- Plan needs to better address/emphasize profitability.
- If "job creating" is included in the Vision, then a matrix should be included.
- MEP needs to make the case that manufacturing is going to help restore the economic health of the U.S. and not that MEP is helping only the poor, struggling small manufacturer. Focus should be effect on U.S. industrial base.
- Reference of what other countries are doing should be re-examined.
- Overreaching focal point for American manufacturing - MEP must be a catalyst.
- Manufacturing has been and can be the backbone of the U.S. economy.
- Manufacturing is vital to the national security.
- MEP should be the "trusted" advisor.
- MEP is the only Federal agency focused on manufacturing. MEP pulls other agencies together.
- The use of the word "connector" should be a theme throughout the document.
- The plan needs a paragraph about the future of manufacturing. American manufacturers have the ability to manufacture anything, including energy; manufacturing is a growth industry.

General Observations

- No country has had a strong national defense without a strong economy.
- Each MEP Center will examine the MEP Strategic Plan and adapt it to the Center's needs.
- Need to reconceptualize the Federal role in manufacturing.
- MEP has transformed itself, which is to be applauded.

Announcements

Speaker: Karen Lellock, Senior Policy Advisor, NIST MEP

- The 2009 National MEP conference will be held April 18-22, 2009, at the Orlando World Center Marriott in Orlando, Florida.
- The next MEP Advisory Board Meeting will be held on April 19, 2009, during the National Conference.

Adjournment

Mr. Hill adjourned the meeting by thanking the Board members, presenters, and meeting organizers.