Massachusetts’ Medical Device Industry: Anatomy of a Business Ecosystem

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With 304 companies, Massachusetts’ Medical Device Industry — one of the nation’s largest — remains an energizing contributor to the state’s economic growth. The industry’s broader ecosystem involves synergies with the state’s life sciences and biotechnology firms, research hospitals and universities, and materials manufacturers.
MEDICAL DEVICES: INTRODUCTION TO THE CLUSTER

Massachusetts is home to one of the largest and densest biotechnology clusters in the world, with biotechnology defined broadly to include all life sciences product-focused activities excluding healthcare delivery. Well known for its more than 100 universities, the region is also home to five of the United States’ top ten research hospitals, including Massachusetts General Hospital, Brigham & Women’s Hospital, Beth Israel Deaconess, and Dana Farber Cancer Institute. Massachusetts, a premier R&D center for life sciences, biotechnology, and medical devices, was identified in 2004 by Battelle as ranking second in the nation in the number of biomedical devices and instrumentation companies and fourth in the nation in employment in this industry.

From defibrillators to angioplasty stents, to arthroscopic surgery devices, the medical device industry provides the everyday tools that doctors, surgeons, hospitals, and home health aides rely on. The United States remains the largest medical device market in the world, with a market size of around $110 billion, and it is expected to reach $133 billion by 2016. U.S. market value represented about 38 percent of the global medical device market in 2012. U.S. exports of medical devices in key product categories identified by the Department of Commerce (DOC) exceeded $44 billion in 2012, a more than 7 percent increase from the previous year.

In Medical Devices: Supporting the Massachusetts Economy (2004) Alan Clayton-Matthews and Rebecca Loveland found that the medical device industry was “important beyond its size, from several perspectives.” They pointed out that the industry required a highly educated workforce and cutting-edge technical components. They noted that the industry’s impact extended “beyond the employment and earnings of medical device workers: every hundred jobs is associated with another 79 jobs in Massachusetts, and every dollar of medical device output is associated with an additional 45 cents of outputs from Massachusetts firms.” Industry success, they determined, required strong collaboration among manufacturers, researchers, and medical staffs (2004). A recent update to the study using current industry conditions found that every hundred jobs is associated with 92 additional jobs in Massachusetts and every dollar of medical device output spins off an additional 70 cents of economic activity by other firms.

The Massachusetts life sciences labor force numbers approximately 73,313 workers. Firms are found in various sectors and venues, including biotechnology, pharmaceutical and medical devices, academic medical centers, academic research institutions, independent clinical research organizations, and a broad range of functional areas and occupations. According to the 2014 Quarterly Census of Employment and Wages data from the Bureau of Labor Statistics, the most recent employment count available for the medical device industry in the Commonwealth was 22,775.

Despite the state economy’s vicissitudes, the Massachusetts medical device industry maintained its position as the second-biggest cluster in the country, behind California, according to a report prepared by KPMG LLP for the Massachusetts Medical Device Industry Council. KPMG determined that medical device exports from Massachusetts represented 19 percent of the state’s exports in 2014, up from 14 percent 2011. The value of exports climbed from $4.72 billion in 2005 to $5.82 billion in 2014. Also, the number of medical device companies grew 20 percent in that period.

There are some 6,500 medical device companies in the U.S. The Commonwealth is home to approximately 304 such firms. Leading companies include well recognized giants like Johnson & Johnson, General Electric, Medtronic Inc., and Siemens AG. However, more than 80 percent of firms nationwide have fewer than 50 employees, and many (notably innovative start-up companies) have little or no sales revenue. Medical device companies are mainly concentrated in regions known for other high-technology industries, such as...
microelectronics, nanotechnology, and biotechnology. States with the highest number of medical device companies include California, Florida, New York, Pennsylvania, and Massachusetts (selectusa.commerce.gov). For 2013, Massachusetts ranked third per capita in employment and second per capita in annual payroll nationally. The Commonwealth’s strength in the sector stems in part from its competitive advantage in several industries that device makers utilize, including precision machining, microelectronics, instrumentation, biotechnology, and software development.

INDUSTRY SYNERGIES

Medical devices as a category includes seven NAICS industries — ophthalmic goods, surgical appliances and supplies, surgical and medical instruments, laboratory apparatuses and analytical instruments, irradiation apparatuses, electromedical apparatuses, and in-vitro diagnostic substances. The broadest description of the life sciences cluster comprises 1,888 firms in Massachusetts, many of them in Middlesex, Essex, Norfolk, and Worcester Counties. In the narrower category of medical device makers, there were 304 firms and approximately 22,700 jobs in Massachusetts as of 2014. Similarly, many medical device firms are in Middlesex, Essex and Worcester counties, as are their key suppliers. Currently in Massachusetts, sheet-metal boxes and plastic parts from neighboring small firms are embedded just-in-time in thousands of high-tech devices. Carefully engineered gears and sophisticated electronic switches produced in shops along Route 114 in Middleton or Route 128 in Beverly turn up in aircraft engines built at General Electric and Pratt and Whitney. Perfectly designed molds built in tiny metalworking companies in Leominster are finding their way into machinery used to produce medical equipment parts.

Among precision metalworking customers, surgical/medical device employment grew by 34% from 2000 to 2007. Middlesex County now accounts for about 30% of the state’s metalworking employment. While employment has dropped with the current recession, there are still many metalworking firms that can work with medical device innovators. While it is true that high-tech districts such as the Route 128/I-93/I-95 and Interstate 495 areas in Massachusetts are often unique in terms of their technologies and research agenda, metalworking firms in these districts exhibit the innovation characteristics common to a sustainable regional-growth approach to development. While a vertically integrated company can carry out experiments at each stage of production, in a well-coordinated district, dozens of simultaneous experiments take place through a series of relationships with enterprises with complementary capabilities, such as in the medical device cluster. This concentration of firms allows them to enjoy the benefits of large scale industrial production and of technical and organizational innovations beyond the scope of any individual small and medium-size firm.

There are large concentrations of metalworking and plastics firms in Middlesex and Worcester counties. Many of these firms specialize in prototype manufacturing and build the precision tools, molds, fixtures, and machine attachments used by producers of final goods. They also build specialized production machines for printing, paper, textile, electronics and plastics firms. In addition, approximately two hundred companies perform services like heat treating, painting, testing, and plating. Despite macro data showing declines in employment in most precision metalworking categories, the significance of these firms to the health of the Commonwealth’s economy should not be underestimated. With over 2,300 firms and close to 62,000 well-paying jobs, these firms are intricately connected with what many economic pundits consider the “next big things” in the Bay State, including measuring and controlling devices, environmental cleanup equipment, and medical devices.

The synergies between metalworking companies, plastics companies, and medical device makers are critical for the state to maintain some level of manufacturing vibrancy. While figures on firms and employment vary from one data source to another, the state’s plastics cluster contains approximately 700 firms and 24,000 employees, with total sales of roughly $4 billion. The plastics cluster comprises an important manufacturing concentration in Worcester County. There are 62 plastics firms in the Leominster-Fitchburg-Gardner area, a figure that jumps to 90 when Clinton and Worcester are included. With related mold makers, machinery builders, and materials makers included, the five communities contain approximately 120 firms and almost 4,000 jobs. The long-run success of plastics firms is predicated on three factors: their ability to develop new products; their capacity to work with new materials; and their ability to
train a new generation of workers in advanced technologies. Linking these firms with emerging medical device companies is thus critically important.

For specialty producers in the medical device field, the challenge is to be able to engage in rapid new product development using state-of-the-art materials and to work to extremely high quality and delivery standards. Success is contingent upon the ability of these firms to tap into a network of service providers and a rich constellation of production partners. In many respects this is a highly localized process, one built on long-standing relationships.

**A CLOSER LOOK AT THE UMASS LOWELL-UMASS MEDICAL CENTER CONNECTION**

A large number of the Commonwealth’s medical device firms conduct business activities in or near the fifty-mile corridor between Lowell and Worcester. This cluster differs from the life science one in the Greater Boston area in that the Lowell-Worcester corridor has a greater concentration of materials and manufacturing companies than exists in the Boston-Cambridge area. In addition, UMass Lowell’s Massachusetts Medical Device Development Center (M2D2) is in the cluster, harnessing the medical and engineering capabilities of UMass Medical and UMass Lowell with the specific mission of assisting the industry. Collaborations with the medical school in Worcester and the UMass Lowell M2D2 are critical. They provide a scope of services available to startups beyond UMass Lowell’s engineering and business strengths to the clinical and regulatory expertise available at the medical school. Life science startups need the medical team’s feedback and expertise at the medical school in developing products that both treat the problem and serve medical professionals.

Calling itself “a lifeline for the state’s smaller medical device companies,” M2D2 assists entrepreneurs in the medical device and biotech sector, with all aspects

![Figure 2. Medical Device Industries in Central and Eastern Massachusetts](image)
of the process of moving new products from concept to the marketplace. Services include engineering and design assistance; prototype design and development; consultation for clinical pathway studies; and access to patient population for clinical trials. The Center also offers referrals to a rich network of private sector design, fabrication, and testing firms. Since its founding in 2007, M2D2 has worked with more than 100 client companies, which in turn have secured more than $40 million in external funding for their ventures. Additionally, 57 start-up companies received services such as medical and market analyses and prototype development, moving them farther down the product pathway, and helping them to attract private and federal funding.

M2D2 assists startups in developing prototypes, defining the clinical regulatory path, providing business guidance, and connecting them to needed resources. According to Steven Tello, UMass Lowell Associate Vice Chancellor of Entrepreneurship and Economic Development, “This service is critical to nurturing the startups that are helping to support the state’s economy. Without places like M2D2, companies will tend to flounder — spending a lot of time chasing resource needs, rather than focusing on product and business development.” When asked about the challenges faced by companies like her own, Nancy Briefs of Infobionic, an M2D2 resident company, noted: “Entrepreneurs are faced with a myriad of challenges building their companies. One of the important considerations is where to locate. Infobionic is fortunate enough to be a client company at M2D2. We are able to leverage both the physical network at the accelerator as well as numerous state and regional services.”

As a case in point, in January 2016, M2D2 announced its fifth annual $100,000 Challenge, a nationwide competition that showcases the innovative ideas of early-stage medical device, diagnostic, and biotech companies. For Stephen McCarthy, a UMass Lowell professor and co-director of M2D2, the goal of the initiatives “is to help entrepreneurs gain valuable services needed during the tenuous stages of early product development. Expert advice, mentoring, and access to facilities can be the difference between failure and success.” Albert Lauritano, director of strategic technology partnerships for Becton Dickinson and Company — a sponsor of the Challenge — remarked: “To develop new solutions to the challenges facing health-care delivery, it will take innovation and partnership; participating in the M2D2 $100K Challenge provides both for BD. He added, “We get to collaborate with startup entrepreneurs and their cutting-edge technologies by providing BD’s global market and product development expertise. It is a winning combination for the startup, BD and, ultimately, the health-care system.”

Competing for space and talent in the Boston-Cambridge area is a challenge for small companies. UMass can help with that.

For UMass Lowell’s Tello, the business climate in the Commonwealth for medical device companies is improving. Howard Loree of Flow Forward Medical, another M2D2 resident company, agrees: “My sense is that the medical device industry in general in the U.S., and specifically in Massachusetts is healthy and growing.” There has been an increase in venture capital investment over the last several years. The Patrick Administration supported growth of the life science industry through the Massachusetts Life Science Center and encouraged the emergence of a startup culture around the state through support of incubator and accelerator programs. Suppliers, contract manufacturers, and service providers are all benefitting from the pace of startup activity in the state. Competing for space and talent in the Boston-Cambridge area is a challenge for small companies, something that UMass can help with. Tello notes, “Clinical and regulatory processes are most challenging for medical device/biotech companies. This path is complex, expensive, and full of uncertainty. This, however, is a federal challenge, not a problem particular to Massachusetts.”

To reach additional firms, M2D2 opened in October 2015 what it calls an Innovation Hub, which already has several tenants. In an article about the opening, Lowell Sun reporter Amelia Pak-Harvey found scientist Catherine Pujol-Baxley already hard at work in one of the lab spaces, where she’s developing a single-cell protein for fish, a project of the small company, KnipBio.5 “It’s a brand-new space and you have all this equipment that you basically cannot find anywhere else,” said Pujol-Baxley, the start-up’s director of research and development. “The location is amazing, and then you’re very close to facilities such as UMass Lowell, so we’re going to have some collaborations.” The new space is a potentially cheaper option for the M2D2 space at Wannalancit Mills, where tenants have to buy their own equipment. “What we think is that these companies that are very, very small and have very little money can move in to the upstairs on the fourth floor with very little capital,” said M2D2 co-director Professor Steve McCarthy.6

According to Steve Lufkin, CEO of Vantix Diagnostics (www.vantixdx.com), Massachusetts has made it
a priority to create an environment favorable for medical device companies evidenced by the large investments in the new UMass Innovation Hub and M2D2, and the alignment of state, academic, and business needs. The firm relocated to Massachusetts from New Hampshire because of those initiatives and the strong talent pool. When asked about the challenges confronting medical device or biotechnology firms, Lufkin stated: “From our perspective as an early-stage company, we see the challenges as attracting funding and continuing to attract a highly qualified talent pool. Having recently moved from New Hampshire to Massachusetts, we feel the state has made it a high priority to create a business environment that is attractive to medical device companies.”

When asked about the importance of research centers like M2D2, he indicated that they provide firms like his with three major benefits: “1.) Flexibility. It is extremely helpful to be able to pay as we go for what we need without having to commit to a 5- to 10-year lease. This way we can expand as we are ready to expand as opposed to paying for space we don’t need yet. 2.) Access. At the Innovation Hub and M2D2, we have access to equipment and expertise through our membership fees. This equates to being able to dedicate more funds to the critical R&D effort. 3.) Expertise. As a medical diagnostic company, being able to connect with the experts at the medical school is very valuable as we develop a device for physician offices.”

The medical device industry has achieved consistent growth and operating margins for two decades. However, recent reports by global consulting firms A.T. Kearney and KPMG suggest that the years of steady growth may well be over. In Collaboration — The future of innovation for the medical device industry (2015), KPMG suggests that “medical device companies need to embrace more inclusive innovation models, collaborate more frequently and with a broader range of partners, and pursue greater integration with suppliers, development partners, and healthcare providers.” Many of the Commonwealth’s small and medium-size medical device firms and start-ups in the 50-mile corridor between UMass Lowell and the UMass Medical Center in Worcester are already behaving in this way, a prescription for future success.

Endnotes

1.) Alan Clayton-Matthews and Rebecca Loveland, Medical Devices: Supporting the Massachusetts Economy, University of Massachusetts Donahue Institute, May 2004.
2.) Life sciences definition is based on Massachusetts Technology Collaborative’s Bio/Pharmaceuticals, Medical Devices & Hardware Sector, see Massachusetts Innovation Economy Annual Index. Medical device sector definition is based on Clayton-Matthews/ MassMEDIC definition
6.) Ibid.
7.) Email exchange with Steven Lufkin, Vantix Diagnostics, January 2016.

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