

# Christopher P. Molineaux – CEO, Life Sciences PA

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Thousands of diseases affecting millions of patients worldwide still await scientific breakthroughs and successful treatments from our research community.

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17.09.2025

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*Chris Molineaux, CEO of Life Sciences Pennsylvania, highlights Pennsylvania's emergence as a leading life sciences hub, with 3,000+ companies, top NIH-funded universities, and global partnerships drawing investment. He notes that Pennsylvania's pharmaceutical heritage and growing cell and gene therapy expertise – in addition to other cutting-edge modalities – offer unique opportunities if paired with the right policy and funding support.*

## **Could you begin by introducing Life Sciences Pennsylvania and outlining the organisation's mission and activities?**

Life Sciences Pennsylvania serves as the state-wide trade association representing the entire ecosystem of Pennsylvania's life sciences community. We like the high school biology metaphor of an ecosystem because it accurately captures the interconnected nature of our industry. As of today, we have 956 member organisations spanning the complete spectrum of life sciences enterprises.

Our membership encompasses global pharmaceutical companies – every major sponsor you might recognise is represented in our membership – down to start-up biotechnology companies that most people have never heard of and likely never will, given the reality that many get acquired or, unfortunately, cease operations before achieving public recognition.

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The membership extends across pharmaceuticals, biotechnology, medical devices, diagnostics, and research institutions. We include 52 colleges and universities, investment organisations with research and development-based portfolio companies, and the entire service provider community surrounding the industry. This includes contract research organisations, contract development and manufacturing organisations, law firms, accounting firms, public relations firms, and virtually any type of support organisation you can imagine.

The organisation's mission is straightforward to articulate, though not always simple to accomplish: we perform public policy advocacy at both state and federal levels, with the goal of making Pennsylvania the most attractive location to open and operate a life sciences company. This mission presents countless opportunities and challenges.

It is worth noting that we are not geographically constrained. Among our 956 member companies, 120 are based outside Pennsylvania but maintain business interests in the state or are affected by relevant policies.

Our second core accountability involves facilitating strategic connections. This means identifying and creating whatever connections our member companies need to succeed, whether that involves linking a global pharmaceutical company with a start-up biotechnology firm possessing an asset of interest for their pipeline, connecting a start-up with a service provider or investor, or any other strategic relationship necessary for continued success.

**For our international audience, when people consider life science hubs in the US, they typically think of California and Massachusetts. How does Pennsylvania's current life sciences ecosystem compare to these established hubs?**

Before addressing that comparison, I should mention our international scope. We maintain nine international relationships with geographies where our companies conduct business and where organisations in those countries might want to establish operations in Pennsylvania. These include partnerships with organisations such as ASSOBIOTEC Italia, two memoranda of understanding in India with Karnataka and the US-India Trade Federation in Delhi, agreements with One Nucleus in the United Kingdom, Lithuania, Taiwan, two partnerships in Canada, and one in Portugal.

These relationships have yielded tangible results, with companies in our membership opening operations in Italy and one Italian company establishing operations in Pennsylvania. When international companies evaluate the entire US market for potential operations, these agreements direct them to consider Pennsylvania first.

Regarding Pennsylvania's life sciences landscape, it is crucial to understand that while much attention focuses on Philadelphia, our community is geographically diverse across the state. We have approximately 100 member companies in Pittsburgh, about 24 in the Lehigh Valley northeast of Philadelphia, and another 24 in the central part of the state. The highest concentration exists in southeastern Pennsylvania around Philadelphia, but our presence is truly statewide.

The Commonwealth of Pennsylvania hosts more than 3,000 life sciences establishments spanning pharmaceuticals, biotechnology, devices, diagnostics, and universities. This represents 15% growth since 2015 in terms of new company formation. Importantly, 67% of these companies employ 10 people or fewer, demonstrating that entrepreneurialism thrives in Pennsylvania.

However, we must acknowledge that this remains a fragile community. The risk of failure is extraordinarily high—as industry leaders like Steve Ubel and John Crowley will confirm, nine out of

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ten companies will fail. This reality necessitates a supportive environment from both business and public policy standpoints to improve what are already challenging odds.

**Given this existing ecosystem and growth trajectory, where do you identify the greatest opportunities or gaps that need addressing to enhance companies' chances of success?**

From a scientific modality perspective, cellular and gene therapy arguably originated in Philadelphia at the University of Pennsylvania. The pioneering work of researchers like Carl June and Jim Wilson, along with companies such as Spark Therapeutics and Adaptimmune's significant US presence in Philadelphia, established this foundation. Although investment in the cell and gene therapy space has cooled somewhat recently, it continues offering tremendous opportunities for scientific and medical advancement.

Similarly, messenger RNA technology traces back to the University of Pennsylvania through the work of Dr Drew Weissman and Katalin Karikó<sup>3</sup>, the Nobel Prize winners. Groups in Pennsylvania and Philadelphia were instrumental in founding and forming these transformative technologies. Moreover, I must note the Children's Hospital of Philadelphia and their remarkable announcement regarding the world's first patient treated with a personalised CRISPR gene-editing therapy. What an extraordinary milestone for CHOP and the field of precision medicine.

The growth of the cell and gene therapy space, pioneered by Dr Jim Wilson, has created what amounts to a family tree of companies emerging from that technology community, many of which remain in Pennsylvania. While the science, companies, and some executives have expanded across the country, tremendous growth opportunity persists from these modalities and organisations.

**From an infrastructure perspective, what key strengths can Pennsylvania highlight, and are there areas requiring increased support?**

I will address this from two perspectives. Regarding physical infrastructure, numerous start-up incubator sites exist in Philadelphia and Pittsburgh, with accelerator organisations in Philadelphia, Hershey in central Pennsylvania, and the Lehigh Valley. These include, among others, the Hershey Centre for Applied Research, the Ben Franklin Technology Ventures incubator site in the Lehigh Valley right on Lehigh University's campus, and Innovation Works, which operates an incubator site with start-up companies in Pittsburgh.

The University of Pittsburgh, partnering with Wexford Science & Technology, is investing in laboratory and office space for life sciences. Since 2018, there has been what I would characterise as a gold rush of enthusiasm and effort across Pennsylvania to build and develop life sciences laboratory and office space. While everything paused during 2020-2021 due to the pandemic, this activity has resumed with considerable energy.

Among our most prominent partners in this space is Wexford Science & Technology, which operates several incubator spaces in Philadelphia. The Cambridge Innovation Centre also maintains a significant presence in Philadelphia, where our office is located. The University City Science Centre, the oldest urban life sciences incubator in the country, remains an important player, providing laboratory space. Pennovation, part of the University of Pennsylvania, serves as an incubator site primarily for university spin-outs but not exclusively.

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Pittsburgh hosts similar but smaller-scale activity. There has been tremendous growth in real estate, laboratory space, office space, and physical infrastructure.

The Massachusetts Life Sciences Centre represents the gold standard that many states attempt to replicate. Pennsylvania has historically lagged in this area. We have not had a gubernatorial administration in Harrisburg that truly supported our industry for approximately 25 years. However, starting a year and a half ago under our current Governor Shapiro, we are seeing extremely strong interest and support.

The governor's current budget proposal includes a 50 million USD Innovation Fund. While this may seem modest compared to Massachusetts's approximately 100 million USD annually, when combined with Pennsylvania's existing programs, the total exceeds 100 million USD annually.

These existing programs include the Life Sciences Greenhouses—three seed capital organisations across the state, funded annually by tobacco settlement dollars. This traces back to the last supportive governor 25 years ago, Governor Tom Ridge, who created the Tech 21 initiative. This initiative identified seven industry sectors requiring government support, including life sciences. They created this plan, remarkably, before knowing how to fund it—a truly bold and visionary approach. When tobacco settlement dollars became available in 2000, they had a plan ready for immediate execution.

Additional programs include the Ben Franklin Technology Partners, four state-funded entities across Pennsylvania focused on innovation generally, not exclusively life sciences. We maintain a research and development tax credit with a current pool of 65 million USD that we are working to increase to 120 million USD. Keystone Innovation Zones provide tax-free status for 10 years in designated geographic areas designed to support start-up companies.

When combining the governor's proposed 50 million USD with these existing programs, the total investment significantly exceeds 100 million USD.

### **What unique value propositions does Pennsylvania offer as an alternative for companies choosing where to start, build, innovate, or expand?**

Beginning with the foundation of our pipeline, Pennsylvania hosts two of the top 10 NIH-funded universities in the country: The University of Pennsylvania and the University of Pittsburgh. These institutions alone continuously generate new technologies and assets, creating tremendous commercialisation opportunities.

Given that pharmaceutical companies face patent cliffs and struggle to maintain robust pipelines as patent protections expire, they require new assets to fill these pipelines. The University of Pennsylvania and the University of Pittsburgh represent what I would call a field of dreams for potential assets that pharmaceutical companies can acquire to strengthen their portfolios.

From a scientific heritage standpoint, Philadelphia is home to the first college of pharmacy, and the legacy of pharmaceuticals in this region is unmatched. While I acknowledge that Cambridge, Massachusetts, is arguably the biotechnology centre of the world, Philadelphia's pharmaceutical heritage extends back more than 100 years. The Philadelphia College of Pharmacy's alumni include industry founders Eli Lilly, Robert McNeil, Henry Wellcome, and Silas Burroughs of Burroughs Wellcome, now part of GSK.

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These alumni remained in the area and established companies in southeastern Pennsylvania. As these companies grew, the talent base expanded and remained, forming the foundation for numerous large pharmaceutical companies and countless start-up enterprises.

While discovery and early-stage companies emerge globally in Cambridge, Boston, San Diego, and San Francisco, no region possesses larger pharmaceutical development, manufacturing, and commercialisation experience than southeastern Pennsylvania, due to its established presence.

The building where I currently sit is a 1 million square foot facility that formerly served as GlaxoSmithKline's US research and development headquarters. GSK moved west to Collegeville, Pennsylvania, but remains in the state, and its biologics manufacturing remains on this campus. Pfizer operates literally next door to that GSK facility in Collegeville. Johnson & Johnson is located about 25 minutes away in Horsham and Spring House, while Merck operates in West Point. This proximity creates an unparalleled concentration of talent, legacy, and expertise.

Geographically, Pennsylvania sits almost equidistant between regulatory bodies in Washington—an hour and a half train ride or two-hour drive to the FDA, NIH, HHS, and Department of Defence—and the capital markets in New York, approximately an hour and a half train ride north.

In western Pennsylvania, Pittsburgh sits between Toronto and Cleveland, Ohio, which we consider part of the medical technology belt. The pharmaceutical belt extends from Boston to North Carolina, with Pennsylvania positioned in the centre as the buckle of this pharmaceutical belt, while the medical technology belt spans the western portion of the state.

The cost of living in Pennsylvania, whether around Philadelphia, Pittsburgh, or the central part of the state, cannot be compared to Boston or other major biotech hubs. Additionally, Pennsylvania experienced significantly less snowfall last year than Massachusetts, providing quality of life advantages.

### **The emergence of contract research organisations appears to be a particular strength for Pennsylvania. Could you elaborate on this development?**

This represents a specific but significant advantage. The pharmaceutical industry's evolution over the past 15 to 18 years, particularly following the 2008-2009 contraction when pharmaceutical research and development organisations needed to reduce costs and fill pipelines, created unique opportunities in Pennsylvania.

What emerged was the rapid formation of contract research organisations founded by former pharmaceutical research and development executives. When I became CEO of this organisation 15 years ago, we had two CROs in our membership. Today, we have 56, many serving as niche players handling specific segments of the development chain.

A specific example illustrates this pattern: Flow Metric was founded by an executive who previously ran flow cytometry for Johnson & Johnson. When Johnson & Johnson determined that flow cytometry was a function they could outsource, they eliminated his entire group. He formed his own company, continuing to perform flow cytometry services, with Johnson & Johnson becoming one of his first customers because they knew him, his work, and his capabilities.

This story has been repeated countless times across the industry. We now maintain 56 CROs in our membership and serve as the only state partner for ACRO, the Association of Clinical Research

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Organisations, at the national level. ACRO has 19 members nationally, while we represent 56 CROs at the state level, reflecting the heavy concentration of these organisations in Pennsylvania.

This again demonstrates the legacy of pharmaceutical expertise, particularly in development, manufacturing, and commercialisation stages.

**Looking ahead to the next two to three years, what are your primary focus areas for advocacy, and what is your outlook for Pennsylvania's life sciences ecosystem?**

At the federal level, we maintain a strong and supportive congressional delegation across party lines—Republicans, Democrats, House, and Senate members all support our industry because they recognise its economic impact and importance. Pennsylvania's more than 3,000 life sciences establishments employ 112,000 Pennsylvanians directly, with a multiplier effect of approximately 4.5 jobs for each direct position, involving roughly half a million Pennsylvanians either directly or indirectly in our industry.

The current environment in Washington has created tremendous, unprecedented uncertainty for our industry. Our congressional representatives are learning about developments simultaneously with us, creating reactive rather than proactive responses.

We have four key federal priorities moving forward. Most urgently, we need reauthorization of the SBIR and STTR programs. We continue advocating for comprehensive NIH funding, as universities operating on July-June fiscal years have already begun incorporating potential indirect cost caps into their planning, representing a significant financial impact.

We support reauthorization of the paediatric priority review voucher program, which affects many start-up companies. For medical technology, we advocate for the proposed Medicare coverage for the emerging technologies program, which would provide immediate Medicare coverage for devices approved through priority review, eliminating the typical two to three-year coverage delay. Companion legislation, the Ensuring Patient Access to Critical Products Act (Senate Bill 1717), would enable this coverage.

We continue educating our congressional delegation about the dangers of most favoured nation pricing schemes and government regulation of prescription drug prices, which create uncertainty that keeps investors sidelined.

Long-term, we seek continued appropriate NIH funding levels. While we support greater government efficiency, the implementation method and location matter significantly. We remain optimistic that recent FDA changes have not disrupted reviewers and review processes in drugs, biologics, or devices, and we want this continuity maintained.

At the state level, we fully support Governor Shapiro and his Innovation Fund. The administration has demonstrated dramatic support for our industry. We want to see the 50 million USD fund approved, begin realising its benefits and resulting growth, and build upon this foundation over the coming years.

**Do you have any closing thoughts or messages on behalf of Life Sciences Pennsylvania?**

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It is important to recognise the value of various associations in our industry. Even during this challenging period from capital markets and scientific perspectives, we are already ahead of our annual projection for new member growth, expecting more than 115 companies to join our association this year alone. They recognise the importance of public policy advocacy and environmental shaping.

These challenging times are cyclical and temporary. We expect recovery, as evidenced by major pharmaceutical companies rebounding in the second quarter from a difficult first quarter. Scientists continue pursuing their work and innovation, much of which occurs in our universities and start-up companies. This persistence provides cause for optimism.

The number of small companies in Pennsylvania represents additional cause for optimism. People continue pursuing this industry to benefit the ultimate beneficiaries—patients. Thousands of diseases affecting millions of patients worldwide still await scientific breakthroughs and successful treatments from our research community.

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