
ENHANCING BIOMANUFACTURING IN MASSACHUSETTS

CENTRAL MASSACHUSETTS BIOMANUFACTURING SUMMIT REPORT

NOVEMBER 2, 2015

The Commonwealth of Massachusetts is a global leader in life and health sciences and biomedical research and development. In a rapidly changing innovation industry, the Commonwealth's Life Sciences Super Cluster must continuously adapt to maintain its role as a domestic and global leader. One significant area of dynamism in the life sciences industry is Biomanufacturing. On November 2nd, 2015, Massachusetts Biomedical Initiatives (MBI) convened industry leaders and over 70 stakeholders for a Central Massachusetts Biomanufacturing Summit. The event featured Lieutenant Governor, Karyn Polito, and Travis McCready, President & CEO of the Massachusetts Life Sciences Center with the intention of discussing opportunities as well as barriers for expanding Biomanufacturing in Central Massachusetts and all across the Commonwealth.

In 2013, PricewaterhouseCoopers (PwC) published a report entitled *Super Cluster: Perspective on Enhancing Biopharmaceutical Manufacturing Employment Opportunities in Massachusetts*. The report identified the Commonwealth and specifically Central Massachusetts as an ideal location for Biomanufacturing growth. As the western anchor of the Biomedical Corridor between Worcester and Cambridge, the report suggested that Worcester and Central Massachusetts were poised for growth in this sector due to the lower cost of living, access to talent, and proximity to the corridor's research and development activity.

The Summit provided an opportunity for industry leaders to revisit the PwC report and provide an update on current and future challenges to expanding Biomanufacturing jobs and economic growth in the Commonwealth. The following report outlines the major opportunities and resources for achieving this objective that were identified by the participants of the Central Massachusetts Biomanufacturing Summit held at the AbbVie Bioresearch Center in Worcester.

The Commonwealth's Current Life Sciences Ecosystem

Key Statistics and Figures^{1,2}

- ❖ Over 1,391 drugs in development within the Commonwealth's biopharmaceutical industry with a majority in the early stages (2014)
 - These drugs need to be manufactured in current Good Manufacturing Practice (cGMP) facilities, whether in-state or elsewhere like Asia, North Carolina, and Wisconsin
- ❖ 41 FDA drug approvals in 2014 with 8 (about 20%) of those approvals in Massachusetts, a significant increase over the total 18 FDA drug approvals in 2013
- ❖ 38% growth in life sciences employment since 2005 while many other states have seen declines in biotech research and development employment
- ❖ 28% growth in Biomanufacturing employment in the Commonwealth over the last ten years

¹ Coleman, Timothy P. (2015). *Update to Super Cluster: Perspective on enhancing biopharmaceutical manufacturing employment opportunities in Massachusetts*.

² Massachusetts Biotechnology Council (MassBio). *2015 Industry Snapshot*.
http://www.massbio.org/writable/editor_files/2015_industry_snapshot_9.3.15.pdf

The State of Biomanufacturing in MA

Companies are sending a number of molecules discovered in Massachusetts out of state to North Carolina, California, Wisconsin, and Asia to be manufactured. The outsourcing across state lines and national boundaries is due in part to the current need for additional Biomanufacturing infrastructure in the Commonwealth. While Biomanufacturing in Massachusetts has grown 28% over the last ten-year period, the current reality is cause for action because of the following:

- ❖ Life sciences innovation is intrinsically tied to manufacturing, and the geographic proximity of R&D to Biomanufacturing is a force multiplier for innovation
- ❖ Changes in technology are enabling more efficient and cost-effective Biomanufacturing. Demand for state-of-the-art flexible, modular manufacturing facilities is increasing as emerging biopharmaceutical companies must now make smaller batches faster than ever while under tight budgetary and regulatory constraints

Central MA Regional Resources

- ❖ A history of **collaboration and success**, as evidenced through the UMass Medicine Science Park that was developed in the late 1980's and early 1990's through collaborative efforts of the Commonwealth of Massachusetts, Worcester Business Development Corporation (WBDC), University of Massachusetts Medical School, Worcester Regional Chamber of Commerce, and Massachusetts Biomedical Initiatives (MBI)
- ❖ Worcester's **affordable cost of living**, central location, access to public transportation, and the potential for creating biopharmaceutical manufacturing sites
- ❖ Access to **high-quality human capital**
 - Worcester Technical High School is engaged in efforts to train students in life sciences technology and research
 - Twelve colleges and universities with over ten new science buildings and 35,000 college students that contribute to the ecosystem
 - The Biomanufacturing Training & Education Center (BTEC) at Worcester Polytechnic Institute is a pilot-scale Biomanufacturing facility for innovative training that fosters academia and industry collaboration for workforce development. Quinsigamond Community College also has programs targeted at developing a pool of qualified technicians
- ❖ Dedicated and available **research facilities**
 - UMass Medicine Science Park: A 470,000-square-foot, five-building bioscience park that accommodates office and laboratory tenants ranging from start-up incubator space to full-building footprints, and is home to dozens of biotechnology companies
 - Worcester Polytechnic Institute's (WPI) Gateway Park: A master-planned, 12-acre park that envisions five buildings totaling 500,000 square feet of flexible laboratory and office space for a range of research, commercial, and Biomanufacturing activities
 - Massachusetts Biomedical Initiatives (MBI) Life & Health Sciences Incubator Facilities
 - Grafton Science Park: Tenants of the 84-acre park have access to Tufts University's Cummings School of Veterinary Medicine Campus research infrastructure and scientific environment

Increasing Competitiveness and Enhancing Relevancy

- ❖ Develop **Biomanufacturing infrastructure** to meet the needs of life sciences research and development companies and accelerate the commercialization of new pharmaceuticals
 - Promote the growth of contract manufacturing organizations (CMOs) to allow for local research dollars to remain in the local economy and provide a more complete continuum of services from discovery through commercialization
 - Capitalize on the current scale opportunity in the Commonwealth to provide funding for CMOs, connect them with biopharmaceutical partners, and convene leaders to discuss best practices in Biomanufacturing technologies
 - Identify low-cost opportunities for growth in Central Massachusetts with pre-permitted, pad-ready sites that provide adequate utility infrastructure to enable the industry to grow
- ❖ **Strategically focus** on one area of Biomanufacturing and do it well, whether it's small molecules or biologics
- ❖ Increase the sustainability of **Public-Private Partnerships**
 - Foster cooperation between government, universities, and private sectors to support continuous innovation, learning, and economic development
 - Build a Public-Private Partnership focused on cultivating commercially sustainable manufacturing infrastructure in Worcester to complement Boston/Cambridge research and development activities
- ❖ Grow the **local talent**, particularly employees on the production floor – the middle-skilled technical workers that support downstream expansion
 - Increase interest in Biomanufacturing through highlighting the technical base of the sector and other facets that set it apart from traditional manufacturing
 - Promote workforce development that fosters an understanding of both the science and the regulatory requirements because technical knowledge and business understanding are a powerful combination
- ❖ Make efforts to **retain talent** once they are in Massachusetts and within the Central MA region
 - Ensure young professionals have the resources they need in the area including public transportation opportunities and a strong public educational system

Tools for Enhancing Biomanufacturing Employment Opportunities

- ❖ **Establish a Biomanufacturing Zone in Worcester**
 - A unique opportunity exists to develop biopharmaceutical manufacturing infrastructure in New England's second largest city through a Public-Private Partnership
 - In similar fashion to the collaborative effort to develop the Biotechnology Research Park in the 1980's and 1990's, State and local entities could collaborate to create pad-ready development sites for Biomanufacturing in Central Massachusetts
 - The Commonwealth could examine the development potential of the approximately 85 acres of underutilized property adjacent to the UMass Medicine Science Park and consider conveying it to a development partner to provide the Commonwealth's Biopharmaceutical industry with desperately needed access to state of the art commercial biopharmaceutical manufacturing facilities

- A Master Plan coordinated by MassDevelopment and the Division of Capital Asset Management & Maintenance (DCAMM) in cooperation with local stakeholders should be considered to determine the number of potential development sites, required infrastructure, and proposed zoning requirements
- ❖ Increase state-level support for life sciences advanced manufacturing companies including CMOs
- ❖ Expand the personal property tax local option exemption for non-corporate business entities (LLCs, partnerships, and others) to help stem the outflow from Massachusetts
- ❖ Continue to improve transportation connections between the Commonwealth’s life sciences and biomedical hubs

Conclusion and Summary of Findings & Recommendations

Participants in the Biomanufacturing Summit recognized the great progress that has been made in the area of Biomanufacturing, but also identified opportunities for further growth. The following were the major concepts that the participants identified as future opportunities for exploration by the Commonwealth, Massachusetts Life Sciences Center, MassBio, MBI, and other industry partners.

I. Foster Contract Manufacturing Organization (CMO) & Contract Research Organization (CRO) Growth

Massachusetts research and development companies are bringing research funding to the Commonwealth but are having a difficult time identifying local CMO/ CRO services that meet their organizational needs. Expanding opportunities for CRO/CMO work in the Commonwealth would retain these multimillion-dollar contracts in state.

The Commonwealth could encourage this growth by providing grants, matching funds, development plans, tax exemptions, and other funding incentives to support more investment in contract research and manufacturing and grow local companies or attract companies to Massachusetts. Support could also include increasing efforts to connect CMOs and CROs with biopharmaceutical partners and convening industry and educational leaders to discuss best practices in Biomanufacturing.

II. Assist Companies from Research to Commercialization to Biomanufacturing

Federal and other funding sources are available for research surrounding new products. However, there is a gap in funding and resources for companies to convert these products from research to commercial products. Finding opportunities to fill this gap, known as the “valley of death” for small companies, would lead to the manufacturing of a greater number of homegrown products in the Commonwealth.

The perception is that the Commonwealth does not provide enough incentives to offset the higher costs of operation within the Biomedical Corridor. Creating programs that directly incentivize companies to grow in Massachusetts would encourage growth in the sector and retain investment dollars in the Commonwealth.

III. Expand Tax Exemptions for Biomanufacturing Companies

The Commonwealth has long provided a statewide exemption for to the personal property tax to manufacturing corporations, enabling them to avoid taxation on the expensive equipment required to manufacture their goods. A few years ago the Commonwealth created by statute a local option which allows, but does not mandate, municipalities to similarly exempt the equipment of research and development corporations. Both of these exemptions, however, are only allowed for entities

organized as corporations and are not available for independent Limited Liability Companies (LLCs), partnerships or other non-corporate business entities. This is problematic, as many small life science companies, including both R&D companies and biomanufacturers, start out as LLCs or some other non-corporate entity. Expanding the local option exemption to include R&D and manufacturing companies organized as LLCs or other non-corporate structures would support and help fuel growth for a large number of smaller job creators that are driving this economy.

IV. Create Additional Parcels for Biomanufacturing Growth

Real estate opportunities are critical for growing Biomanufacturing in the Commonwealth, and we must provide the infrastructure to support downstream expansion. The Commonwealth and local and regional stakeholders have a proven track record in this arena as demonstrated through the development of what is now known as the UMass Medicine Science Park, Gateway Park, and Grafton Science Park.

The Commonwealth's recent investment in the Worcester Recovery Center & Hospital created an potential opportunity to use approximately 85 acres of underutilized state land for the development of a Biomanufacturing park in Central Massachusetts. The first step to furthering this vision would be to conduct a Master Plan to analyze the potential of this opportunity to grow the industry. MassDevelopment, DCAMM, and local stakeholders were identified to possibly conduct this analysis.

V. Promote Worcester as a Place for a Growing Workforce

Several company representatives at the Summit discussed their struggles with attracting employees outside of the I-495 belt. Perception is part of the issue, but it also relates to real challenges with public transportation and public education. Worcester has made phenomenal progress in the past decade and is now a very attractive place to live and work. However, continuing to advance initiatives like the non-stop Commuter Rail Service to Boston, investing in the public schools and STEM education, and promoting Worcester's livability will benefit the Commonwealth by allowing these businesses to grow in a lower cost environment with strong industry support.

In summary, the Central Massachusetts Biomanufacturing Summit highlighted the continuing robust state of life sciences research and development in the Commonwealth and the leverage that these strengths provide for downstream expansion. Summit participants also emphasized the need to capitalize on current and future shifts in Biomanufacturing. Massachusetts and the Central MA region in particular have an opportunity to shape and ensure the future of the Life Sciences Super Cluster economy by supporting the development of Biomanufacturing infrastructure and the strength of the life sciences network from drug discovery to full commercialization. As Lieutenant Governor Karyn Polito stressed, a unique "connectivity" exists from the Central Massachusetts region to Cambridge and Boston along the biomedical corridor. This distinctive advantage must continue to be harnessed and nurtured so that life sciences innovation can, in the words of Travis McCready, President of the Mass Life Sciences Center, remain "a powerful tool for economic development and combatting disease."

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