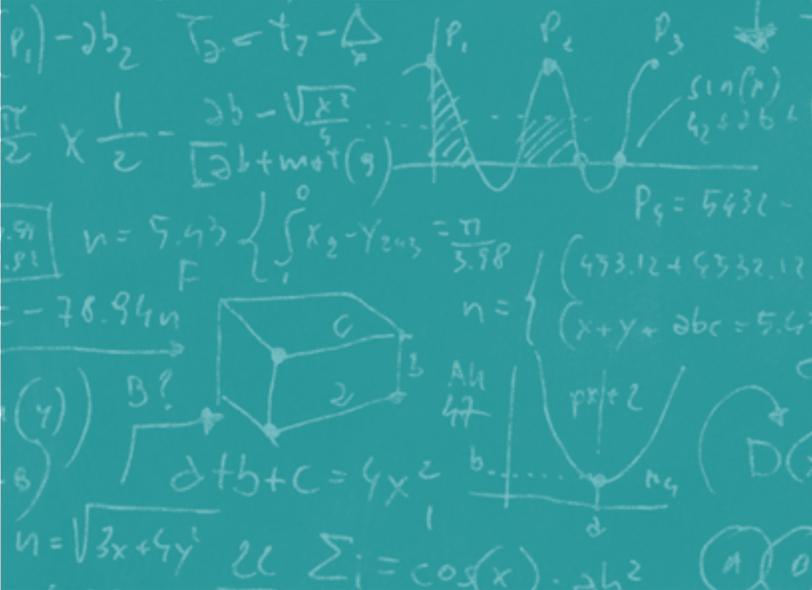




Enhancing Today's STEM Workforce to Ensure Tomorrow's New Medicines:

Biopharmaceutical Industry
Partnerships with U.S. Colleges
and Universities



June 2017

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Table of Contents

4	Executive Summary
5	Key Findings
7	I. Introduction
8	Study Approach and Methodology
10	II. The Economic Importance of the U.S. STEM Workforce and Risks to Global Competitiveness
11	Shortfalls in U.S. STEM Talent
12	U.S. Students Trailing International Counterparts in STEM Achievement
14	Implications for the Biopharmaceutical Industry
16	III. Evolving Skill Needs and Talent Dynamics in the Biopharmaceutical Industry
17	Biopharmaceutical Industry Trends with Workforce Implications
19	IV. Partnerships among Biopharmaceutical Companies and Educators to Grow the Talent Pipeline
19	The Biopharmaceutical Industry Gets Involved
34	Conclusion: Connecting STEM Education with Careers to Maintain U.S. Leadership in Innovation
35	Endnotes

Executive Summary

Virtually all elements of the innovative biopharmaceutical enterprise from discovery and development to manufacturing and delivery of new medicines require well-educated, highly skilled and talented individuals, particularly in the fields of science, technology, engineering, and mathematics (STEM). In fact, one of the most important elements of success for the innovative biopharmaceutical sector is the talented people who dedicate their lives to the discovery, development, and manufacturing of new treatments and cures to meet the needs of America's patients.

Biopharmaceutical and other industry executives in the United States are increasingly speaking out about the challenges associated with finding and retaining STEM-related talent, and how this challenge is placing a strain on their ability to compete not just with other competitors in the United States but with other countries, many of which continue to make substantial investments in STEM education while the United States struggles to bridge the gap. The strain is felt by U.S. manufacturers broadly as they work to fill open positions and see first-hand a significant "skills gap" (see text box).

Across the U.S. economy, STEM-related occupations play an increasingly important role in driving innovation and ultimately economic growth. The origins of the challenges experienced by employers can be traced to the early stage of the nation's talent development pipeline where U.S. students at all levels are demonstrating a lack of basic proficiency in STEM-related subjects and lagging behind their international counterparts in achievement. Ultimately, U.S. students are less likely than those in competitor nations to pursue STEM-related studies in college, which directly corresponds with chosen career paths.

The implications for the U.S. biopharmaceutical and other innovation- and STEM-intensive sectors are stark as they face the greatest risks and competitive challenges when there are shortages of qualified workers with STEM-related skills and expertise in the U.S. labor pool. Biopharmaceutical manufacturing, for example, employs more than four times the share of STEM workers relative to the overall economy in jobs that span the drug development process.

Facing these challenges, the industry, not standing idly by, is engaged on many fronts to ensure a high-quality workforce and to maintain the U.S. role as the global leader in innovative biopharmaceutical research and development into the future. This report builds on the findings of a 2014 STEM education study commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA) that was the first-ever systematic survey of leading biopharmaceutical company efforts to support STEM at all educational levels within the United States. That report found innovative biopharmaceutical companies are engaging on all educational levels across the United States to improve student achievement and foster interest in pursuing STEM-related classes in elementary and high school as well as in college and ultimately as a career. Biopharmaceutical companies require a very broad range of

Growing Skills Gap in U.S. Manufacturing

In their third assessment of the skills gap in U.S. manufacturing, the Manufacturing Institute and Deloitte find the skills gap is widening.* Between 2015 and 2025, U.S. manufacturers will need to hire about 3.4 million workers. The assessment found that an estimated 60 percent of those positions, or 2 million jobs, will likely go unfilled due in large part to a growing U.S. gap in STEM-related skills in the workforce. (Eighty-four percent of executives surveyed in the study agree there is a talent shortage)

* The Manufacturing Institute and Deloitte, "The Skills Gap in U.S. Manufacturing 2015 and Beyond," 2015.

STEM talent from high school graduates with specialized training to work on highly complex manufacturing lines, to college graduates who are statisticians and computer scientists to assess ever-growing amounts of data collected through clinical trials, to physicians and a range of workers with doctoral degrees involved in developing tomorrow's new treatments and cures to meet patient needs. Recognizing that the pipeline for STEM talent is dependent on the training and expertise of educators, companies are increasingly supporting and developing creative ways to work with educators to enhance their knowledge and skills, including partnering with schools to provide access to life sciences lab equipment and lab techniques and to provide a range of other hands-on, experiential opportunities for educators as well as students.¹

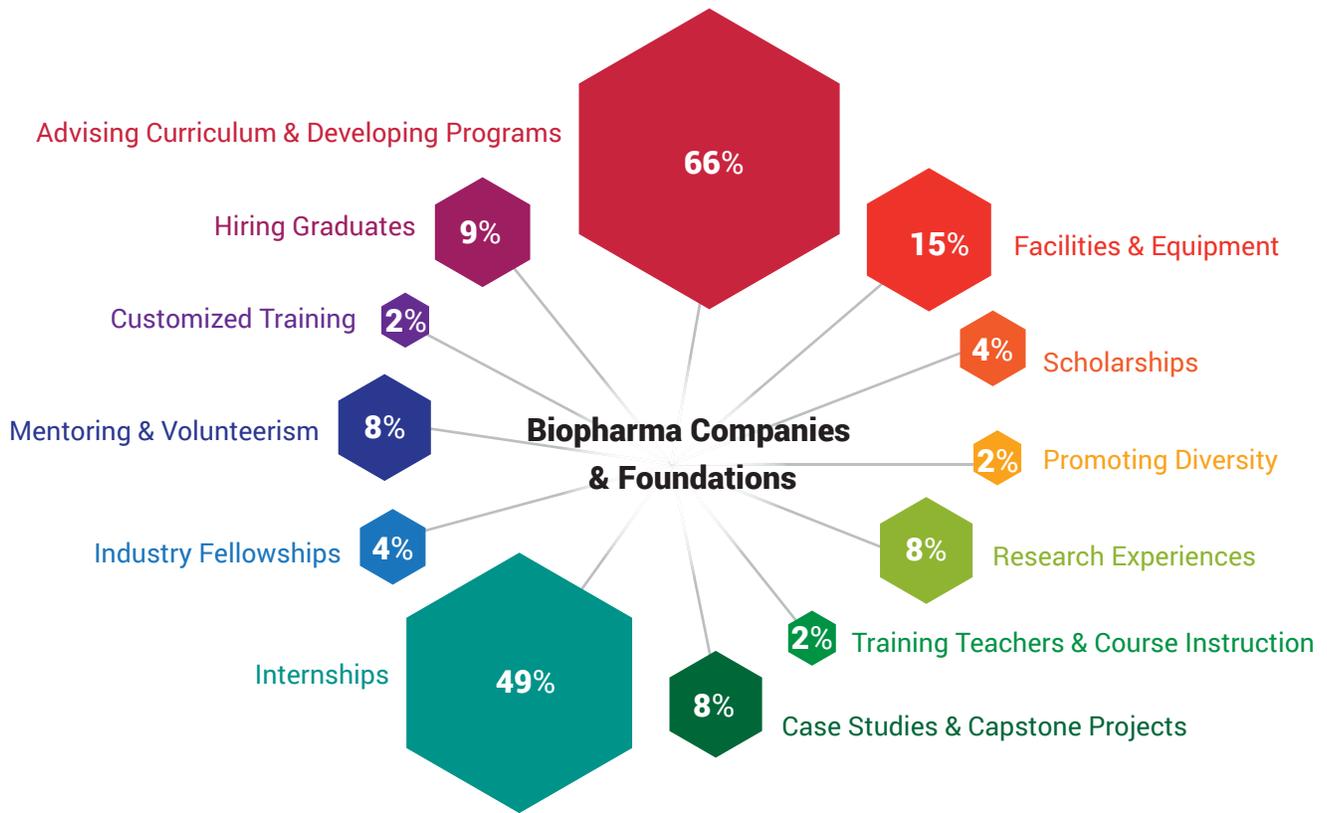
The focus of this study, supported by PhRMA, is to provide additional insight into biopharmaceutical company efforts beyond the K–12 levels to support education and training collaborations between the private sector and public and private U.S. colleges and universities. This study finds biopharmaceutical companies are leveraging educational partnerships across dozens of U.S. institutions to prepare students for specific careers within the industry and utilizing a range of partnerships to develop specific workforce skills, to boost diversity and inclusion, to demonstrate robust and exciting career opportunities, and to more broadly continue the innovative work of this industry.

Key Findings

Key findings from this assessment of industry-collegiate education and training partnerships include the following:

- Support and engagement by companies is happening at all levels of the postsecondary pipeline from various certification and associate's programs through master's and doctoral programs and worker training programs.
- Across various educational institutions there were 75 educational programs with direct ties to biopharmaceutical companies.
- The biopharmaceutical industry's STEM education support often takes a multifaceted approach that encompasses program and curriculum design, scholarships, experiential learning, capstone projects, fellowships, equipment and facilities donation, and more (**FIGURE ES-1**). The most common partnerships of biopharmaceutical companies with universities involve the following:
 - **Participating on an Industry Advisory Board** for the program (66 percent of documented programs) to inform educational programs and curricula to provide perspective on industry's STEM needs;
 - **Providing Industry Internships for students** (49 percent of documented programs);
 - **Donating or developing facilities and/or equipment** to an educational program (15 percent) and hiring program graduates (9 percent).²
- Biopharmaceutical companies and their corporate foundations are increasingly partnering to address both current and future workforce and talent needs of the industry. While some companies may be more focused on current high-demand job areas, some of their corporate foundations are more focused on longer-term challenges and opportunities such as fostering diversity.

FIGURE ES-1: Biopharmaceutical Industry Connections and Interactions with U.S. Colleges and Universities (Shares Represent Documented Incidence of Activities across Individual Institutions)



Specific programs demonstrating the variety and depth of direct biopharmaceutical industry engagement have been identified and highlighted in the report in brief vignettes, including the following:

- The Merck Company Foundation's initiatives to support diversity through its Ciencia (Science) Hispanic Scholars Program and The Science Initiative with the United Negro College Fund
- The Rutgers Institute for Pharmaceutical Industry Fellowships partnering with 17 companies in preparing clinical pharmacists for careers in the biopharmaceutical industry
- Major initiatives of the Amgen Foundation in inspiring the next generation of biopharmaceutical researchers and advancing the biomanufacturing workforce
- Keck Graduate Institute's applied graduate programs working directly with biopharmaceutical companies to solve real-world challenges
- MiraCosta College's training of the bioprocessing workforce of the future with industry partners in several capacities
- The Biomanufacturing Education and Training Center at Worcester Polytechnic Institute, which works in close partnership with industry to customize job training in a world-class facility.

This report also includes examples of a range of other identified partnerships at various postsecondary educational levels and program design.

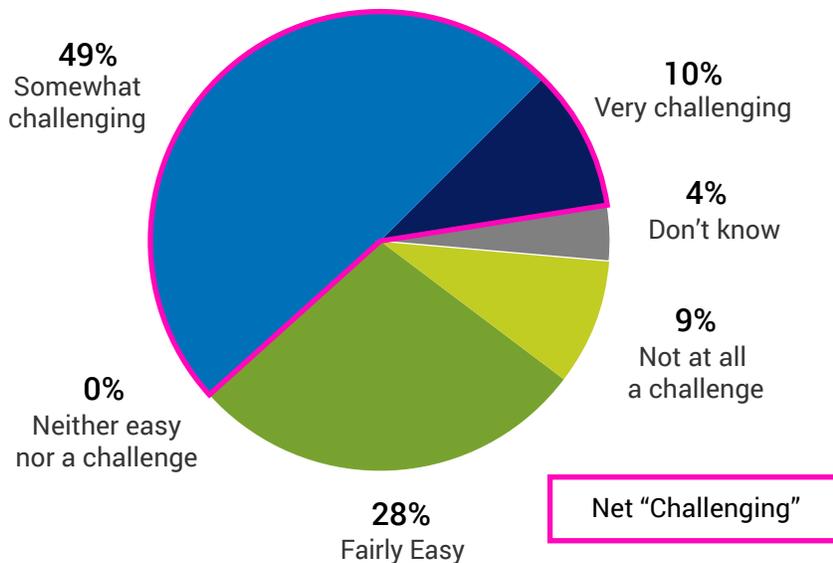
The United States has worked to establish its leadership in terms of its innovation and R&D ecosystem, and to maintain this position requires the types of partnerships with the nation's colleges and universities illustrated in this study.

I. Introduction

The United States is home to a robust research and development (R&D) ecosystem that is the envy of the world. The United States leads the world in global biopharmaceutical R&D in large part due to the vibrant research-based biopharmaceutical companies that employ the best and brightest. One of the most important elements of success for the innovative biopharmaceutical sector is arguably the talented people who dedicate their lives to the discovery and development of new treatments and cures to meet the needs of America’s patients. Innovative biopharmaceutical companies operate not only leading-edge R&D operations but also execute highly advanced manufacturing and complex distribution systems. Virtually all elements of the biopharmaceutical R&D enterprise from discovery and development to delivery require well-educated, highly skilled and talented individuals, particularly in the fields of science, technology, engineering, and mathematics (STEM). In fact, the ability to source, hire, and retain talent drives key innovation and is core to companies’ ability to compete in the United States and globally and influences companies’ determinations regarding where to locate facilities, conduct trials, and make key R&D and capital investments now and in the future.

Biopharmaceutical executives have consistently reinforced the importance of finding talented STEM workers to the sustainability and growth of the innovative biopharmaceutical industry and its ability to bring new treatments to patients and to continue to grow local and state economies across the United States. PwC’s Global Innovation Survey finds talent tops the list of innovation challenges for pharmaceutical executives, ahead of other critical areas such as speed to market of innovative ideas, establishing an innovative culture, and finding the right partners for collaboration.³ Nearly three in five biopharmaceutical executives say “finding and retaining the best talent to make innovation happen” is a challenge for their company, higher than the average for respondents across all industries (53 percent) (FIGURE 1).

FIGURE 1: Innovation Challenges for Pharmaceutical Executives. More than half cite finding and retaining the best talent to make innovation happen as a key challenge.



Source: PwC Global Innovation Survey, 2013; Pharmaceutical specific responses.

Note: Does not include “Don’t know” responses so will not sum to 100 percent.

The Pharmaceutical Research and Manufacturers of America (PhRMA) previously supported a survey of its members, the nation's innovative biopharmaceutical companies, by Battelle's Technology Partnership Practice. The survey focused on capturing information on the many ways in which its members are "partnering with schools, investing in STEM education, and bringing their expertise and resources to bear to improve STEM education in the U.S." ⁴

The 2014 Battelle-PhRMA STEM education study found the biopharmaceutical industry is very active in its support for STEM-related educational programs and initiatives, particularly at the K-12 levels working to excite and inspire the next generation of scientific and technical talent. Many of these programs and initiatives are driven by the philanthropic efforts of individual companies and their corporate foundations and are designed to develop, within the communities they operate, the robust and diverse workforce and talent needed to support their drug lifecycle from discovery and development to delivery to patients.

For this study PhRMA commissioned TEconomy Partners to provide additional insight into biopharmaceutical company efforts beyond the K-12 levels to focus on collaborations with U.S. colleges and universities at all postsecondary educational levels to develop the next generation of workers and to provide staff development programs.

This study provides information on a range of documented partnerships between industry and colleges and universities to develop specific workforce skills, to boost diversity and inclusion, to demonstrate robust and exciting career opportunities, and to more broadly continue the innovative work of this industry.

Study Approach and Methodology

The TEconomy project team identified and reviewed documented partnerships between biopharmaceutical and biotechnology companies and U.S. colleges and universities. The team used a variety of sources to first narrow the universe of postsecondary life science-related educational programs to identify those programs most likely to have direct linkages and interactions with industry. By design, many programs across the postsecondary spectrum build in interactions with industry to ensure that students and graduates are instructed in industry-relevant curriculum, provided with experiential learning opportunities, and skills appropriate for today's STEM-related jobs in the biopharmaceutical or other technology and R&D-driven industries. Graduate programs like the relatively new and growing Professional Science Master (*PSM*, see page 23 for a description) build in interdisciplinary program design, industry internships, case studies and capstones with industry participation, and more. Many of the applied manufacturing and lab-related programs related to direct biopharmaceutical industry needs, for example, occur at the community college level. And postdoctoral researchers are participating in a range of highly specialized industry fellowships. A primary emphasis and focus was placed on reviewing these types of programs as they represented the most likely areas of industry-institutional interaction.

These program partnerships can be identified from the vantage of either the educational institution and its associated program websites, literature, brochures, scholarly articles, or participation in industry-related events. Similarly, the biopharmaceutical companies and foundations may document these initiatives and strategic workforce development partnerships via their own websites, news releases, scholarly or media articles, and other ways.

The project team worked to identify documented program interactions via the educational institutions themselves through the following:

- Identification of applied biopharmaceutical and biotech-related programs via the National Center for Education Statistics' Integrated Postsecondary Education Data System (IPEDS) database, with a prioritization of programs that had at least 10 graduates in the most recent year ⁵
- The database of PSM programs via the PSM National Office
- Utilization of National Science Foundation-Advanced Technological Education (NSF-ATE) program grant information.

From the vantage of the biopharmaceutical industry, partnerships were identified by using the following:

- The 2013 PhRMA-Battelle STEM Education Survey of PhRMA Members and selected outreach to companies and their corporate foundations
- The Foundation Center Database of corporate foundation grant-making activities
- Review of selected biopharmaceutical company and foundation websites.

Once potential programs were identified where the engagement of industry is likely, individual programs were reviewed. The TEconomy team reviewed approximately 200 individual educational programs at various levels across the country, with these programs spanning just over 100 institutions. Where at least one biopharmaceutical or biotechnology company was documented, the project team sought to characterize the interaction which, as the study will show, took many forms from program advisory board participation to sponsoring internships and advancing research experiences.

This report begins by setting the context for why companies are proactively engaging in U.S. STEM education and ultimately partnering with colleges and universities to develop the biopharmaceutical and broader STEM workforce. Section II examines the situation around STEM education and skill sets both from a student achievement and teacher quality perspective within the primary and secondary U.S. educational system and within a broader context of concerns around the quality of the STEM education pipeline and corresponding skills gaps in the labor market for U.S. manufacturers and other large employers. Section III discusses evolving skill needs and talent dynamics for the biopharmaceutical industry. Section IV then profiles the partnerships between the biopharmaceutical industry and U.S. colleges and universities to meet the talent needs of today and tomorrow.

II. The Economic Importance of the U.S. STEM Workforce and Risks to Global Competitiveness

The U.S. STEM workforce is helping to drive economic growth through its development and deployment of innovative new products and processes. These innovations maintain U.S. competitiveness in R&D-intensive industries including biopharmaceuticals, information technology, and aerospace, to name a few. Beyond innovation, STEM-related occupations are responsible for an outsized contribution to the nation's economy, including the following as examples:

- **High-quality, high-wage jobs growing rapidly.** Average wages for STEM occupations are 81 percent greater than overall averages—\$87,524 in 2015 compared with \$48,320. STEM-related occupational employment has increased by more than 18 percent since 2004, more than twice the growth rate for all occupations (7.6 percent).⁶
- **Greater employment impacts across the rest of the economy.** One STEM job often supports several additional jobs through multiplier effects. Industries utilizing a greater degree of STEM-related talent tend to have much greater employment multipliers and thus broader impacts.⁷

What are STEM-related Jobs?

Broadly speaking, STEM occupations typically include math and computer science jobs, architecture and engineering occupations, and life and physical scientists; and they span middle- and high-skilled occupations.

Considering the work of others, and utilizing its own experiences in workforce-related studies across the United States, TEconomy Partners has developed a definition of the STEM workforce presented in TABLE 1. In 2015, the STEM workforce was estimated at nearly 7.8 million jobs, representing almost 6 percent of national jobs (TABLE 1, 2).

TABLE 1: U.S. Employment in STEM Occupations, 2015

Occupational Groups	2015 Employment
All Occupations	137,896,660
Computer-Related	3,971,750
Engineers & Engineering Technicians	2,299,880
Life & Physical Sciences	932,330
Architects, Drafters, & Surveyors	427,470
Math-Related	151,370
Total STEM-Related Employment	7,782,800

Source: TEconomy Partners' analysis of U.S. Bureau of Labor Statistics, Occupational Employment Statistics data, 2015.

Shortfalls in U.S. STEM Talent

Looking across the U.S. talent pipeline for both today's and tomorrow's STEM educated and skilled workforce, one sees troubling signs. Achievement among U.S. students is middling in science and math relative to their international peers and falls further behind as students reach high school. At the postsecondary level, there is less interest among U.S. students in pursuing degrees in science and engineering relative to other large and leading global economies. At the same time, the current and projected demand for workers with STEM education and skill sets is outpacing non-STEM areas, and studies indicate STEM-related job openings are going unfilled. As one would expect, this dynamic is placing a strain on the ability of U.S. companies and science and technology-driven industries to meet customer demand, to drive innovation, and more broadly, to compete effectively today and into the near future.

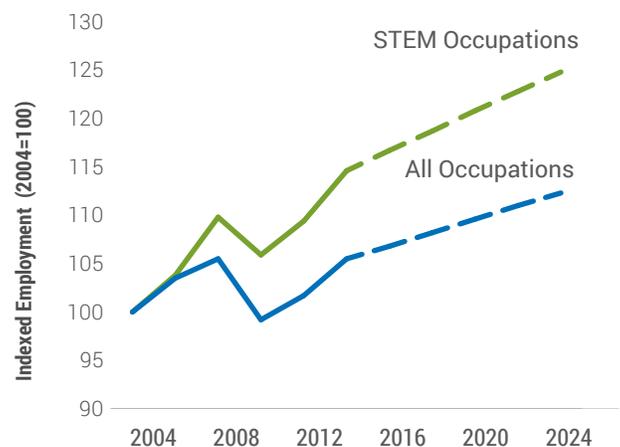
The strain is felt by U.S. manufacturers trying to fill open positions and seeing first-hand a significant "skills gap." In their third assessment of the skills gap in U.S. manufacturing, the Manufacturing Institute and Deloitte find the skills gap is widening.⁸ For 2015 to 2025, the authors estimate that U.S. manufacturers will need to hire 3.4 million workers and that an estimated 60 percent of those positions, or 2 million jobs, will likely go unfilled due to shortages in talent. Among other factors expected to contribute to this gap is a lack of STEM-related skills in the workforce. Executives agree, with a large majority (84 percent) in the Deloitte–Manufacturing Institute study agreeing there is a talent shortage.

The demand for workers with STEM-related education, skills, and experience goes beyond manufacturing to include a wide swath of the economy, with technical skill sets in demand by numerous industries. For nearly two decades, Bayer has been conducting its *Facts of Science Education* surveys. Its 2013 survey focused on talent recruiters at 150 larger, Fortune 1000 companies and their experience and thoughts on current and future demand for STEM hires with two- and four-year degrees.⁹ The survey confirmed findings by others that the demand for STEM skill sets spans both high-R&D or "STEM" companies/sectors as well as increasingly in sectors that are traditionally considered to be "Non-STEM." Key findings speak to both current and future demand and include the following:

- Six in ten (59 percent) talent recruiters say four-year STEM degree graduates are "more in demand" than their non-STEM counterparts *today*; for two-year degree graduates the tilt toward STEM fields is 44 percent;
- Seven in ten (69 percent) say four-year STEM degree holders will be "more in demand" than their non-STEM counterparts *10 years from now*; for two-year degree graduates in STEM fields the share is nearly half (47 percent);
- Two in three (67 percent) recruiters reported their companies are creating more STEM jobs than non-STEM jobs today;
- Just half of recruiters report being able to find adequate numbers of candidates with STEM degrees at both the two-year (55 percent) and four-year (50 percent) levels in a "timely manner." Of these recruiters 90 percent plus believe it is due to a shortage of qualified candidates.

Federal occupational projections echo these studies, showing strong demand for STEM workers—they continue to show STEM-related jobs outpacing the demand for workers overall (FIGURE 2).

FIGURE 2: Occupational Employment Trends and Projections for STEM and All Occupations

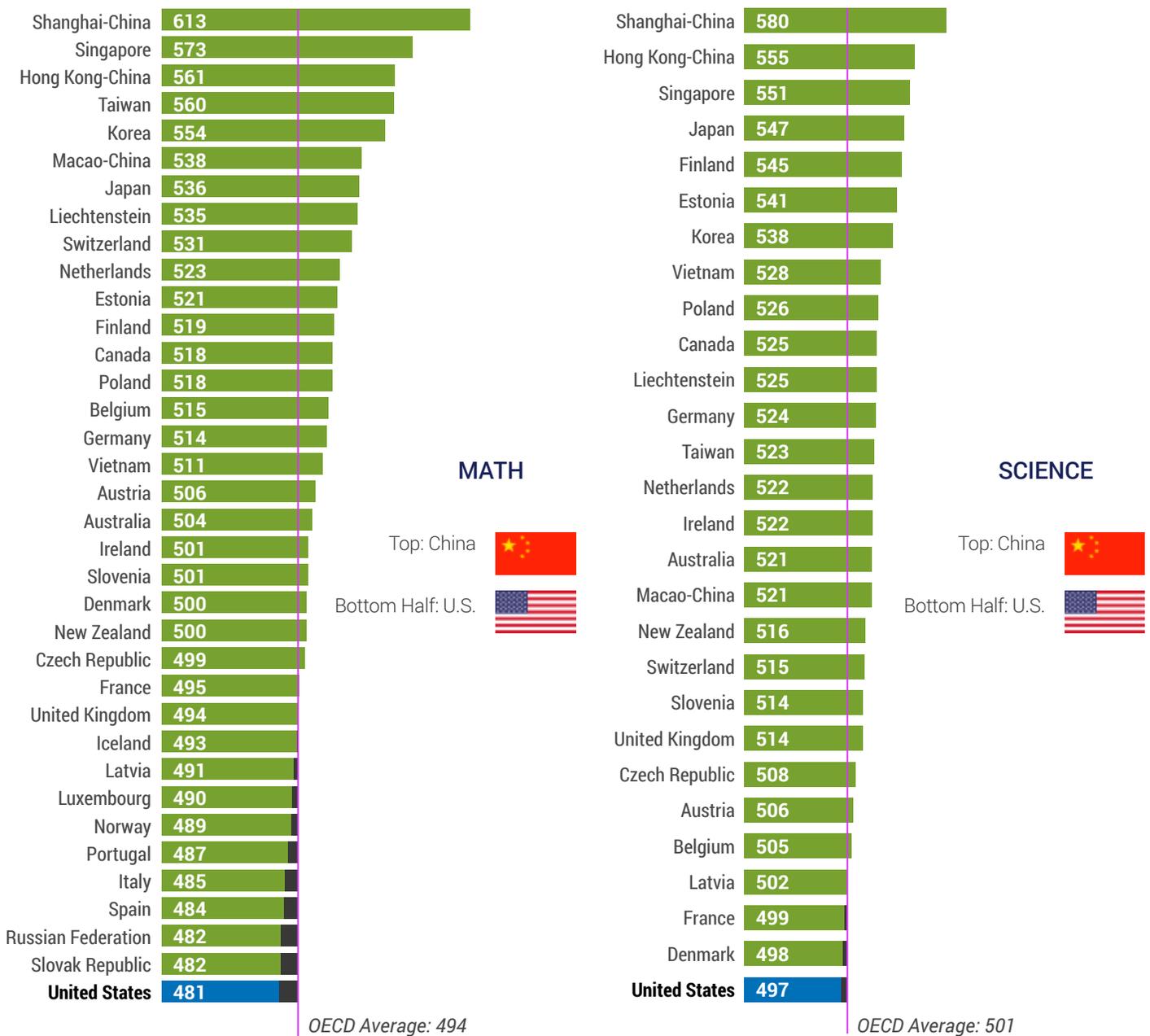


Source: TEconomy Partners' analysis of U.S. Bureau of Labor Statistics, Occupational Employment Statistics and projections, 2014–24.

U.S. Students Trailing International Counterparts in STEM Achievement

U.S. students are lagging behind their peers internationally in science and math at the elementary, middle, and secondary levels, with their rankings moving progressively lower as they move into high school. According to the National Center for Education Statistics, student scores on international tests show U.S. students in the lower end of the top 10 or 11 among fourth and eighth graders out of nearly 60 other countries, though behind Russia and much of Asia. U.S. fourth and eighth graders performed above-average across all countries, while U.S. high school students scored at or below average compared with other industrialized countries.¹⁰

FIGURE 3: Shanghai Ranks at the Top in Math and Science Achievement among Ninth Graders while the United States Ranks among the Bottom Half of OECD Countries, 2012



Source: Organization for Economic Co-operation and Development (OECD), Programme for International Student Assessment (PISA).

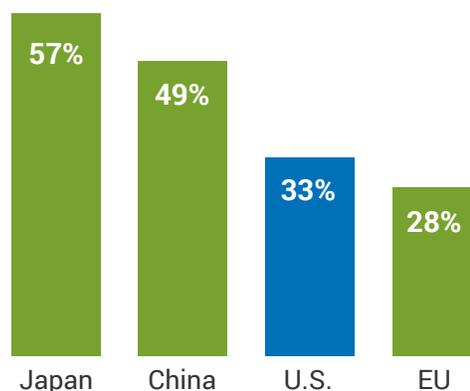
Note: Data presented for countries with scores at or above the United States. Examples of some additional countries below the United States include Sweden, Israel, Turkey, and Brazil.

U.S. high schoolers lag well behind most Organisation for Economic Co-operation and Development (OECD) countries in math and science (FIGURE 3). Their average scores are below the OECD average in math literacy, with U.S. ninth graders ranking 27th out of 34 OECD nations and 36th out of 65 when OECD partner countries and regions are included. In science literacy, the average U.S. score was about average among OECD countries, ranking 20th among the 34 OECD nations and 28th among all 65 countries and regions.

U.S. students are less likely to pursue a degree in a science or engineering field compared with other countries, with just one-third earning a bachelor's degree in one of these fields. This rate is significantly lower than that for Japan and China (FIGURE 4).

The United States is the leading destination for international collegiate studies, and foreign students are disproportionately likely to study STEM or business compared with U.S. students. The Institute of International Education found that, for the 2014–15 academic year, U.S. colleges and universities enrolled nearly 975,000 international students, up 10 percent from the prior year, a growth rate not seen since the late 1970s.¹¹ This is a record number of foreign students and places the United States first among any other country in hosting foreign students. Foreign students are more likely to pursue degrees in a STEM or business field, with nearly two in three foreign students enrolled in these programs.

FIGURE 4: Share of First University Degrees in Science and Engineering Fields, 2012



Source: National Science Board, Science and Engineering Indicators 2016.

Note: Data for each country represent 2012 or the most recent data available. EU includes only locations for which relatively recent data are available.

Concerns Regarding the Quality of Teachers

High student achievement in STEM disciplines requires a high caliber of STEM teachers. While quality of teaching can be difficult to measure, it begins with establishing basic credentials in both education and in specialized areas of assignment. In reports by the U.S. Department of Education, many teachers assigned to STEM-related fields did not earn a degree in those fields in college; in other words, they do not have “in-field qualifications.” The 2011–12 Schools and Staffing Survey found that, among high school math teachers who exclusively teach that subject, 36 percent do not hold both a postsecondary degree and teaching certification in math; likewise, that share is 26 percent for science teachers and in biology/life sciences is 38 percent.¹²

Implications for the Biopharmaceutical Industry

STEM-intensive industries with the largest concentrations of R&D and innovation face the greatest risks and competitive challenges when there are shortages of qualified workers with STEM-related skills and expertise in the U.S. labor pool. Biopharmaceutical manufacturing employs more than four times the share of STEM workers relative to the overall economy in jobs that span the drug development process (TABLE 2 and FIGURE 5).

As established in the 2014 Battelle-PhRMA study, with the stakes so high, biopharmaceutical companies are engaging on all educational levels across the United States to improve student achievement and interest in pursuing a STEM-related college major and ultimately career, both systemically and in individual school districts. In addition, companies are supporting and developing creative ways to help educators and their ability to stay current in life sciences labs and other hands-on, experiential opportunities.¹³

At the college and university levels, biopharmaceutical companies are leveraging partnerships with educational institutions to prepare students for specific careers within the industry. The Manufacturing Institute–Deloitte study recommends that, among multiple strategies to affect the skills gap, companies should “design curriculums in collaborations with technical and community colleges” and corporate executives seem to agree, with “72 percent agreeing involvement with local schools and community colleges is effective.” The study recognizes that executives “see the need to develop the talent pipeline both in their companies and communities.” As this study will show, the biopharmaceutical industry is engaged on both fronts in developing and supporting the current and next generation of STEM-related talent both systematically across local communities as well as within their own companies or directly for their own more immediate workforce needs.

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The Manufacturing Institute–Deloitte study recommends that, among multiple strategies to affect the skills gap, companies should “design curriculums in collaborations with technical and community colleges” and corporate executives seem to agree, with “72 percent agreeing involvement with local schools and community colleges is effective.” The study recognizes that executives “see the need to develop the talent pipeline both in their companies and communities.”

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TABLE 2: Share of U.S. STEM-Related Jobs in All Industries and in Biopharmaceutical Manufacturing, 2015

Share of STEM Jobs, All U.S. Industries:	6%
Share of STEM Jobs, U.S. Biopharmaceutical Manufacturing:	27%

Source: TEconomy Partners’ analysis of U.S. Bureau of Labor Statistics, Occupational Employment Statistics data by industry.

FIGURE 5: **STEM-Related Jobs across the Drug Development Process**



III. Evolving Skill Needs and Talent Dynamics in the Biopharmaceutical Industry

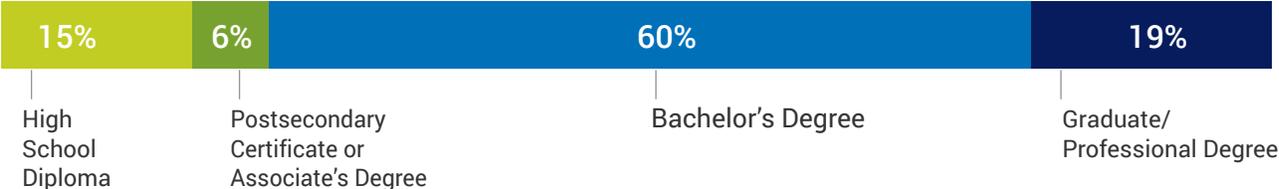
The biopharmaceutical industry has wide and varied needs for talented individuals across an innovation pipeline that spans R&D, highly advanced manufacturing, and on to distribution. This industry structure and life cycle requires a workforce that, for the most part, requires advanced degrees beyond a high school diploma, but contrary to the perceptions of many, the industry is not just the domain of those with a doctorate or medical degree. And while degree requirements vary, there is a common thread that winds throughout the biopharmaceutical workforce—its emphasis on STEM-related skills and knowledge. The industry relies on well-educated and trained workers who have strong competencies not only in the life sciences, but also in mathematics, computer science, engineering, business, and other technical disciplines.

Recent assessments have found the vast majority of national life science industry jobs require college credentials. In its 2014 workforce study, the Coalition of State Bioscience Institutes (CSBI) and Burning Glass Technologies examined the educational requirements of industry job postings and found that 60 percent of job postings require a bachelor’s degree, 19 percent required a graduate or professional degree, and 6 percent require some postsecondary or associate’s degree.¹⁴ While job postings were not exclusive to biopharmaceuticals, these findings are indicative of the educational needs of the life sciences subsector.

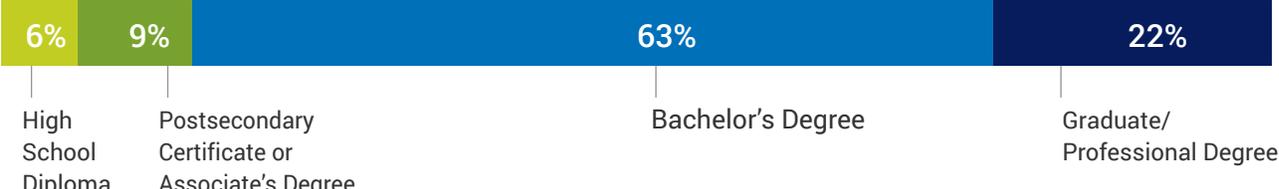
In California, a global leader in the biosciences and specifically in biopharmaceuticals, industry associations are conducting regular detailed assessments of talent needs, highlighting the importance of a steady, predictable pipeline of talented individuals to the state’s innovative sector. The latest study by the California Life Sciences Institute and the Biocom Institute surveyed 248 California life science companies in early 2016 (in which the largest individual sector share of actual and expected hires were in drugs and pharmaceuticals) to gauge educational requirements and confirm the earlier findings from CSBI, with the breakdown of degree requirements shown in **FIGURE 6**.¹⁵

FIGURE 6: Life Science Workforce Degree Requirements Based on Industry Job Postings (National, 2013) and Company Surveys (California, Q1:2016)

National, 2013



California, Q1:2016



Source: National data from CSBI and Burning Glass Technologies; California data from California Life Sciences Institute and Biocom Institute 2016 survey.

Biopharmaceutical Industry Trends with Workforce Implications

While the biopharmaceutical industry requires and continues to demand strong candidates from various degree programs along the educational continuum, the industry is intervening and demonstrating strong demand in biomanufacturing in particular. Executing the translation of life science discoveries into safe and effective medicines requires highly skilled scientists and engineers who work at this important intersection and can design and oversee the bioprocessing and scale-up manufacturing. In addition to science and engineering expertise, biomanufacturing jobs often require knowledge in process validation, quality control, and regulatory compliance.

Biopharmaceutical manufacturing is becoming increasingly complex as companies focus on biologics and more targeted therapies including gene and cell therapies. The manufacturing process is incredibly complex and requires specialized knowledge and expertise. Going forward, several factors will have implications for the industry's workforce demands, including advancements in bioreactors and other equipment, the growth of "single-use" products, and advancements toward more automated processing of biologics. Dr. Kamal Rashid, Director of the Biomanufacturing Education and Training Center at Worcester Polytechnic Institute (WPI) has noted, "The sheer amount of biopharmaceuticals in company pipelines and the amount of bio-related discoveries being made in R&D laboratories worldwide are testament to the fact that we are on the cusp of an exponential growth surge in biomanufacturing."¹⁶

From an education and training standpoint, these trends in biomanufacturing take on many flavors from developing associate's-level technicians to certificate programs that are utilized by not only two- and four-year degree holders, but also by those with master's degrees who need to complement, enhance, or update their applied knowledge and hands-on training. According to Dr. Rashid, "Students often graduate without landing jobs but for a short bit of further training... Particularly for workers looking for further training to make them more employable in biomanufacturing positions, just the right group of hands-on courses and training might be sufficient."¹⁷ At WPI, his team is training incumbent workers in customized programs focused on these needed hands-on skills including optimizing conditions in a bioreactor, protein chemistry, and purification (see WPI program case study page 33).

The genomics revolution and applications in molecular diagnostics and personalized medicine are driving vast amounts of data collection. In turn, biopharmaceutical companies need technical expertise around the analysis and management of large data sets. In a recent workforce and talent study by TEconomy for Indiana's health and life sciences industry, surveys, interviews, and focus groups identified the need for health and bioinformatics talent across the biomedical research and clinical trials enterprise.¹⁸ Individuals with advanced math and statistical skill sets, however, are in high-demand across many technology industries and so the competition for talent is intense. In the Indiana study, companies indicate they are conducting national hiring searches for these high-demand individuals.

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"The superior talent, competitive skill set and collaborative approach to problem-solving characteristic of our company's global employee population make them our greatest strength and most powerful resource for business growth. They are the fundamental link to our vision of solving the greatest healthcare challenges and helping the world 'be well.'"
.....

—Merck & Company,
Corporate Responsibility Report, 2014

Bioinformatics degree programs, particularly at the graduate levels, are increasing in the United States to meet this demand, but education and training at other degree levels are also placing greater emphasis on analytical capabilities.

Scientific and regulatory expertise remains critical for biopharmaceutical companies, though much of this is not learned in a formal academic setting or degree program but rather on the job. This goes hand in hand with a consistent need for quality assurance and control professionals. These jobs are critical across all major phases of biopharmaceutical product development including R&D, manufacturing, and in the consumer marketplace. While no formal degree structure exists to develop regulatory expertise, industry fellowship models are proving popular and effective with biopharmaceutical companies partnering with postdoctoral Doctor of Pharmacy holders at institutions like Rutgers University and the Massachusetts College of Pharmacy and Health Sciences (see case studies that follow on both of these fellowship programs).

The economic models and environment surrounding life science innovation is also shifting, again with implications for the workforce. PwC, in the introduction to its new “Beyond 2020” report, notes the following:

“The competitive landscape for pharmaceutical and life science companies around the world is changing rapidly. We are now in the “New Health Economy” in which drug pricing pressures, scientific breakthroughs, expanding global demand for healthcare access, and emerging digital and analytical capabilities are pushing the healthcare industry toward a new ecosystem defined by collaboration, quality, and consumer value. Change requires a new strategic approach—one that enables companies to understand market trends, and build the internal capabilities needed to execute.”¹⁹

Taken together, these industry, technology, and market trends are yielding changes in biopharmaceutical industry workforce and talent demands. While the industry has always required advanced degrees and technical know-how, the characteristics of the ideal job candidate and employee are shifting. Today, recent studies find U.S. biopharmaceutical companies are emphasizing a broader need for workers in the following capacities:^{20, 21}

- Top scientific and engineering talent and broad STEM education backgrounds but supplemented with multidisciplinary skill sets, for example, life sciences and business or engineering and computer sciences;
- A scientific orientation toward development and real-world applications rather than simply basic research;
- Strong communications and management skills, including the ability to work among and across teams.

In addition to these broader characteristics, market and broader industry trends are driving demand increases for different or shifting areas of expertise including the following:

- Understanding of the science and regulatory process to ensure compliance with relevant federal regulations
- Coverage and reimbursement knowledge as well as understanding of broader health economics and related research skills
- Bioinformatics and more generally expertise in managing “big data”²²
- Biomanufacturing and bioprocessing, which refer to manufacturing or biomanufacturing using biological systems to produce materials for use in medicines and techniques to produce biologic material, respectively.

IV. Partnerships among Biopharmaceutical Companies and Educators to Grow the Talent Pipeline

Effective partnerships between industry and academia matter. The industry relies on a lengthy education and training pipeline that begins in preschool and extends through postsecondary degrees and the early stages of a career. For innovative industries to thrive, talent must be generated that is closely aligned with the education and skill needs of industry. While elementary and secondary education is a critical time for students to gain a foundation and interest in core academic subjects including STEM-related fields, postsecondary education is critical for learning skills most relevant to a career.

The evolution of skill needs in the biopharmaceutical industry are driving changes in the approach to teaching and learning in the classroom, laboratories, and well beyond. Today's postsecondary education and training programs (and even at K–12 levels) are increasingly emphasizing the following:

- Broad-based experiential learning including, but not limited to, internships, lab experiences, cooperative fellowships
- Learning by doing
- Inquiry-based learning
- Industry-relevant curricula
- Hands-on training in labs and with new technologies and techniques.

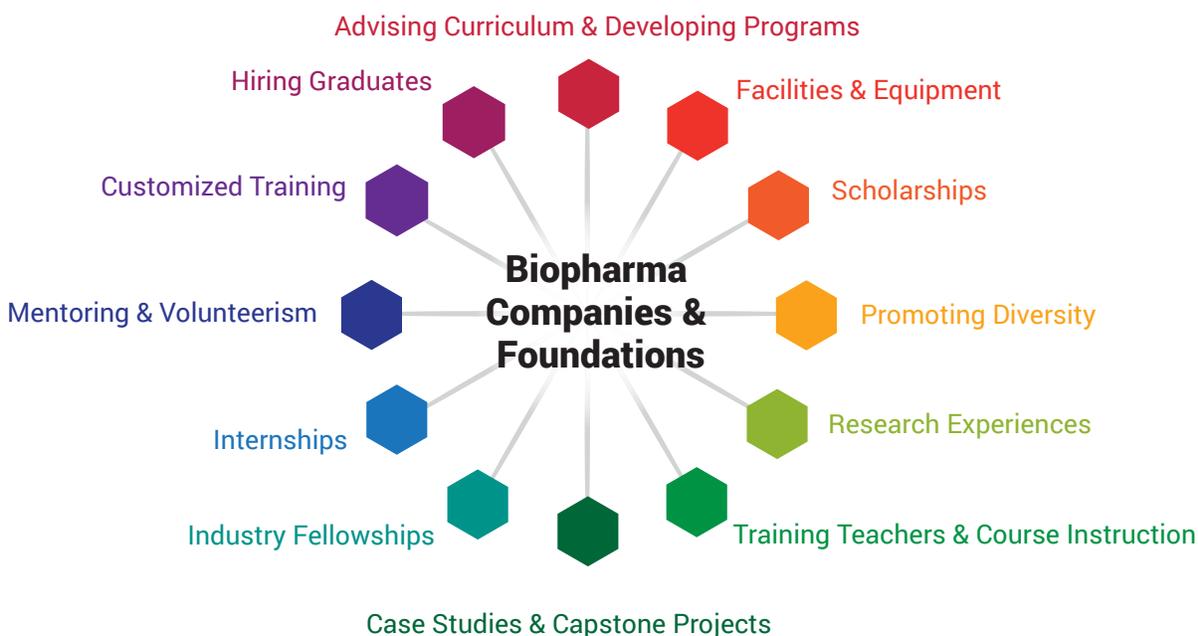
Ultimately, the ideal educational model to meet industry STEM needs is now a more seamless meld of the classroom, the lab, experiential learning, and actual work in the industry, such as that seen in the applied programs illustrated in this section. Designing and executing this education and training model requires partnerships between academia and industry. Establishing these types of hands-on, industry-relevant programs is complex and requires a concerted effort on behalf of both companies and universities to come together. The education and training programs described here are examples of effective partnerships that are emerging and working well. These partnerships are helping shape the next-generation workforce needed to discover and develop the treatments and cures necessary to tackle our toughest healthcare challenges, including such complex diseases as Alzheimer's, various cancers, and many rare diseases.

The Biopharmaceutical Industry Gets Involved

The TEconomy project team has identified 53 individual colleges and universities with documented interactions with at least one biopharmaceutical or biotechnology industry partner.²³ Across these institutions were 75 individual educational programs with direct ties to industry.

So, how are biopharmaceutical companies and their foundations getting involved and how do educational institutions adapt to meet industry needs? **FIGURE 7** illustrates key interconnections and the examples and vignettes that follow illustrate examples of each type of support.

FIGURE 7: Biopharmaceutical Industry Connections and Interactions with U.S. Colleges and Universities



Advising curriculum and developing programs. Industry advisory boards and councils are a more formal approach utilized, but colleges and universities are also often working one-on-one with industry partners on the development of curricula and to design real-world lab experiences.

Facilities and equipment. Companies are donating financial resources and industry-grade equipment to institutions to facilitate hands-on learning and industry-relevant training. In some cases, companies are working in partnership with colleges and universities to help build facilities with specialized wet-lab and pilot-scale manufacturing capabilities.

Scholarships and promoting diversity. Often one in the same, companies and their corporate foundations are supporting outstanding students in STEM and, more specifically, life sciences studies often combined with unique opportunities for research, internships, and mentoring. Some companies are seeking to better attract women and minorities who are underrepresented in science and engineering professions for these opportunities.

Focused research experiences. Biopharmaceutical companies and their foundations offer internships, scholarships, and other support for unique, hands-on research opportunities with universities.

Teacher training and course instruction. Foundation efforts are supporting teacher training at multiple educational levels that include university professors training high school teachers for applied instruction. In addition, companies are offering some employee instruction in the classroom, particularly as partners in customized job training.

Classroom case studies and capstone projects. Company scientists and other researchers are participating in capstone and other team projects to ensure that students are learning how to work together to solve real-world challenges that are faced in biopharmaceutical R&D.

Industry fellowships. Postdoctoral fellowships offer top talent in the life sciences with the opportunity to explore career paths outside of academia in real-world industry settings.

Internships and other experiential learning. Gaining experience on a job while working toward a degree is not a new concept; however, there is an increasing emphasis on internships, mentoring, industry-relevant lab experiences, and other experiential learning opportunities as a requirement for completing a certificate or degree program for a biopharmaceutical or biotechnology credential.

Mentoring and volunteerism. Industry career and technical guidance is valued by colleges and universities and, while this may often be structured more informally and therefore not as prevalent in program documentation, the 2014 STEM study found significant volunteering by biopharmaceutical industry professionals. At postsecondary levels, this often means sharing career guidance and exposing students and recent graduates to career opportunities.

Customized job training. There is a recognition that many individuals with bachelor's or master's degrees in biology or engineering graduate with a strong core academic background, but many are still lacking key applied lab or other technical skills. Learning these skills can be a barrier to entry-level jobs in the industry or can require expensive in-house training or "onboarding" by companies, so industry often turns to technical institutes or community colleges for customized training programs.

The Important Role of Community Colleges in Workforce Education and Training



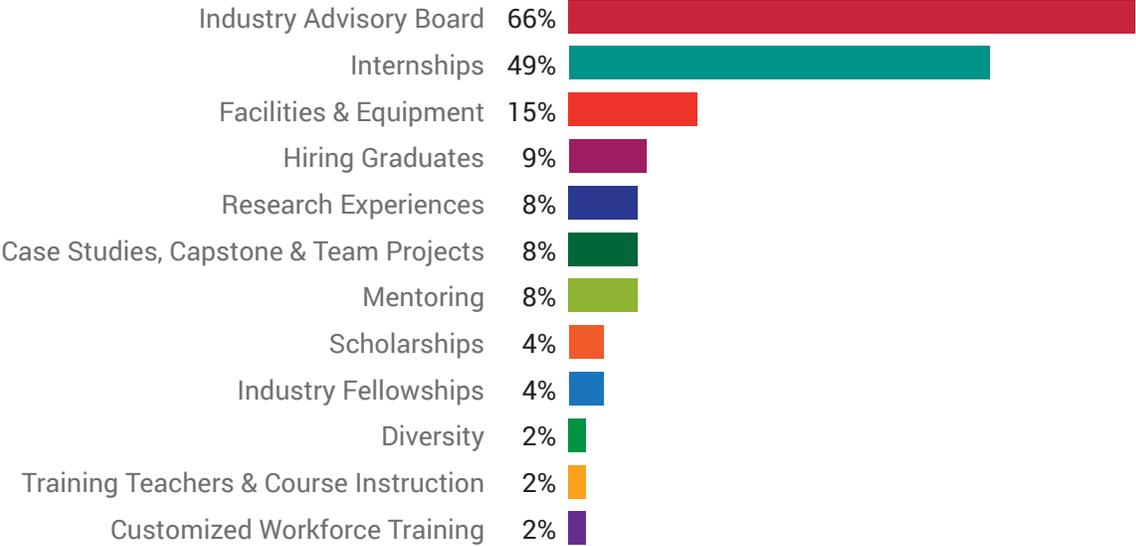
Community colleges play a key role in preparing the American workforce by doing the following:

- Providing postsecondary education at a reasonable cost
- Teaching and focusing on technical skill sets
- Partnering often with industry for hands-on training
- Providing opportunities for shifts in careers
- Offering short-term certificate credentials key for professional development
- Offering flexible schedules for students with jobs including online classes
- Allowing credits to transfer to other academic institutions.

Throughout this study are examples of the role community colleges play in training the biopharmaceutical workforce, not only in terms of conferring associate's degrees, but also with respect to offering key postbaccalaureate and other certificate programs for easily accessible training and professional development.

Many colleges and universities are increasingly focused on ensuring that their students will meet U.S. workforce needs. Many have created Industry Advisory Boards with the goal of ensuring that curricula will help meet companies' talent needs. These partnerships are the most common engagement of biopharmaceutical companies with colleges and universities—two in three documented programs had this type of interaction with many among the formal structure of a Professional Science Master's degree (FIGURE 8). One in two documented programs feature industry connections for internships, often required in today's applied postsecondary programs.

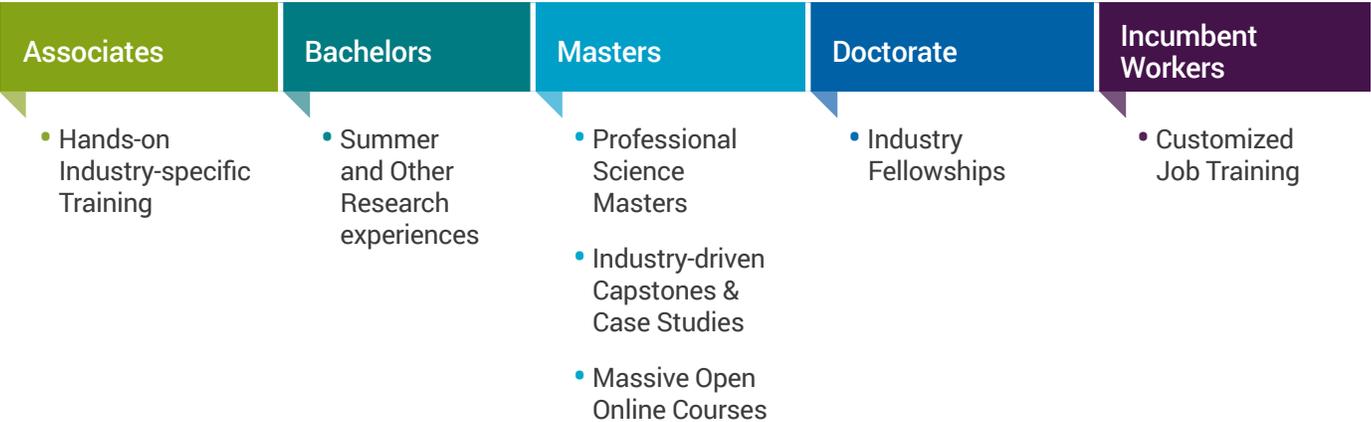
FIGURE 8: Incidence of Documented Biopharmaceutical Industry Connections and Interactions with U.S. Colleges and Universities



The interplay between the biopharmaceutical industry and educational institutions occurs across all postsecondary education levels, with much of the support provided cutting across all levels and some identified as more specific to certain degrees (FIGURE 9).

FIGURE 9: Industry Engagement and Support across the Postsecondary Continuum

Cross-cutting engagement for: program and curriculum development, internships, facilities and equipment support, course instruction, scholarships, promoting diversity





Professional Science Master's Programs:

MEETING A NEED FOR INTERDISCIPLINARY TRAINING

The increasing emphasis on interdisciplinary talent needs for scientists, statisticians, and other technical areas of expertise has spawned a unique program design that is reaching significant scale across the U.S.—the Professional Science Master's degree or PSM. PSM programs are designed for two years of coursework combined with a professional component that can include concentrations of coursework in business, project management, communications, policy, law, and/or regulatory affairs. Programs leverage industry relationships for internships and curriculum development and most require a final project or team experience or other experiential learning opportunities for students.

Since initial grants were awarded to fund the first PSM programs in 1997, the number of PSM program offerings has increased to more than 300 today. Life science–related programs account for more than 40 percent of the 333 active programs with the most prevalent in biotechnology (41 programs, 12 percent); other biological sciences (36 programs, 11 percent); medical-related sciences (27 programs, 8 percent); bioinformatics/computational biology (15 programs, 5 percent); and pharmaceutical science/pharmacology.

PSM graduates are prepared to better interact with research teams and more easily and intelligently interact with scientific researchers and business and legal managers. Overall, the programs are viewed as important to maintain U.S. industry competitiveness via talent development and deployment.



"Employers in the for-profit, nonprofit, and government sectors should partner with higher education institutions to create and sustain PSM programs. They should participate on employer advisory councils through which they can assist with and benefit from program conception, curriculum development, mentoring, employer sponsored projects, internships, employment, and financial support."

.....

—**National Research Council**, *Science Professionals: Master's Education for a Competitive World*, 2008

The Merck Company Foundation

The Ciencia (Science) Hispanic Scholars Program

Since 2008, the Merck Foundation has supported 10 Ciencia Scholars each year with college scholarships, summer research opportunities, and mentoring support. The Foundation launched the program with \$4 million in a partnership with the National Alliance for Hispanic Health (NAHH); and from 2009 through 2013, Hispanic students showing promise in STEM-related fields were selected from high schools in Brownsville, Texas; Elizabeth, New Jersey; and Los Angeles, California. The undergraduate scholarships were worth up to \$20,000 over a four-year college program, and up to \$22,500 in support was provided for summer research experiences. By 2014, 18 Ciencia Scholars had graduated.

In addition to scholarship support, the scholars participate in an annual symposium designed to learn new skills and present their research. The symposium is delivered with partner organizations including the American Association for the Advancement of Science, the Food and Drug Administration (FDA), the Howard Hughes Medical Institute, the National Institutes of Health, and the National Aeronautics and Space Administration.

Eighty percent of Ciencia Scholars who have graduated earned a bachelor's degree in a STEM field. This compares with just 16 percent of Hispanic students who enter college intending to pursue a STEM-related degree and actually graduate with a degree in a STEM-related area.²⁴ Ciencia program graduates are finding success postgraduation, with 56 percent pursuing careers in STEM fields and the remaining 44 percent pursuing graduate degrees, research fellowships, or postbaccalaureate programs.

Beyond the larger scholarships, the Merck Foundation's partnership with NAHH also includes awarding one-time \$2,000 scholarships to 25 Hispanic college students with STEM majors. To date, 125 of these awards have been provided.

The Science Initiative with the United Negro College Fund (UNCF)

The Merck Foundation, recognizing how few U.S. African Americans hold PhDs in the biological sciences and chemistry, has partnered with UNCF since 1995 in the Science Initiative, which supports the education and training of African American research scientists in biological, chemical, and engineering fields.

Under the Initiative, 37 outstanding African American students are supported each year spanning the undergraduate, graduate, and postdoctoral levels. Students are selected in a national competition with awardees receiving financial support, hands-on training, mentoring from Merck and other scientists, and institutional support. The program focuses on "key transition points in education" including when undergraduates are entering their final year, when graduate students are midway in their dissertation research, and when postdocs are entering training. Undergraduates in the program can participate in paid summer internships at Merck.

To date, Merck has awarded more than 700 fellowships and committed more than \$43 million in total since 1996.²⁵ Among the 60 undergraduate fellows completing the program, 72 percent have begun graduate studies at the PhD or MD level. Forty-six percent of graduate Fellows have completed their studies, and 11 of the 30 postdoctoral fellows have moved into research positions in industry or academia. Merck has hired 18 fellows since 2002.

EXAMPLES OF BIOPHARMACEUTICAL INDUSTRY POSTSECONDARY EDUCATIONAL PROGRAMS

Provided here are examples of the types of industry-university education and training partnerships focused on science and innovation and advanced manufacturing.

Science and Innovation

Scientific and engineering expertise and occupations drive biopharmaceutical innovation spanning drug discovery and the early-stage product life cycle into preclinical development and clinical trials. While the focus here is on science and engineering degree areas where the industry is engaging with postsecondary institutions, it is critical to note other high-skilled occupations such as information technology, management, and other business functions play key roles as well.

Program examples with biopharmaceutical industry engagement include the following.

The University of Arizona PSM in Applied Biosciences

The Applied Biosciences Program consists of foundational and practical training in various areas of applied biosciences along with a professional component that includes required internships and “cross-training” in workplace skills, such as business, communications, and regulatory affairs. The program offers specialized tracks in Industrial Microbial Biotechnology, Molecular and Cellular Biology, and Diagnostic Lab Sciences. Sanofi participates on the Industry Advisory Board and hires students as interns.

“We have found the PSM initiative and AB program to be a great source of interns. The students that we have brought on board have been motivated, hard-working and prepared to go the extra mile to benefit from their internship at Sanofi.”

—Paul August, PhD,
Discovery Biology Dept. Head,
Sanofi Tucson Innovation Center, member
ABS-PSM Industrial Advisory Board

San Francisco State University PSM in Biomedical Science

The program includes two internship-based concentrations: Master in Biotechnology and Master in Stem Cell Science. The program's goal is to fill an important niche for training midlevel scientists working in the biomedical sciences, and to meet strong workforce demands from Bay Area regions and the State of California. Introductory courses in business management, clinical regulations and bioethics prepare graduates for career paths in the corporate world. Students are required to conduct an applied research project and internship. External Advisory Board members include representatives of BioMarin Pharmaceutical, Celera Corporation, Asterias Biotherapeutics, SanBio, and Genentech.

Companies providing internships have included Genentech, BioMarin Pharmaceutical, Qiagen, Life Technologies/Applied Biosystems, SanBio, BetaStem Therapeutics, Cellerant Therapeutics, IncellDX, MedImmune, CellSight Technologies, Baxter, and Nodality.

Indiana University Bloomington PSM in Biotechnology

The Graduate Biotechnology Program was initiated in 2009 to train students for employment in the biotechnology industry. Successful students in the one-year training program receive a Master of Science degree in Biotechnology. Recent graduates have obtained positions in companies that manufacture macromolecules or agricultural chemicals or that conduct biopharmaceutical R&D. Students are required to complete a research project as well as an internship.

External advisors to the program include representatives from Eli Lilly and Company, Johnson & Johnson Pharmaceutical Research and Development, Cook Pharmica, and Alios BioPharma.

Massachusetts College of Pharmacy and Health Sciences (MCPHS) University Postdoctoral PharmD Fellowships

The fellowship programs at MCPHS University are designed to expose PharmD graduates to prestigious organizations and provide them with the scientific skills, technical knowledge, and leadership experience necessary to take their careers to the next level. Three different types of fellowship opportunities are offered including Biopharmaceutical Fellowships. Since 2003, the Industry Fellowship Program has provided Doctor of Pharmacy graduates with deep experiences in specialized training at many companies. The two-year fellowships include significant hands-on experience in various functional areas, professional development through quarterly conference series, and networking. Fellows receive an adjunct faculty appointment, develop and precept a clerkship for PharmD students, conduct and publish research, and present projects at conferences and professional events.

The following companies partner with MCPHS University for the Fellowship Program (a sampling of their focus areas are provided):

- Biogen: Regulatory Affairs and Safety and Benefit-Risk Management; Regulatory Affairs—Advertising, Labeling, and Promotion; Medical and Value-Based Outcomes
- Sanofi Genzyme: Global Commercial Strategy—Rare Diseases; Global Pharmacovigilance and Epidemiology; Regulatory Affairs
- Novartis Institutes for Biomedical Research—Fellowships in Early Clinical Development: Clinical Sciences and Innovation; Biomarker Development; Translational Clinical Oncology
- Pfizer: Pharmaceutical Sciences Quality Assurance; Clinical Supply Chain Strategy and Management; Clinical Research Pharmacy
- Sunovion Pharmaceuticals: Medical Information/Medical Affairs
- Takeda Pharmaceuticals: Global Medical Information Fellowship; Global Pharmacovigilance Fellowship.

St. John's University Master of Science in Biological and Pharmaceutical Biotechnology (New York)

This interdisciplinary master's degree program, which requires a private-sector internship, is a joint effort of the College of Pharmacy and Health Sciences and St. John's College of Liberal Arts and Sciences and is housed in the College of Liberal Arts and Sciences. The program gives students a thorough understanding of the scientific theory and advanced laboratory research techniques vital to success in pharmaceutical and biotechnology industries. Students also receive valuable internship experience in this revolutionary field. Core and elective courses include biotechnological drug delivery systems, principles of drug design, foundation of regulatory affairs, biomolecules and cell structure, and bioinformatics.

Companies serving as members of an Advisory Board for the program include Aureon Laboratories; Regeneron Pharmaceuticals; OSI Pharmaceuticals, Inc.; and Sanofi-Aventis US, Inc.

North Carolina State University Master's of Microbial Biotechnology Program

The Master's of Microbial Biotechnology (MMB) Program was developed in response to the biotechnology industry's desire for employees with a strong technical aptitude along with an understanding of business issues and well-developed professional skills. The MMB curriculum includes academic coursework in science and business along with professional training provided by local companies through case study projects and internships. The program at North Carolina State University represents one of the first and most successful PSM programs in the country. Since 2005 the program has had 117 graduates. Forty-three percent of MMB students are hired before graduation and 93 percent are hired within six months. A summer internship is required and the master's program includes case-study projects.

Biopharmaceutical and biotechnology companies in the Research Triangle Park area partner with the MMB program to host case-study projects and internships, provide guest speakers, and guide curriculum. These include Biogen, GlaxoSmithKline, Merck & Co., Novartis, Novo Nordisk, Pfizer, and others.

"One of the most essential skills in our business world today is collaboration, which is a core strength of the NC State PSM/MMB program. These students are acquiring and improving skills by collaborating between themselves and industry representatives throughout the case studies. These collaborative skills were previously learned only through on-the-job training."

—Michael Stocum, Managing Director at Personalized Medicine Partners

Rutgers Institute for Pharmaceutical Industry Fellowships

For several decades, Rutgers University has maintained a close relationship with leading biopharmaceutical companies in and around New Jersey. In 1984, the partnership began as a pilot project between Rutgers and two biopharmaceutical companies. Today, this unique industry-university partnership has resulted in more than 100 postdoctoral fellows annually placed at 17 partner companies.

Pharmacists have a key role to play not only in direct patient care, but also utilizing clinical knowledge for breakthroughs in drug development. The Industry Fellows Program is structured to provide PharmD graduates with an opportunity to develop specialized knowledge, training, and real-world experience within the biopharmaceutical industry. This intensive, hands-on training spans a wide range of disciplines, including clinical pharmacology, clinical research, regulatory affairs, medical information, medical affairs, market research, and marketing.

The program is designed for individuals with a Doctorate of Pharmacy to advance their training and professional development through both work experience and clinical research. The hands-on training spans a range of functional areas from coordinating clinical trials to acting as a liaison between regulatory agencies and research organizations. In addition to the industry fellowship, the program is structured to include the following:

- An adjunct faculty appointment in the School of Pharmacy with the opportunity to teach and develop courses;
- Completing one of the following electives: a research publication, a rotation at a Rutgers teaching/clinical site, serving on a committee, developing a special project, or coordinating an initiative to support/market/publicize Rutgers' program(s); and
- Participating in biweekly Professional Development Days that include informational and interactive seminars.

The duration of postdoctoral industry fellowships is typically one or two years and can vary in form and focus depending on the company and its needs. Selected companies and fellowships are listed below:

- Acorda Therapeutics: Clinical Development and Medical Affairs; Regulatory Affairs
- Actelion Pharmaceuticals: Global Clinical Science and Epidemiology
- AstraZeneca: U.S. Medical Affairs—Therapeutic Area Concentration; Global Regulatory Affairs
- Bayer: Business Development and Licensing; Clinical Operations; Early Pipeline Strategic Marketing; Global Regulatory Affairs
- Bristol-Myers Squibb: Regulatory Affairs—Advertising and Promotion; Strategic Analytics and Business Intelligence
- Celgene Corporation: Global Scientific Communications/Medical Information; Global Clinical Research and Development
- Daiichi-Sankyo: Medical Affairs; Marketing Sciences
- Johnson & Johnson and Janssen: Global Scientific Engagement; Commercial Insights and Strategy
- Merck & Co.: Clinical Safety and Risk Management (Pharmacovigilance); Translational Pharmacology
- Novartis: Clinical Pharmacology (Phase I–II); Commercial Strategy/Brand Marketing
- Pfizer: Clinical Research and Development; Global Regulatory Affairs
- Roche: Clinical Science Translational Medicine
- Sanofi: Clinical Documentation; Global Pharmacovigilance and Epidemiology; Health Outcomes Research and Communications

The program cites more than 800 alumni with prominent positions in the biopharmaceutical industry and, with more than 100 fellows per year, an extensive network of alumni.

INSPIRING THE NEXT GENERATION OF BIOPHARMACEUTICAL RESEARCHERS AND THE BIOMANUFACTURING WORKFORCE

Initiatives of the Amgen Foundation

The Amgen Foundation is focused on making significant impacts on science education among both students and teachers, and across all education levels. The Foundation's mission statement reads simply:

"The Amgen Foundation seeks to advance excellence in science education to inspire the next generation of innovators, and invest in strengthening communities where Amgen staff members live and work."

At the postsecondary education levels, the Foundation has several initiatives.

The Amgen Scholars Program provides "cutting-edge" research experiences for undergraduate students at 17 premier partner universities in the United States, Japan, and Europe. The scholars work full-time on an independent research project under the guidance of top faculty, are part of a cohort experience participating in seminars and networking events, and participate in an annual symposium to share their research with peers and to learn from leading scientists. Academic research areas are numerous and varied and include biochemistry, bioinformatics, immunology, medical pharmacology, neurobiology, and toxicology, to name just a few.

Partner universities in the United States include University of California (UC) Berkeley, UCLA, UC San Francisco, Washington University in St. Louis, Caltech, Columbia University, Harvard University, Massachusetts Institute of Technology (MIT), and Stanford University.

The Foundation has made a 12-year, \$50 million commitment to support this program which, to date, has provided hands-on research experiences for more than 3,100 undergraduates. These figures represent the growth and global expansion of the program as it reaches its 10-year anniversary, with applications for these coveted experiences continually increasing. More than 95 percent of Amgen Scholars alumni who have completed their bachelor's degree have gone on to pursue either an advanced degree or a career in a scientific field.

Amgen, in partnership with MIT, recently supported the development of a new online course called the **Amgen-MIT Biomanufacturing Educational Initiative**. The undergraduate course, titled "Making Biologic Medicines for Patients: The Principles of Biopharmaceutical Manufacturing," is focused on the importance of biologics manufacturing and how protein therapeutics are manufactured and builds on the university trend toward offering Massive Open Online Courses. By making the course available to anyone online and free of charge, the Foundation is both increasing exposure to the field and encouraging students to explore it as a career option. The course has been fully taught twice thus far and has been completed by more than 1,100 students from nearly 140 countries. A variety of participants are using the course for different purposes from teachers to PhD students to incumbent workers at biopharmaceutical companies. The Foundation is polling students regarding the experience, and there is evidence that the program is influencing students' interest in a career in the biopharmaceutical industry.

The Amgen Biotechnology Training and Learning Enhancement for Students or "Amgen BioTalents" Program is conducted in partnership with the University of Puerto Rico–Mayaguez to provide in-depth and comprehensive training in biomanufacturing and to prepare students to become part of the industry. The program emphasizes both hands-on and interdisciplinary approaches including tracks in biomanufacturing, industrial environment, and management leadership.

"Not only did I learn many laboratory and research techniques that I will use in the future, but more specific to my laboratory experience, I was able to gain a holistic perspective of how biological research can directly improve patients' lives. This has helped me confirm my decision to strive for an M.D.–Ph.D. as I have seen the way in which research and medicine coincide and reinforce each other."

—Amgen Scholar Jenny Lai

The Varied Applied Programs of the Keck Graduate Institute

The Keck Graduate Institute (KGI) of Applied Life Sciences in Claremont, California, was founded in 1997 and is the only U.S. graduate institution focused solely in bioscience education and discovery. KGI was created to prepare industry leaders by reducing barriers between academia and industry by focusing degree programs on the unique and specific demands of the bioscience industry. Because of this focus, programs at KGI are intentionally designed to be interdisciplinary with guidance from industry and to incorporate technical instruction and applications with management, policy, leadership development, and hands-on experiences.

KGI's academic programs are varied, cutting across the biopharmaceutical and biosciences R&D process and include the following:

- Master of Bioscience (MBS)
- PhD in Applied Life Sciences
- Postdoctoral Professional Master in Bioscience Management
- Postbaccalaureate Premedical Certificate Program
- Certificate in Bioscience Management.

Industry involvement occurs on several levels and with varied biopharmaceutical partners including the following:

- Facilities Development:
Amgen Bioprocessing
Center developed in 2004
with donation from the Amgen
Foundation for industry-focused
training
- Participation on KGI Board of
Trustees: Amgen, Astellas Pharma,
Regeneron Pharmaceuticals, and
Gilead Sciences
- Corporate Postdoctoral
Residency Programs: Regeneron
Pharmaceuticals.
- Team Master's Project (Capstone of MBS), corporate partners working
with students on real-world projects and a sampling of these projects:
 - Boehringer Ingelheim: Innovation Management 2.0; Developing
an incubation chamber for continuous viral inactivation
 - BioMarin Pharmaceutical: Supply chain scenario planning and
optimization; Sustainability assessment
 - Bristol-Myers Squibb: Development and qualification of a model
of commercial-scale mammalian cell culture bioreactor for
production of a biopharmaceutical medicine; Best practices in
portfolio optimization
 - Eli Lilly and Company: Putting videography to work in the lab of
the future
 - Gilead Sciences: Biologics contract manufacturing landscape
 - Pfizer: Clinical trial diversity action plans
 - Takeda Pharmaceuticals: Digital strategy

EXAMPLES OF BIOPHARMACEUTICAL INDUSTRY POSTSECONDARY EDUCATIONAL PROGRAMS

Advanced Manufacturing

Beyond its early-stage R&D activity, the industry operates as a leader in advanced manufacturing; and it must compete among other advanced industries for talented individuals.

Program examples with biopharmaceutical industry engagement include the following.

Mount Wachusett Community College's Biotechnology/Biomanufacturing Degree and Certificate Programs (Massachusetts)

This program provides an opportunity to earn associate degrees and certificates focused in Biotechnology/Biomanufacturing as well as Analytical Laboratory Quality Systems preparing students for positions in an array of manufacturing and engineering settings. The Quality Systems emphasis is unique with a focus on FDA regulations, documentation of standards and procedures, and ultimately prepares students for jobs as quality technicians. The program was recognized by the Massachusetts Life Sciences Education Consortium with their "Gold" endorsement which "recognized the programs' accomplishments and explored how the institutions and industry can continue to work together to cultivate and support the next generation of the life sciences workforce." While Internships are not required, they are an elective component to courses. Bristol-Myers Squibb is cited as a manufacturing industry partner in providing input to curriculum, training and hiring graduates.

Wake Technical Community College Biopharmaceutical Technology (North Carolina)

The Biopharmaceutical Technology curriculum provides certificates and associate degrees for employment in pharmaceutical manufacturing and related industries, including chemical quality assurance, microbiological quality assurance, product inspection, documentation review, manufacturing, and product/process validation. Certificate programs are offered in Biopharmaceutical Regulations, Biopharmaceutical Manufacturing and Quality, Pharmaceutical Basics, and Applied Biotechnology.

Numerous biopharmaceutical companies are cited as employers of program graduates, including Biogen, Eisai, GlaxoSmithKline, Johnson & Johnson, Eli Lilly and Company, Merck & Co., Novartis, Novo Nordisk, and Pfizer.

North Carolina State University—Raleigh's Master's Programs in Biomanufacturing

North Carolina State University offers two programs through its Golden LEAF Biomanufacturing Training and Education Center (BTEC)—the Master of Science in Biomanufacturing and Master of Biomanufacturing, both are PSM programs that include internship requirements.

The Master of Science in Biomanufacturing is a research-based degree that requires a written thesis in addition to completion of advanced hands-on courses in the BTEC simulated current Good Manufacturing Practice (cGMP) facility. The Master of Biomanufacturing combines BTEC's advanced biomanufacturing courses with curriculum in bioscience-focused MBA courses; a thesis is not required. Both degrees offer students the choice of upstream (fermentation) or downstream (purification) concentrations to accompany courses in global regulatory affairs, protein characterization techniques, case studies in cGMP manufacturing of influenza vaccine, case studies in monoclonal antibody production, biocatalysis, biomanufacturing research, and an industry internship. Both degrees also include professional skills training in effective oral, electronic, and written communications for both technical and business careers.

BTEC's 82,500-gross-square-foot main facility features high-tech classrooms and laboratories with bench-scale and pilot-scale bioprocessing equipment. The BTEC Annex has an additional 5,000 gross square feet for viral processing, cell culture, and purification. The largest laboratory area is a simulated-cGMP production facility.

The BTEC Advisory Board has been established to guide the Center in the following: course content, curriculum development, instruction, certification requirements, assessment, marketing, and facilities/equipment needs. Industry Advisory Board members include representatives from Pfizer; Novozymes; Biogen; Eisai Co., Ltd.; PharmaMatrix; Quintiles; KBI Biopharma, Inc.; Grifols; Novo Nordisk; Merck & Co., Inc.; and Fujifilm Diosynth Biotechnologies.

Quincy College's Biotechnology and Compliance Programs (Massachusetts)

The Biotechnology Program provides certificate and associate's degree programs to prepare students for entry-level positions in the biomanufacturing industry. Students develop a broad laboratory science-based background through courses focused in the life and chemical sciences and obtain industry-specific knowledge in the areas of quality control, process development, and upstream and downstream processing, all while following cGMPs.

Biopharmaceutical firms engage with the program by serving as industry advisors, donating equipment, and hiring students as interns and for permanent positions. Companies partnering with the College include Shire Human Genetic Therapies; Lonza Biologics; Xcellerex (a GE company); and Millennium Pharmaceuticals, Inc. (a Takeda Company).

City College of San Francisco's Biotechnology and Biomanufacturing Programs (California)

The Biotechnology Program of the Department of Engineering and Technology at City College of San Francisco provides certification and associate's degree programs to prepare students for careers as technicians and lab assistants in companies and academic institutions of the San Francisco Bay Area. The program has options for students with a background in biology and for those new to science. The Internship course provides an off-campus internship experience in Bay Area biotechnology companies and bioscience research laboratories. Students are placed in biotechnology-related internships including, but not limited to, glassware washers, laboratory assistants, animal technicians, biomanufacturing technicians, calibration technicians, environmental health and safety technicians, quality control technicians, and quality assurance technicians.

Biopharmaceutical firms partner by providing equipment and financial donations, hosting interns, hiring graduates, and advising curriculum. Companies partnering with the College include Amgen; Celgene Corporation; DNASTAR; Life Technologies; Roche; BioMarin Pharmaceutical; Bionovo, Inc.; Cel Analytical; Cytokinetics; Evolve Biosystems; Genemed; Genentech; Gladstone Institutes; MCLAB (Molecular Cloning Laboratories); Nektar; Prosetta Biosciences, Inc.; VWR International; and XDx Diagnostics.

MiraCosta College Biotechnology Program

Biotechnology courses were first offered at MiraCosta College in Oceanside, California (near San Diego), in 1990 and, since its beginnings, the Biotech Program has had the support of local industry. With early successes in talent development, the College partnered with IDEC Pharmaceuticals in 2002 to meet workforce training needs and develop a new program for the unique needs of biologics production including process scale, process control, and compliance. At this time, the industry was moving beyond research and further into later-stage biologics development.

With input from IDEC (and later Biogen and Genentech), the program in Bioprocess Technology was established and further bolstered when Biogen donated nearly \$400,000 to MiraCosta to remodel facilities and attract a lead faculty member. By 2006, the 3,500-square-foot facility was opened and included \$1 million in industry-grade equipment for hands-on training. Today, the lab models a real-world industry work environment and includes an instructional lab area and bioprocessing suite designed to handle lab-scale mammalian and microbial culture.

The program currently offers an associate's degree in Biotechnology as well as certificates in Bioprocess Technology, Research and Development, and Laboratory Skills. The programs utilize applied lecture in combination with hands-on laboratory training to prepare bioprocess technicians (both new and incumbents) for the biopharmaceutical industry. The training also includes operating specialized equipment and instrumentation to produce biopharmaceuticals or reagents and learning to follow GMPs through proper record keeping and other compliance. Internships are available through an elective course in the program and have helped MiraCosta to begin and maintain many industry relationships. For those already employed, the program will help arrange for a co-op experience where the individual can undertake a 40- to 60-hour work-based project outside of their current work areas.

In addition to internships, Biogen and Genentech have been involved in program and curriculum development and provided funding for the facility, lab equipment, scholarships, and job placement. Genentech, who ultimately purchased the Biogen site, has hired the most graduates locally in developing protein therapies and monoclonal antibodies. Gilead Sciences, with a new biologics operation in the region, is participating in the program advisory board and hiring graduates.

The Biotechnology Program has been designated by the Department of Labor as a Center of Excellence in Bioprocessing, and the program cites a 90 percent success rate in placing its graduates, about 30 per year, in immediate employment or transferring into additional education. MiraCosta is building on its success and will begin to offer a bachelor's degree program in Biomanufacturing in 2017.

"The guiding principle of our program that makes what we do unique is our commitment to hands-on learning. We have a program that is lab-based. Our students are learning the skills that they can take with them right to the workplace."

—Mike Fino, Dean of Math and Science,
MiraCosta College

The Biomanufacturing Education and Training Center at Worcester Polytechnic Institute

Worcester Polytechnic Institute (WPI) in Worcester, Massachusetts, developed the Biomanufacturing Education and Training Center (BETC) in partnership with the biotechnology and biopharmaceutical industry for customized workforce training. The BETC offers a unique 10,000-square-foot facility for hands-on training that is customized to meet specific company needs in biomanufacturing. In addition to customized training and workshops, the BETC also has open-enrollment opportunities for individuals, including graduate-level courses.

The ability to conduct effective, hands-on training appeals to industry. BETC's "fully-functional pilot-scale biomanufacturing suite" provides students and trainees with the opportunity to learn how to operate large-scale bioreactors, centrifuges, fermenters, chromatography, depth filtration, and ultrafiltration. The facility also has analytical capabilities for process monitoring and analysis.

WPI faculty and industry professionals have partnered to develop the BETC. Industry experts have guided the design and use of space, choice of lab equipment, and course and curriculum design and delivery. Training can take various forms including one-day modules and weeklong programs for instruction in bioprocessing. Current training programs include the following:

- Fundamentals of Bioprocessing for Engineers
- Downstream Principles and Techniques
- Upstream Processing of Animal Cell Culture Products
- Troubleshooting the Biomanufacturing Process and Root Cause Analysis
- Fundamentals of Biomanufacturing
- Biomanufacturing for the Non-Specialist: What You Need to Know
- Single Use Systems
- Microbial Fermentation Development, Scale-up and Manufacturing
- Insect Cell Culture and Baculovirus Expression Vector System.

In addition to working with Biogen to develop curricula and other materials, the BETC has developed and conducted customized training programs for a number of other companies as well as sought their subject matter experts for course instruction. These companies include AbbVie, Boston Scientific, Bristol-Myers Squibb, Eppendorf, Genzyme, Merrimack Pharmaceuticals, Pall Corporation, Pfizer, Shire, and Validation Technologies. In addition to its primary role as educator and trainer, BETC offers contract manufacturing and consulting services including small-scale non-GMP manufacturing.

"It's very important to be able to customize because in this field things are constantly changing so we need the ability to be flexible in what we're teaching."

—Danielle Thompson-Reynolds,
Manager of Performance
Development Manufacturing, Biogen

*From Biogen and BETC Partnership
web video*

Conclusion: Connecting STEM Education with Careers to Maintain U.S. Leadership in Innovation

Academic institutions and industry are recognizing that advancing STEM education alone is not sufficient to effectively integrate STEM graduates into careers in the biopharmaceutical sector. In response, they are collaborating to develop educational and training opportunities that will provide real-world experiences for students and ultimately prepare them to meet the growing STEM workforce needs of innovative biopharmaceutical companies, which are recognized for the high wage jobs they offer. The challenge, particularly for elementary and secondary educators, is that STEM studies often exist in a vacuum, without a connection to real-world discovery and invention. Likewise, this same challenge exists at a postsecondary level where the classroom is often disconnected from the industry laboratory or manufacturing plant and its cutting-edge technologies, and students struggle to connect, or to envision themselves in those innovative industrial environments.

This report describes some of the innovative partnerships between academia and our nation's biopharmaceutical companies. As the examples illustrate biopharmaceutical companies are seeking to bolster the educational system to ensure the existence of the talent pipeline needed to help discover, develop, manufacture, and deliver tomorrow's new treatments and cures. The U.S. has worked to establish its leadership in terms of its innovation and R&D ecosystem, and to maintain this position requires the types of partnerships with the nation's colleges and universities illustrated in this study. It also requires continued investments to compete with other countries that are increasing their own investments in STEM and more specifically, life sciences education and training. Public policies should seek to further foster and expand these partnerships which are critical not just to the future of medical discovery but to the economic sustainability and growth of a vibrant innovative biopharmaceutical industry.

Endnotes

1. Battelle Technology Partnership Practice, *STEM: Building a 21st Century Workforce to Develop Tomorrow's New Medicines*, January 2014.
2. Based on the level of engagement with individual postsecondary institutions, it is assumed that many companies are hiring program graduates; however, this figure represents an explicit written documentation that the participating companies hire program graduates.
3. PwC, *Managing Innovation in Pharma*, see: <http://www.pwc.com/gx/en/pharma-life-sciences/assets/pwc-managing-innovation-pharma.pdf>. Includes results and analysis from the PwC Global Innovation Survey.
4. Battelle Technology Partnership Practice, *STEM: Building a 21st Century Workforce to Develop Tomorrow's New Medicines*, January 2014.
5. The project team focused on degree fields across U.S. postsecondary institutions that are generally more “applied” in nature including, for example, Biotechnology, Bioinformatics, Biostatistics, Genomics, Quality Assurance, Medical Informatics, Pharmacology, and Pharmaceutical Science. These were prioritized ahead of more general science fields such as Biology or Chemistry to refine the potential universe to a manageable programmatic review.
6. Based on TEconomy Partners’ analysis of U.S. Bureau of Labor Statistics, Occupational Employment Statistics program data.
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9. International Communications Research prepared for Bayer Corporation, *The Bayer Facts of Science Education XVI: U.S. STEM Workforce Shortage—Myth or Reality? Fortune 1000 Talent Recruiters on the Debate*, “Executive Summary,” October 2013.
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17. Louis Garguilo, *Outsourced Pharma*, “Are There Enough Biomanufacturing Workers in the U.S.?” October 14, 2015.
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19. Edmunds, et al., *Pharmaceutical Executive*, “Beyond 2020: Building Strategic Coherence in the New Health Economy,” March 2016.
20. CSBI, *Life Sciences Workforce Trends Report 2014*.
21. Kathy Nugent and Avi Kulkarni, *Nature Biotechnology*, “An interdisciplinary shift in demand for talent within the biotech industry,” September 2013.
22. Merriam-Webster defines “big data” as follows: an accumulation of data that is too large and complex for processing by traditional database management tools.
23. This figure represents a review of selected U.S. postsecondary educational programs most likely to have industry-institution interaction and does not represent a census of all U.S. life science–related educational programs. See the “Introduction” for a description of the project approach to study design and methodology.
24. Higher Education Research Institute at UCLA. *Research Brief: Degrees of Success. Bachelor's Degree Completion Rates Among Initial STEM Majors*, January 2010.
25. For program impact results, see: <http://www.msdrresponsibility.com/our-givingcommunity/education/#tab-558d7f2238c6e>.
26. See: <http://mwcc.edu/news/2014/12/02/mwccs-biotechnology-programs-receive-gold-industry-rating/>

