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Comparison Analysis and Case Studies of
the Biotech Industry in Maryland,
Masaachustes and California

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Thanks to all the entrepreneurs, scientists, and regulators agreeing to support or join this program

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Introduction

This paper is the result of the 2023 Yuan Foundation white paper project. The entire project spanned a duration of two months, involving the examination of extensive information and data, interviews with numerous pertinent professionals, and seeking advice from several experts.

Yuan Foundation is a non-profit organization started in 2021. The mission of Yuan Foundation is to enrich the United States by encouraging Asian American citizens to embrace their rights and responsibilities, by promoting the founding ideals of liberty and democracy and providing a platform that voices their common concerns and interests. To enhance the political engagement skills and awareness of Asian students and to mirror the Asian community's involvement in policy making, the Yuan Foundation has initiated a white paper initiative centered on industry analysis and policy suggestions. This project specifically concentrates on the biotechnology sector within the context of Maryland's state dynamics. In this project, a team of five graduate students coming from renowned universities engaged in comprehensive research. Our work encompassed extensive interviews with entrepreneurs, government officials, and scientists in the biotechnology field. The project team undertook a comparative analysis of the status, policies, and distinctive features of the biotech industry in California, Massachusetts, and Maryland. Drawing from the research, we made some recommendations aiming to advance the biotech sector in Maryland.

It's worth noting that our research, constrained by factors such as human resources, financial resources, and time, has certain limitations and shortcomings. Nevertheless, we view this as a starting point and remain committed to further in-depth research, with the aim of contributing to Maryland's economic development.

Executive Summary

This paper centers on the growth of Maryland's biotechnology sector, aiming to offer theoretical support and case studies. The intention is to provide policy recommendations to actively develop the potential of the biotechnology industry in Maryland. To further understand the current challenges facing Maryland Biotech startups, the Yuan Foundation White Paper Project team conducted interviews with local Biotech entrepreneurs, regulators, and scientists. After analyzing the results of the interviews, we found that controlling costs, retaining talent, and finding investment are the main difficulties faced by startups today. To learn experiences from other states, this paper also did policy comparison analysis among Maryland, Massachusetts, and California in terms of tax incentive, technology transfer and area economic development. Since Boston and Silicon Valley are the two most successful Biotech Parks areas across the country, we hope to learn from the successful examples. After a series of studies, we made the recommendations to Maryland State government that the government should put efforts on promoting the current policies, working with the federal government to encourage scientists to be entrepreneurs, and further launching the Maryland tax system reforms.

Part 2: Research Data (Three States Comparison)

To better provide the Maryland government with policies to promote the biotechnology industry and to fully realize its own shortcomings and potentials, this paper will compare and analyze the biotechnology industry in Massachusetts and California from three perspectives: the current situation, regional characteristics, and policies.

State	Number of Companies	Number of Practitioners	Market Size (\$ billion)	Nearby University	Main Focus
Massachusetts	1,000	74,500	190	MIT, Harvard, BU	drug discovery and development
Maryland	3,000	54,000	20	JHU, UMD	vaccine development, immunology, and infectious diseases
California	13,000	334,690	414	Stanford, UCLA, Caltech	genomics, biotechnology tools and instrumentation, and stem cell research

Graph 1: Comparison among the Biotech Industry in Massachusetts, Maryland, and California

California

Current Biotech Industry Situation in Silicon Valley, California

California's biotech sector, especially in Silicon Valley, remains a global leader in life sciences innovation. As of Q3 2023, the San Francisco & San Jose MSA boasts a commendable life sciences employment count of approximately 153,000, according to CBRE (CBRE, 2023) reflecting the sector's healthy growth and the state's broader contribution of nearly 1 million direct and indirect jobs in the industry. (CALSA, 2020)

California's prominence in the biotech industry is also about the quality and impact of the work produced. The state leads the nation in patent generation across various facets of biotechnology, from microbiology and genetics to cutting-edge fields like bioinformatics (CALSA, 2020).

This leadership is backed by substantial financial support: California secured its position as the nation's top recipient of NIH funding in 2021(CALSA, 2020).

Moreover, by 2022, the state benefitted from a combined funding of \$6.1 billion from the National Science Foundation (NSF) and the National Institute of Health (NIH), ensuring the continuation of groundbreaking research and innovation (ca.gov). These investments have translated into impressive economic outputs. In 2021, the biotech industry in the region produced an economic output surpassing \$100 billion. (Biocom.org, 2023)

Characteristics of Silicon Valley

Silicon Valley is an industrial powerhouse nestled around the southern shores of San Francisco Bay in California. Its epicenter is Palo Alto, the home of the prestigious Stanford University. The region stretches to encompass northwestern Santa Clara County, reaching as far inland as San Jose, and includes parts of Alameda and San Mateo counties.

The economic pulse of Silicon Valley is robust. As of 2021, the GDP for San Jose-Sunnyvale-Santa Clara stood at over \$410,000 million (bea.gov, 2023). Impressively, the region is distinguished for its high-tech prowess, with Silicon Valley alone boasting 225,300 of the San Francisco Bay Area's 387,000 high-tech positions (CBRE, 2023). The job growth rates have seen fluctuations in recent years due to the pandemic, with an impressive growth of over 30% from 2010-2022, a slight dip in 2019-2022, and a modest increase of about 5% between 2021-2022. (Bls. gov, 2023)

Silicon Valley's demographics provide an informative overview into its societal fabric. According to the 2021 United States Census Bureau, the majority age group lies between 25-44 years, making up 30% of the population, indicative of the region's allure for young professionals. Asians represent 37% of the population, followed by the White community at 30%. Hispanic or Latino residents constitute 25%, while the Black or African American and Multiple and other groups are relatively minor, at 2% and 6%, respectively (census.gov, 2023) Silicon Valley prides itself on its highly educated workforce. Based on United States Census Bureau's data, a substantial 28% of its residents have a bachelor's degree, and an impressive 25% hold either a

Graduate or Professional Degree (census.gov, 2023). Silicon Valley's academic environment is top tier, anchored by Stanford University, a globally recognized institution renowned for producing many tech experts who often transition into the local tech industry.

Silicon Valley is home to numerous venture capitalists, angel investors, and financial institutions. Silicon Valley has produced some of the most successful companies in the world, from the early days of Apple and Google to the recent success stories of Airbnb and Uber.

Analysis of Relevant Policies for California's Biotech Sector

(a) Tax Incentive Policy

The biotech sector in California, particularly within Silicon Valley, enjoys a robust range of financial and tax incentives strategically designed to bolster the industry's growth and competitiveness.

One of the primary incentives is the California Competes Tax Credit. This program allows businesses, specifically manufacturing and research firms, either new or expanding within California, to earn tax credits over five years, which can be carried over for six more years. The eligibility and quantum of the award are contingent upon eleven evaluation criteria, with the main focus on capital investment and the creation of new jobs in the state. (ca.gov, 2023). Further, the Capital Investment Incentive Program (CIIP) authorizes local governments to offer rebates on property taxes exceeding an assessment of \$150 million for up to 15 years. This is tailored to benefit manufacturers with a significant capital footprint. There is a reciprocal requirement for the recipient to adhere to predetermined criteria, including job creation and wage benchmarks. This is complemented by a community service fee, capped at \$2 million annually (ci. vacaville, 2023).

Manufacturers also stand to gain from the Sales Tax Exemption. Firms manufacturing at their facilities can avail a partial tax exemption on purchases and leases of manufacturing and energy generation equipment. The application process is

straightforward, requiring just a certificate presented to the vendor when ordering.(ci.vacaville.ca, 2023).

Another salient feature of California's pro-biotech ecosystem is the Research & Development (R&D) Tax Credits. Businesses can benefit from a 15% credit on incremental research expenditures or a 24% credit for basic research payments to external organizations. Qualifying expenses encompass wages, supplies, and contracted research costs. Moreover, the California Manufacturing Exemption, further benefits companies involved in manufacturing and R&D. Equipment, or machinery predominantly used in the manufacturing process can be exempted from sales and use tax (universitypartner.com, 2023).

Recent legislative changes have also buoyed the sector. In February 2022, Governor Gavin Newsom enacted Senate Bill 113, reinstating two pivotal tax advantages for biotech companies: California's Research and Development Tax Credit and the Net Operating Loss (NOL) Tax Deduction, temporarily halted in 2020 (bio.news, 2023)

In conclusion, California has implemented a gamut of policies and tax incentives. These are crafted to ensure that startups and established companies thrive, contributing significantly to the state's economy.

(b) Government Grants/Loans

California boasts a robust and comprehensive incentive ecosystem that fosters the growth of biotech companies, encompassing everything from government loans to the Employment Training Panel (ETP).

The state of California offers an array of government grants tailored for startups to fuel their innovation and evolution. At the state level, initiatives such as The California Rebuilding Fund, Loan Guarantee Program, Disaster Relief Loan Guarantee Program and California Capital Access Program (CalCAP) are provided for businesses that suffer financial risk from the Covid-19 (ca. gov) specifically, The California Redevelopment Fund, funded by a public-private partnership that includes an initial \$25 million investment from the California Infrastructure and Economic

Development Bank (IBank), is designed to serve micro and small businesses. The Small Business Loan Guarantee Program (SBLGP) supports businesses with fewer than 750 employees with financial assistance to expand and is administered primarily by the California Infrastructure and Economic Development Bank (IBank). GoGreen Business is administered by the State Treasurer's Office and serves the financing needs of small and medium-sized businesses and nonprofit organizations. On a national scale, The U.S. Small Business Administration (SBA) consistently supports small businesses by establishing loan guidelines and mitigating lender risks source (sba. gov, 2023).

Also, the California Dream Fund is a one-time \$35 million program designed to provide seed money for entrepreneurship and small business creation in California. New entrepreneurs will complete training through participation in the Technical Assistance Extension Program (TAEP). New businesses that successfully pass the test will be eligible to apply for small grants of up to \$10,000 (calosba. gov).

The CalCRG program, embedded within the Adult Use of Marijuana Act (Proposition 64), empowers GO-Biz to allocate grants to local health departments and eligible community-centric non-profit entities. In September 2023, the Governor's Office of Business and Economic Development received 325 applications for the California Community Reinvestment Grant (CalCRG) program. The amount of grants available for award is \$48 million, and the total amount of funds requested from the 325 applications submitted is more than \$484 million, demonstrating the strong vitality of California businesses (ca.gov, 2023). Beyond direct funding, the Employment Training Panel (ETP) emerges as an innovative catalyst for biotech progression in California. ETP was established by the California State Legislature in 1982 and is funded by California employers through a special payroll tax (etp. ca, 2023). ETP provides funding to employers to assist them in upgrading the skills of their workers through training, thereby gaining the opportunity to achieve skill growth in their workforce that will lead to technological advancement in their companies. California's ETP is a performance-based program that provides funding for trainees

who successfully complete the training and are placed in higher paying jobs for a specified period. Funding is provided for trainees who successfully complete training and are employed in a higher paying job at the required minimum wage for a minimum of 90 days (etp.ca.gov). Reimbursements are granted to businesses only when trainees fulfill specific performance criteria, such as completing a minimum of 8 hours of training, full-time employment, and a post-training employment-retention period, while also earning at least the ETP minimum wage source.

Moreover, ETP-funded training isn't exclusive to employees; it extends to managers and supervisors, fostering technological advancements for biomedical personnel and propelling the industry's overarching growth.

(c) Technology Transfer

Recognizing the importance of patent protection to the commercial success of these inventions, NIH pursues intellectual property protection for commercially valuable inventions domestically and internationally. The NIH licensing process is very comprehensive. Companies interested in commercializing an NIH invention, whether patented or not, must obtain a license (nih.gov). California has established a comprehensive framework for the commercialization of biotechnology innovations, ensuring that their research results are available for public use and benefit.

California's approach to patent protection and technology transfer in the biotechnology industry is unique because of its comprehensive understanding of intellectual property, detailed guidance on patents, structured approach to technology transfer, and the impact of the Bayh-Dole Act. In addition, universities such as Stanford University and California State University have profound insights into intellectual property and patent protection, making them distinct from other states.

Stanford University recognizes the value of intellectual property generated by research and provides resources for its transfer for public benefit. Stanford research often results in intellectual property that may be protected by patent, copyright, or trademark laws. The Office of Technology Licensing (OTL) manages intellectual property developed by the University through formal licensing. Stanford's Office of

Technology Licensing (OTL) manages intellectual property and ensures innovations are effectively licensed and commercialized (Stanford, 2023). Stanford University emphasizes the responsibility of principal investigators, students, and researchers to disclose potentially patentable inventions and ensure that innovations are protected and can be commercialized.

California State University is leading in Technology Transfer due to the Bayh-Dole Act and its impact. The Bayh-Dole Act of 1980 allows universities and nonprofit organizations to retain ownership of inventions made under federally funded research projects. California State University emphasizes key provisions of the Bayh-Dole Act that encourage universities to participate in technology transfer activities, ensuring that universities retain ownership, patent rights and commercialization of inventions and share the benefits with the public. In addition, California State University provides a step-by-step guide to technology transfer, from initial contact with the technology transfer office to final licensing of the invention. This approach ensures that the innovation is assessed for market potential, protected through patents, and then sold to interested companies for commercialization.

Massachusetts

Massachusetts Biotech Industry Situation:

In 2022, Massachusetts showcased remarkable growth in the biotech sector, solidifying its reputation as a pivotal player on the global stage. The state's Research & Development (R&D) workforce expanded by an impressive 8.5% year-over-year, outstripping other biotech hubs like California and Pennsylvania, concluding the year with over 64,000 R&D professionals (U.S. Bureau of Labor Statistics, 2023, April 25). Concurrently, the state's biomanufacturing segment experienced a growth of 6.3%, resulting in nearly 10,500 specialized employees by the end of 2022 (U.S. Bureau of Labor Statistics, 2023, April 25). On the investment front, Massachusetts-based biotech firms attracted a remarkable \$3.73 billion in venture capital funding in just the first half of 2023 (Massbio, 2023). Even more notably, these Massachusetts-headquartered entities represented 32% of all venture capital inflows into the biotech

industry (Massbio, 2023). Infrastructure also saw major advancements with 6 million square feet dedicated to life sciences spaces being completed in 2022 (Massbio, 2023). Reflecting its significant contributions on a national scale, Massachusetts' drug development initiatives comprise a substantial 14.9% of the entire U.S. pipeline (Massbio, 2023). With these milestones, Massachusetts has clinched the top spot, surpassing California to become the world's leading biotech hub (Massbio, 2023).

Characteristics of the area:

Massachusetts is located at the east western part of the United States. It enjoys great economic development and ranks 12th in economy size among all states and the District of Columbia (USA facts, 2023). Specifically, in the 1st quarter of 2023, the real GDP for MA was \$713.6 billion in goods and services per year, and the real GDP growth rate for MA was 2.5% per year. Ranked 20th, this growth rate is higher than the US overall data.

Demographically, there are nearly 7 million people in MA in 2023, with about 5.6 millions of adults (World Population Review, 2023). The Age Dependency Ratio (the number of dependents / the number of working-age population) for MA in 2023 is 57.3%. Massachusetts residents' education levels are relatively high, with 20.67% of the people over 25 having a graduate degree and 25.12% having a bachelor's degree (as the highest education). MA also has an unemployment rate of 2.5%, which ranked 10th from the lowest to the highest (USA facts, 2023).

As for funding sources, state government provides lots of resources including grants and loans (Mass.gov, 2023). Also, private equity is largely invested in Massachusetts. According to Raw Selection's research (2023), 188 private equity firms are operating in Massachusetts, with more than 2,500 employees in the industry. Large firms including ABRY Partners and Bain Capital have more than 45 people in their teams.

Analysis of relevant policies:

(a) Tax Incentives

The Massachusetts Life Science Center was established according to the Massachusetts General Laws. It is an independent quasi-governmental organization that is authorized to award different kinds of grants, loans, and tax incentives. From July 1, 2013 to June 30, 2017, the Massachusetts Life Science Center has awarded 221 types of awards, with the total amount achieving nearly 233 million (Mass.gov, 2023).

Based on the main business and organizational characteristics of the company, different tax credits can be claimed. 5 kinds of tax credits are aimed particularly at life science related companies (Mass.gov, 2023):

- 1. Refundable investment tax credit (ITC):** Equal to 10% of the cost of qualifying property through acquiring, constructing, or erecting during the tax year. This property must be used exclusively in Massachusetts. If ITC exceed personal income tax or corporate excise otherwise due, 90% of the credit balance can be refundable. However, corporates taking the life science ITC are not allowed to take the 3% Investment Tax Credit or the Low-income Housing Credit (two kinds of general tax credit that are not particularly for life science companies).
- 2. Refundable FDA user fees tax credit:** Available for user fees paid to the U.S. Food and Drug Administration (FDA) upon submission of an application to manufacture a human drug in MA. This credit equals to 100% of the user fees actually paid by the taxpayer. The firm must have more than 50% of the research and development costs for the drug incurred in MA to be eligible for this tax credit. 90% of the balance of credits remaining is refundable.
- 3. Refundable section 38M research tax credit:** According to MA General Laws Chapter 63, Section 38M, a company may receive the research credit for a portion of its qualified research expenses. At the option of taxpayer and to the extent authorized under the Life Sciences Tax Incentive Program, 90% of the balance of the remaining credits may be refundable.

4. Research tax credit: This is a research credit calculated in the same manner as the 38M research credit but for certain expenses that is not covered by the former one. Qualified expenditures include spendings for research related to legally mandated clinical trial activities performed both inside and outside Massachusetts. This is not refundable, but any unused credit can be carried forward for 15 years.

5. Refundable jobs tax credit: If the taxpayer commits to the creation of more than 50 net new permanent full-time positions in MA, it may get jobs tax credit determined by the Massachusetts Life Sciences Center, in consultation with the Department of Revenue. 90% of the credit balance may be refundable but excess credit amounts may not be carried forward.

Besides, companies may also benefit from other general tax credit opportunities. For example, Economic Development Incentive Program Credit (EDIPC) is for generally creating and stimulating business, Economic Opportunity Area Credit (EOAC) is for encouraging certified projects that advance the overall economy in MA, Employer Wellness Program Credit (EWPC) is for companies implementing a “certified wellness program” for its employees, and Veteran’s Hire credit is for encouraging hiring veterans.

Government Grants and Loans

Various funding options are provided at the state level. Specifically, MassDevelopment, a finance agency, offers various general funding options for local businesses through its loan programs; the Massachusetts Growth Capital Corporation specifically helped companies that are unable to acquire traditional fundings; the Small Business Innovation Research (SBIR) program and the MassRamp program are especially for research and development purposes; the MassVentures particularly focuses on early-stage, technology-driven companies.

Also, companies from specific regions can seek help from regional financing options, and firms can get special fundings for specific activities including promotion and training.

To help firms better get assistance, local state government also provide related online courses for learning and maintain an investor database for reaching out.

Technology Transfer

Patent Protection

In Massachusetts, as in the rest of the United States, patent protection is a vital instrument that promotes innovation and economic growth. It offers inventors exclusive rights to their inventions for a limited time, allowing them to protect their work from being used or replicated without permission. The United States Patent and Trademark Office (USPTO) is the federal agency responsible for granting U.S. patents, and its regulations apply uniformly across all states, including Massachusetts.

However, Massachusetts has its own initiatives and programs aimed at supporting inventors and promoting innovation. For instance, various institutions, such as universities and research centers in the state, often provide resources and guidance to inventors looking to patent their innovations (Geiger and SA, 2005). The state also promotes local innovation through grant programs, incubators, and other supportive environments for startups and technology enterprises (Geiger and SA, 2005).

Furthermore, Massachusetts is known for its robust legal community specializing in intellectual property law. Numerous firms in the state offer assistance in patent applications, litigation, and other related matters. As a hub for technology and research, especially in fields like biotechnology, Massachusetts recognizes the importance of strong patent protection to maintain its competitive edge.

Massachusetts has a legacy of championing innovation and has taken pivotal steps to streamline the technology transfer process. Recognizing the value of converting

research outcomes into market-ready solutions, the state has fostered a conducive environment for seamless tech transfer through various policies and measures:

- 1. Collaborative Research Initiatives:** Leading academic institutions in the state, such as MIT (MIT office of innovation, 2019) and Harvard (Harvard Office of Technology Development, 2007), have specialized technology transfer offices. These offices serve as bridges, connecting academic research with industries, ensuring that innovations are not just confined to labs but find real-world applications.
- 2. Support for Innovation Ecosystem:** Massachusetts encourages the establishment of innovation hubs, accelerators, and incubators. Institutions like the Massachusetts Biomedical Initiatives (2023) and the Cambridge Innovation Center (2023) play a pivotal role in nurturing startups and aiding them in bringing their technologies to market.
- 3. Funding Mechanisms:** State agencies, including the Massachusetts Technology Collaborative (1982), provide financial backing for projects that show promise in bringing technological breakthroughs. This financial support acts as a catalyst, accelerating the journey from research to market.
- 4. Networking and Capacity Building:** The state organizes regular events and seminars, aimed at enhancing the knowledge base around technology transfer (Massbio, 2023). These platforms enable stakeholders to learn, share, and collaborate, ensuring that the technology transfer process is both efficient and effective.
- 5. Public-Private Partnerships:** Massachusetts promotes collaborations between public institutions and private enterprises (Massachusetts Life Sciences Center, 2023; Wyss Institute at Harvard, 2009). These partnerships often result in co-developed technologies, which have a swifter path to commercialization due to shared resources and expertise.

In essence, through a mix of policies, funding mechanisms, and collaborative platforms, Massachusetts ensures that technology transfer is streamlined, effective, and brings socio-economic benefits to its citizens.

	MIT	NIH
Nature of Institution	<ul style="list-style-type: none"> • a private research university • focus on technology, innovation, and entrepreneurship 	<ul style="list-style-type: none"> • a federal agency under the U.S. Department of Health and Human Services • focus on biomedical and health-related research
Focus Areas	Diverse topics including engineering, life sciences, and physical sciences	Dedicated to medical and health research, covering areas including genetics, infectious diseases, cancer, and public health
Policies and Procedures	more flexible and industry-friendly approach	influenced by federal regulations and mandates
Technology Licensing Office	<ul style="list-style-type: none"> • MIT Technology Licensing Office (TLO) • manage MIT's intellectual property • engage in various licensing agreements with various industries 	<ul style="list-style-type: none"> • NIH Office of Technology Transfer (OTT) • manage its technology transfer activities • responsible for patenting, licensing, and managing the intellectual property developed within the NIH and FDA

Graph 2: Comparison among MIT and NIH technology transfer

Analysis of Maryland Biotech Industry Policies

About Maryland Biotech

Maryland is one of the states that has many advantages in developing the Biotech Industry. According to the Maryland Department of Commerce, Maryland is home to the largest concentration of scientists and engineers with doctoral degrees in the United States. In addition, it is home to the U.S. government that governs the biopharmaceutical industry, with the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH), the U.S. Pharmacopeial Convention (USP), the Frederick National Lab for Cancer Research, and Walter Reed Hospital (In 2014, more than 41,000 employees worked in the biomedical industry here, and \$4.05 billion of the region's \$15 billion in tax revenue came from the biomedical industry.

Challenges facing Maryland Biotech

Despite its strengths, Maryland's biotech industry has grown at a rate of 7.4 percent over the past five years, lagging Massachusetts' 58 percent growth rate and North Carolina's 38 percent growth rate. (Milken Insititue, 2021). In addition,

Maryland's Biotech industry is less concentrated than other states, which means Maryland has not formed a large-scale Biotech Industrial Park. This becomes a disadvantage for venture capitalists considering Maryland, which will make it harder for small and medium-sized businesses to control costs.

One of the problems brought by a short budget is hiring talents. According to the State of Maryland's Work Adjustment and Retraining Notifications registry, the Maryland biotech industry has been hit with more than 1,222 layoffs in the past 12 months. The number of lay off employees created a historic record for the Maryland Biotech Industry for the past five years. And even worse, some of the jobs are specific and require long training, it makes these jobs hard to replace.

The Maryland Biotech Industry encounters an additional challenge in the absence of a comprehensive industry chain. Statistical data reveals that most biotech startups in Maryland are primarily engaged in research and development (R&D), with fewer startups venturing into the manufacturing sector. This homogeneity in business types poses a challenge for Maryland in establishing a concentrated industrial park. In contrast to biotech parks in other states where a clustering effect has been achieved, Maryland faces difficulty in creating a similar environment. Successful parks in other regions often feature a combination of major pharmaceutical companies coexisting with numerous smaller companies providing supporting service.

To explore why Maryland lacks large biotech companies to locate in the state, we need to talk about Maryland's tax policy. In the analysis that follows, I will briefly describe Maryland's existing tax incentives for the biotech industry and state the problems with these policies.

Maryland Biotech Tax Incentives

Maryland has been at the forefront of supporting its biotechnology industry through a range of tax incentives and programs. These incentives are targeting to conduct innovation, attracting biotech companies, and spurring economic growth in the state's burgeoning biotechnology sector.

One key incentive is the Biotechnology Investment Incentive Tax Credit, which encourages investment in qualified Maryland biotechnology companies. This tax credit provides investors with a percentage of their investment amount, promoting capital infusion into the state's biotech ventures. The Maryland Biotechnology Investment Incentive Tax Credit provided investors with a tax credit equal to 33% of an eligible investment in a Qualified Maryland Biotechnology Company (QMBC) up to \$250,000 in tax credits. (Maryland. gov)

In addition to investment incentives, the state offers the Biotechnology Research and Development Tax Credit, designed to reward biotech firms for qualified research and development expenses. The Maryland Biotechnology Research and Development Tax Credit provides a tax credit of up to 50% of qualified research and development expenses incurred by biotechnology companies in Maryland.

For companies that create jobs in Maryland, the Job Creation Tax Credit is a valuable incentive. This program provides tax credits based on the number of new, full-time positions generated by biotech firms. The more jobs created, the larger the potential tax credit, serving as an attractive proposition for businesses looking to expand their workforce in the state.

Problems of the Maryland Biotech Tax Incentives

While Maryland offers various tax incentives to promote its biotechnology industry, there are some challenges and problems associated with these incentives:

Less Competitive than other states:

Maryland competes with other states, such as Massachusetts and California, for biotech investment. Some companies may intend to choose locations with more lucrative incentives or established biotech hubs.

High Barrier:

Meeting the eligibility criteria for certain incentives may be challenging for some biotech companies, particularly startups or those in the early stages of development. This can limit the benefits to a subset of the industry.

Limited Scope:

Some incentives may only apply to specific areas of the biotechnology industry, potentially leaving out companies in related fields or those pursuing innovative approaches not covered by the incentives.

Limited Implication:

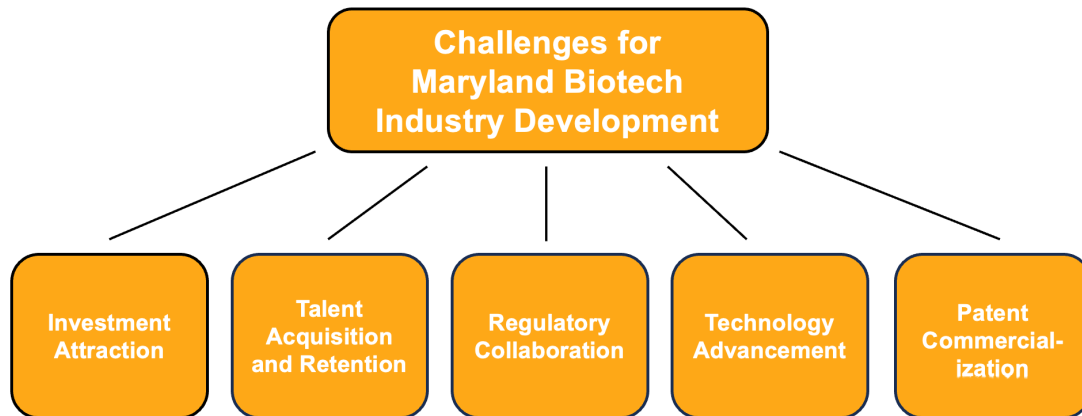
Tax incentives primarily focus on financial aspects of business growth. They may not address other crucial factors for biotech companies, such as access to talent, infrastructure, or collaborative research opportunities.

Complicated Process:

Biotech companies must comply with strict reporting and documentation requirements to maintain their eligibility for tax incentives. This can be an administrative burden and may require dedicated resources.

Lack of Awareness:

Some biotech companies may not be aware of the available tax incentives or may not have the expertise to take full advantage of them. This can lead to missed opportunities for both the companies and the state.



Graph 3: Challenges Facing Maryland Biotech Industry

Technology Transfer of Maryland Biotech Industry

The Restriction of NIH

Restrictions on Employment with Specific Entities: For all NIH employees, compensated or uncompensated employment, consulting, advisory board service,

teaching, speaking, writing, or editing is strictly prohibited with or for certain entities. These entities include substantially affected organizations such as biotechnology, pharmaceutical, medical device companies, hospitals, clinics, health insurers, and educational institutions that have applied for or received NIH funding within the last 12 months. Additionally, self-employment activities that involve promoting the services or products of these entities are not allowed.

Nature and Process of NIH Technology Transfer:

The process of transferring NIH/CDC inventions to the private sector for further research, development, and eventual commercialization is referred to as technology transfer. This involves the creation of a legal agreement, known as a license, in which the inventor commits not to prevent the licensed party from using, making, and selling the invention.

Responsible Entity:

Technology Transfer Professionals are responsible for managing the report and technology protection throughout the licensing process.

Process of Licensing: The licensing process involves two main sides: the NIH side and the company side.

On the NIH side, the steps include:

- Submitting the application to technology transfer professionals.
- Evaluation of the patentability and probability of commercial success.
- Initiating the patent protection process for inventions with commercial value.
- On the company side, the steps include:
 - Submitting the application to the NIH technology transfer office, providing basic information and plans for commercialization, particularly if exclusivity is sought.
 - Reviewing the application for compliance with public interest.
 - Negotiating the license, which can take various forms, depending on patent protection status.

The National Institutes of Health (NIH) plays a critical role in funding and conducting research that leads to innovative discoveries and inventions. The

technology transfer process is essential for bringing these discoveries from the laboratory to the commercial sector. However, the technology transfer process at NIH, like in many research institutions, can face several challenges and problems, including:

Lengthy and Complex Process:

The technology transfer process can be long and complex, involving multiple steps, legal considerations, and negotiations. This complexity can lead to delays in getting innovations to the market.

Bureaucratic Hurdles:

The bureaucratic nature of government agencies like NIH can lead to administrative hurdles that slow down the technology transfer process. This includes issues related to documentation, reporting, and compliance.

Intellectual Property Concerns:

Navigating intellectual property rights and patent issues can be challenging. In some cases, disputes or uncertainty about ownership can hinder the transfer of technology.

Conflict of Interest:

Balancing the interests of researchers, institutions, and commercial partners can be challenging, leading to potential conflicts of interest that need to be carefully managed.

Part 3: Case Study

Case 1: Interview with Dr. Lu, founder of Codex

Dr. Lu, an alumnus of Fudan University, earned his degree in biochemistry and molecular biology in 1988. He furthered his education at Georgetown University in the United States, obtaining his Ph.D. in the same field in 1997. Following his doctorate, Dr. Lu honed his expertise at the National Institutes of Health (NIH), focusing on nuclear receptors and ligands. In the late 1990s, he joined a burgeoning biotech firm in Rockville, making significant contributions to developing novel G protein-coupled receptor (GPCR) medications and various biotechnological

innovations. Presently, Dr. Lu is at the forefront of COVID-19 research, crafting pseudo viruses instrumental in aiding companies like Pfizer in their vaccine development efforts.

Established in 2009, Codex is at the forefront of biological reagent development and provides specialized services to contract research organizations (CROs). With a commitment to innovation, Codex's offerings encompass a range of pioneering products and state-of-the-art biotechnological platforms, catering to a broad spectrum of clients including leading pharmaceutical entities and institutions like the NIH. The company's collaboration with these partners involves the provision of unique products and advanced biotechnological solutions. In the wake of the COVID-19 pandemic, Codex has played a pivotal role by developing pseudo viruses that mimic the virus, which are integral to antibody testing and are utilized by renowned companies in their efforts to devise effective countermeasures against the virus. In a strategic move to bolster its capabilities in organoid research, Codex recently acquired a company with expertise in induced pluripotent stem (IPS) cell and internal organ studies, signifying its dedication to advancing research in this cutting-edge area.

Dr. Lu has offered insightful perspectives on the current state and trajectory of the biotech industry. He has noted that, in contrast to the IT sector, biotechnology demands substantial financial investment and presents high barriers to entry. Adequate funding is crucial for research and development within the biotech field, yet there is a lower emphasis on managerial and service expertise, which can lead to imbalanced growth. Regarding compensation, salaries in biotech lag those in IT and major pharmaceutical companies, often reaching only half the level of these industries. This salary gap hinders local talent, particularly those who have grown up in the region, from pursuing careers in biology. Instead, they may opt for professions in medicine or IT, where the financial rewards are more substantial.

As the main person in charge of Codex, when asked about the current challenges encountered by the company's development, Dr. Lu has said that the company's slow organic growth and financial constraints are the biggest development

difficulties at present. Despite ten years of steady development, the company's growth has been gradual, growing from a small team to its current size. This measured expansion characterizes the initial stages of many startups, where revenue hovers in the million-dollar range and human resources are scarce. Financial constraints further compound this challenge, as small businesses like Codex struggle with the high costs associated with traditional sales methods. To mitigate these expenses, the company has turned to online sales channels and has recognized that outside investment is needed to drive significant growth. Looking ahead, Codex expects growth to surge, with annual revenue expected to rise 30% to 50% over the next two years. However, this ambitious expansion is not without dangers. The company may face a bottleneck, especially after it crosses the \$20 million revenue threshold, where rapid growth could give way to potential stagnation. While injections of external capital can be a catalyst for rapid expansion, they also come with inherent risks. An investment of around \$3 million can deliver strong returns but requires shrewd management and a delicate balance between risk and reward. Such funding also risks diluting founder control and changing the strategic direction of the company.

Additionally, the relatively modest compensation packages in the biotech industry pose another hurdle for Codex to attract and retain talent. This disparity is particularly upsetting to younger generations, who may prefer more lucrative careers in medicine, IT, or law. Competition for skilled professionals is fierce, and Codex finds itself at a disadvantage compared with larger pharmaceutical companies that can offer more attractive salaries and benefits. Additionally, the industry's reliance on an international workforce creates additional complexities, with visa requirements and the lure of better opportunities from competitors making recruiting and retaining foreign talent an ongoing struggle. Despite the many development difficulties currently encountered, Dr. Lu is full of confidence in the company's future development.

Continuously, we have asked how the Maryland government can help startups. Dr. Lu has stated that the government plays a pivotal role in supporting biotech

startups, with institutions like the National Institutes of Health (NIH) offering small business grants that provide crucial funding opportunities. These grants are an essential resource for early-stage companies, aiding them in research and development efforts. However, while government support exists, the resources are finite. Biotech entrepreneurs can apply for grants, but the available funding is limited, necessitating the pursuit of additional sources of capital.

This reality underscores the importance of a multi-faceted approach to funding. While government grants can jumpstart the R&D process, the growth and scaling of biotech ventures often require a blend of funding sources, including venture capital, angel investors, and strategic partnerships. The limited nature of government grants means that startups must be strategic and resourceful, leveraging these funds to reach milestones that can attract further investment.

The interviewees' insights suggest that while government grants are invaluable, they are not a panacea. The biotech industry's growth is contingent upon a robust ecosystem that includes not only government support but also private investment and a conducive regulatory environment. For Maryland, the challenge lies in creating a competitive landscape that can rival established biotech hubs, ensuring that startups have access to the capital, talent, and infrastructure necessary to thrive. Furthermore, Dr. Lu has commented that Maryland faces challenges in attracting sufficient funding for biotech startups, especially compared to established biotech hubs such as Boston and California. Despite Maryland's affluent status and proximity to Washington D.C., the interviewees note a lack of substantial state support and express uncertainty in leveraging the state's attributes for biotech development. Dr. Lu has pointed out the uncertainty in leveraging these attributes for biotech development, emphasizing the need for a concentration of expertise and specialists in the field. The government's role should encompass financial support and tax breaks, along with expedited processing of permits, especially for laboratory operations, which are perceived to be slow.

Dr. Lu has emphasized the significance of government actions, particularly the need for relaxed regulations to foster innovation and growth within the biotech sector. Direct policy support and tax incentives are deemed crucial for attracting investments and ensuring the financial prosperity of small enterprises. Federal support, particularly in the form of financial aid to small businesses, is considered vital for the growth and sustainability of small biotech firms.

While Montgomery County shows some support for small businesses, overall state support, particularly in terms of funding, seems lacking. There is a need for more supportive policies, including tax breaks and simplified lab permits, to attract and retain biotech companies. The proximity to large entities like NIH and FDA is beneficial, stimulating the development of a service-oriented business ecosystem around major players. Despite the challenges, Maryland holds potential for growth in areas like cell and gene therapy, which are gaining attention and providing opportunities for the local biotech industry. The rise of innovative startups in these fields could attract venture capital attention, potentially easing financing challenges.

As a result, Dr. Lu has called for a balanced approach that includes both indirect support through relaxed regulations and direct financial and policy-driven incentives to nurture and sustain the biotech sector's growth. They also point out the challenges in attracting sufficient funding and retaining talent, especially when compared to established biotech hubs like Boston. The presence of influential entities like NIH and FDA near Maryland is recognized, but regulatory and legislative constraints may hinder the encouragement of experts to venture into entrepreneurship. Also, Dr. Lu has emphasized the significance of government actions, particularly the need for relaxed regulations to foster innovation and growth within the biotech sector. Direct policy support and tax incentives are deemed crucial for attracting investments and ensuring the financial prosperity of small enterprises. Federal support, particularly in the form of financial aid to small businesses, is considered vital for the growth and sustainability of small biotech firms.

Case 2: Interview with Dr. Li, founder of SunVax

Dr. Li embarked on an illustrious academic path, undertaking a Master's and Ph.D. in a collaborative program between Peking University and the Beijing Forestry Science Research Institute from 2004 to 2010, with a concentration in biotechnology and a particular focus on genetics. In 2011, Dr. Li's quest for knowledge led to a postdoctoral research position at the Massachusetts Institute of Technology (MIT) in Boston, USA, where a pivotal shift in research interest to immunology occurred, specifically targeting CDAT cells and macrophages. Over a decade at MIT, Dr. Li's academic excellence was marked by the acquisition of six Patent Cooperation Treaty (PCT) patents. One of these patents achieved commercial success, being licensed to a U.S. firm and subsequently sublicensed to an Asian corporate entity, generating a significant licensing fee of \$277 million.

SunVax, a burgeoning biotechnology enterprise, is strategically positioned in the innovation hub of Boston. Launched in November 2021 by a visionary Chinese entrepreneur, SunVax has quickly emerged as a distinguished player in the U.S. biotech landscape. The company's investment strategy is centered on pioneering Lipid Nanoparticle (LNP) and Messenger RNA Vaccine (MRA) technologies, complemented by specialized application software. Leveraging its proprietary LNP and MRA platforms, SunVax is actively engaging in licensing endeavors and collaborative ventures, while simultaneously advancing its software development initiatives. Looking ahead, SunVax is poised to concentrate its research and development efforts on Messenger RNA (MR) therapeutics, targeting a spectrum of applications from vaccines for infectious ailments and cancer to innovative treatments for autoimmune and rare diseases.

As a start-up company, Dr. Li says that SunVax stands at a crossroads, facing dilemmas that span financial, technical, and broader industry challenges. Financially, the company grapples with high labor costs, exacerbated by the United States' cost of living and inflation, making up more than half of its total expenses. Rent, driven by

the premium location of the company, and significant investments in 4G technology for essential communication and data transmission, further strain the budget.

Technically, the company's dedication to pioneering Messenger RNA (MRA) technology demands a significant investment of time and resources to overcome substantial challenges. The field, once met with skepticism, has only recently begun to attract the necessary attention and funding, thanks in part to the pandemic. However, the complexity of MRA technology means that the company must proceed with caution, focusing on resolving technical issues before it can fully exploit various applications.

Dr. Li analyzes that the existing industry dilemma is rooted in the historical skepticism towards MRA technology, characterized by a lack of specialized professionals and proven applications. The company's strategy of prioritizing technical resolution over rapid market expansion is a risk mitigation tactic that reflects a broader industry trend. However, this approach also means potential missed opportunities in a fast-evolving market. The 'lag effect' further complicates matters, with the potential for post-expansion downturns such as layoffs and restructuring looming over the horizon.

When asked why he chose Boston to start his career, Dr. Li attributes Massachusetts' allure for biotech development to Boston's unique ecosystem, which fosters a clustering effect that magnetizes biotech firms and investors alike. This concentration of companies generates a dynamic synergy, enhancing the area's appeal and drawing even more investment into the sector. The presence of premier academic institutions like Harvard, MIT, and Boston University contributes a steady stream of talent, including eager young scientists and graduates, who are pivotal for sustaining innovation and research within the industry.

The universities in Boston are not just talent incubators but also hubs of cutting-edge research and innovation, continually propelling technological advancements in biotech. This academic-industrial symbiosis, coupled with the region's dense biotech presence, allows investors to assess and engage with multiple ventures efficiently,

optimizing capital allocation. Moreover, the comprehensive biotech industry chain established in the Boston area spans the full spectrum from research and development to production, creating a conducive environment for biotech companies to find appropriate partners and collectively enhance the industry's growth.

In terms of government support, Dr. Li notes that government support for businesses primarily takes the shape of grants, which are a prevalent source of funding for startups in the United States. However, the grant application process presents certain challenges. Given the Chinese background of the company's founders and the current U.S.-China tensions, there could be additional scrutiny and potential risks, particularly in collaborations involving Asian nations, most notably China. Consequently, while government grants offer a financial lifeline to companies, they come with inherent constraints and potential risks that must be carefully navigated.

Continuously, Dr. Li emphasizes the government's pivotal role in the biotech sector, highlighting the necessity for a supportive framework that nurtures start-ups and young professionals. He suggests that local governments can accelerate the growth of start-ups by simplifying regulatory hurdles, offering financial support, and providing resources that are critical in the nascent stages of a company. This foundational support is crucial for fostering innovation and enabling these young enterprises to thrive.

Furthermore, Dr. Li points out the importance of cultivating new talent within the industry. He advocates for government programs that offer training, employment opportunities, and career guidance to recent graduates, ensuring a steady influx of skilled professionals into the biotech field. Additionally, he advises a liberal approach to biotechnology safety policies to encourage research and development while avoiding innovation-stifling overregulation. Indirect support mechanisms, such as R&D tax incentives, are also recommended as effective strategies to promote sustained growth and innovation in the biotech industry.

By the end of the interview, Dr. Lee envisioned three pivotal trends shaping the future of the biotech industry:

Magnetic Resonance Technology as a Biomedical Vanguard: The founders regard magnetic resonance imaging (MRI) technology as a cornerstone for the future of biomedicine. Initially, despite the influx of investments circa 2010, the scarcity of experts in the field cast a shadow of doubt over the practicality and challenges of MRI technology. However, with enhanced funding, MRI has achieved notable advancements, particularly in cancer therapy, and is increasingly seen as a beacon for personalized medicine.

Navigating Technical Hurdles with Prudence: The primary technical obstacles in magnetic resonance technology revolve around enhancing delivery efficiency, achieving targeted intracellular delivery, and refining genetic programming. To mitigate risks, the founders have strategically chosen to tackle these technical hurdles before branching out into other applications. This cautious approach is a standard in the industry, equipping the company to anticipate and surmount potential future challenges more effectively.

Broadening the Horizon of Magnetic Resonance Applications: The scope of magnetic resonance technology extends far beyond cancer therapy. It harbors immense potential for preventing genetic diseases prevalent within families. By directing human cells to produce specific proteins, magnetic resonance technology could revolutionize the treatment and prevention of various diseases. The breadth of potential applications is vast and transcends the current focus on cancer.

The Road Ahead for Technical Challenges and Research: The intricate nature of intracellular regulatory mechanisms presents a complex challenge, yet scientists are diligently exploring these frontiers. Breakthroughs are anticipated in the ensuing years or decades, which are expected to catalyze the widespread adoption and commercial success of magnetic resonance technology, marking a new era in biotech innovation.

Case 3: Regulators Interview

*In-person Interview with Dr. Marks and Mrs. Liang
October 28th, DC, SAPA Event*

According to Peter Marks, the Director of CBER (Center for Biologics Evaluation and Research) FDA (Food and Drug Administration), companies do not like the uncertainty about the path forward. If they know what the path looks like, they generally attain the requirements of the pathway. Another challenge in the complex biologic products industry is advancing manufacturing technologies with higher efficiency and lower cost. This is because the industry deals with gene therapies and related difficult topics. Besides, scaling up vaccine productions rapidly with better manufacturing is a third challenge. Therefore, the regulators should create an environment with certainty for development pathways, and make sure they do not put extra and unnecessary barriers in the way of developers.

Xueying Liang serves as the Acting General Manager, as well as the Vice President of Regulatory Affairs (US and Europe) and Quality Assurance for Burning Rock. She argues that the largest challenge for now is the financial difficulty for every company during this economic recession period. It is difficult for companies to be self-sustainable and profitable. She thinks capital, technology and regulations are the three kinds of foundations for the industry. When investments are in high supply, regulators need to provide more support for products that bring good to the public health and to help related companies grow.

Part 4: Policy Suggestions

After conducting an extensive review of comparative studies and case analyses, the team working on the white paper project has formulated the following set of four policy suggestions for the Maryland State government. These recommendations are designed to assist Maryland in fully leveraging its advantages within the biotechnology sector and to serve as a robust driver for the state's economic expansion.

1. Increase publicity of existing Biotech programs and strengthen the communication between the state government and stakeholders.

In our case study, it is evident that information related to some of the Maryland government's existing programs geared toward promoting the biotech industry is not well understood by Maryland's entrepreneurs. This also confirms the need for the

government to increase its efforts to publicize existing programs and policies. We recommend that the state government establish **a specific institution to be** responsible for promoting all the programs that have the intentions to encourage the development of the Biotech industry. The institution can organize regular Biotech Entrepreneurs Conferences to promote and explain the existing policies.

Good publicity not only benefits more biotech companies, but also demonstrates to the nation that the Maryland government is committed to supporting the biotech industry.

2. Work with the Federal government to reduce restrictions of NIH scientists to be entrepreneurs in Maryland.

Biotechnology industry as a high technology barrier industry, scientific and technological exchanges and innovations are the key to maintaining high speed development. We recommend the State government to work with federal government to lift the restrictions on NIH practitioners to join startups, learn from the practices of other colleges and universities, and encourage NIH practitioners to start businesses. “According to the NIH Ethics program, any outside activities involve the employee’s general scientific or professional expertise and require agency approval. (nih.gov) And every NIH employee needs to be aware of “conflict of interest” when they engage in outside activities. We found these regulations relatively vague. They not only hindered the development of scientific and technological communication, but also added difficulties to the commercialization of inventions. In the comparative study mentioned above, we can see that in California, Boston and other areas where the biotechnology industry is well developed, such as MIT, CalTech and other institutions of higher learning have relatively well-developed technology commercialization policies. MIT has more than a hundred spin off companies out of the Media Lab. Some of them have been listed as innovative companies in the healthcare industry (media.mit.edu).

3. Further launch competitive Tax Deductions or Deferrals programs for Biotech Startups, Investors, Practitioners

While the State of Maryland has launched a series of tax incentive programs to encourage investment, entrepreneurship, and R&D, we believe that a sustained, systematic, and comprehensive program of incentives is needed if the biotech industry is to grow significantly. Compared to the Boston area and the Bay Area of California, Maryland lacks a complete biotech industry chain at this stage and has not formed a large-scale biotech park. From two in-depth interviews conducted with entrepreneurs, we can see that Maryland is not very attractive for investors. To address that problem, it is necessary for decision makers to establish an invest-friendly environment to attract investors across the country. For investors, it is not only the size of the return that is sought, but also the rate of return on investment that is of concern. Therefore, the investors would favor the area with a large biotech park like Boston. It not only creates a siphoning effect, but also allows investors to prioritize these areas higher.

It could be hard for the state government to establish a big scale biotech industrial park in the short term. However, the Maryland government can attract investors using more competitive tax incentive policies.

From the case studies we did with Maryland Biotech Entrepreneurs, controlling the burn rate at an early stage is crucial to Biotech Startup survival. Therefore, the startups can really use help from the state government to relieve the tax burdens when the technology has not entered the commercialization stage. Especially for companies hidden beneath the venture capitalists' radar, tax deferral or certain reduction help the startup survive.

4. Provide special retraining programs to biotech entrepreneurs to develop and create a solid biotech workforce (Targeting Talent).

After analyzing our interview record with Biotech entrepreneurs, we found hiring talents while keeping the burning rate low is one of the biggest challenges facing them. Biotech is a high technology threshold but labor-intensive industries. Some entry-level positions require some specialized knowledge but are more

repetitive and the pay is not very competitive. As a result, many talented young people are hesitant to step into the biotech industry. The loss of high-quality talent could harm the industry in the long term. Therefore, we suggest the government provide specialized vocational programs aiming to train young professionals with required skills to take the Biotech Entry level positions. The government can work with some youth centers and community colleges to build a bridge between businesses and young talent. This will not only help small and medium-sized start-ups to help reduce costs, but on the other hand, it will also bring more start-ups into the public eye.

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