BioCrossroads®

Using Post-Baccalaureate Education as a Competitive Advantage for Indiana's Life Sciences Industry

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INTRODUCTION

The phenomenal success of Richard Florida's book, *The Rise of the Creative Class*, published in 2002, struck a chord across America that has been resonating ever since. At the heart of Florida's book is the idea that talent matters. Over the past decade, regions across the United States have come to recognize that it is not enough to leverage their unique natural and locational resources, their industrial legacies, and their networks of suppliers, distributors, and market outlets to remain competitive. They also have to better prepare themselves for the ways in which new technologies and global forces are changing the rules of the game, especially the skills and knowledge of their workforce. If they are serious about retaining and growing their talent pool, states such as Indiana need to re-double their talent development efforts, particularly among highly skilled and professional workers.

With globalization and rapid technological change, innovation and entrepreneurship are becoming more and more essential to all regional economies. In order to remain competitive, it is essential to introduce innovative new processes and products within existing industries as well as create whole new product-oriented industries. At all levels of innovation, entrepreneurship and competitiveness, the talent equation matters. One needs to have intellectual capital working at the forefront of science and technology. Engineering and production know-how are essential to create scalable, affordable products. And entrepreneurial marketing, financing, and organizational skills are needed in order to nimbly adapt to changing markets. Whether an established company, a supplier, a manufacturer, or a business service provider, the skills and competencies of the workforce are essential to being competitive in a rapidly changing world.

The new economic realities that regions are facing seem daunting in contrast to the relatively self-contained marketplace that the United States represented at the end of World War II and well into the 1980s. Today, 95 percent of the customers in the world are outside of the United States. In the old economy, regions in the United States were primarily competing with one another for economic growth opportunities. Today the highest economic performers are in places that were not even taken seriously ten years ago – such as Brazil, China, and India. These countries are not just doing low wage manufacturing, they are also building research and development infrastructure and innovating in new and challenging ways. In addition, they are making substantial investments in human capital. In the year 2000, there were one million college graduates in China, and by 2010 there were six million college graduates. The United States clearly is facing significant challenges and opportunities on the talent front. Industries such as

life sciences must increasingly be global to prosper and, in this age of jet travel and the internet, can hire the best talent available, whether in Singapore, Tennessee, or Indiana.

What civic leaders, educators, and elected officials across the United States are recognizing is that America's economic future is not simply about big companies – finding the next General Motors or General Electric. It is also about supporting regionally–anchored, entrepreneurial, high-growth private companies. Research from the Kauffman Foundation shows that since 1980, start-up firms under five-years old account for nearly all the net job growth in the United States. However, most of these companies require skills and knowledge that most Americans don't have because of rapid changes in technology. Such companies also do not have the established education and training divisions that larger, more mature companies do. These types of companies typically depend on innovative colleges, universities, and training companies for their talent development.

Job creation opportunities are tremendous if regions can find ways to better align education and training programs with their growing innovation sectors such as healthcare information technology, digital media, precision manufacturing, and retrofitting buildings to new environmental standards. This can be done by modifying existing workplace skills or helping recent graduates and mature adults bridge to new jobs. In other words, regions need to be as focused on their talent development strategies as they are on their technology and business development strategies. Esteemed management guru, Peter Drucker, 30 years ago said, "We now accept the fact that learning is a life-long process of keeping abreast of change. And the most pressing task is to teach people how to learn."

The challenge of the moment is that we are moving away from our grandfather's high school education-based economy where an 18 year-old high school graduate would assume he is qualified for good high-paying jobs for his entire career, or a 22 year-old college graduate expects readiness for work for the rest of his or her life at graduation. The changes in the workplace that are occurring are rapid, and often result in the disappearance of whole categories of work and create whole new categories of work: ATMs have replaced bank tellers of the 1950s; routine outpatient procedures today used to require major surgery and a long hospital stay in the 1960s and 70s; and, in the 23 years since the creation of the internet, there has been the extraordinary transformation of the skills needed in publishing, newspapers, public relations, education and training. Today's employees, regardless of industry or skill level, need to upgrade and retrain continually.

Research from Georgetown University in 2010 revealed that there is a growing disconnect between the types of jobs that employers must fill and the numbers of Americans with the right education and training. Many new jobs are being created by innovations in technology developed through university research labs, innovative start-up companies and nimble established industries. However, unless we ensure that workers can get access to the new forms of knowledge and skills required to work in those innovative environments,

we will not only miss important employment opportunities, but we risk losing good companies to other regions or even to other countries where employers can find the skill sets they need. Fewer and fewer employers, even among larger companies, have the internal resources to meet these rapidly changing talent development needs.

According to a recent study by the Accrediting Council of Independent Colleges and Schools, many employers believe colleges are not adequately preparing students for jobs. The Council surveyed more than 1,000 employers in various industries about whether job applicants possessed the skills to thrive in the workplace. More than half of employers said that finding qualified applicants is difficult, and just under half thought that students should receive specific workplace training rather than a more broad-based education. Interestingly, nearly 30 percent of employers said finding the right applicant has grown harder over the past few years. And, in fact, today, there are more than two million jobs U.S. businesses cannot fill because they cannot find American workers with the right skills, a fact chronicled in the book *Closing America's Job Gap*.

What can we do? Clearly, there is a need to more systematically identify the knowledge and skills employers need for today's globally competitive marketplace. There is also a need for leaders of educational institutions and training programs to integrate employer input into the design of their curriculum and the experiences of students in their programs. However, there is also an important need for additional education among people with a solid general education in the liberal arts, as well as skills specific to a given workplace or set of job requirements. For example, a local company which is attempting to go global has to be sophisticated about international manufacturing standards and regulatory requirements, how to be successful in non-U.S. markets, in terms of sales and production issues, and even how to behave in a meeting. To navigate these sorts of challenges requires learning fundamentals, not just techniques.

Employers are looking for people who are highly literate, good thinkers, know how to get information and gather data, exercise judgment, and are good communicators in multiple social and business contexts. This is where a good basic education can pay off. However, employers also need people who can do things. That is why college graduates are enrolling in extension and continuing education certificate programs in record numbers. This coursework is typically taught by practitioners with workplace experience, in contrast to previous eras, when such schools were more like 'second-chance universities' for adults who did not have an opportunity to get a college degree early in life. Today, these programs are hubs of education and training providing the practice-oriented credentials which, combined with a solid AA or BA degree, make for globally competitive careers. Institutions such as New York University, the University of Chicago, and the University of California are experiencing phenomenal growth in these certificate programs because they allow people with general skills, either from previous workplace experience or college degrees, to bridge into the new skills required by new

economy companies. Through enrollment in these certificate programs, recent graduates and mature adults meet a mix of people who are relatively new to the field, as well as those who have been in the workforce for 20 years or more. They get opportunities to not only learn new things, but develop a very practical understanding of what's required in the workplace and where there are new opportunities for employment. These kinds of continuing and professional education programs represent sources of intelligence about the world of work. Every region across America needs to assess if it is meeting the full range of talent development needs of its employers.

These trends have profound implications for Indiana. This report identifies where these new professional development needs are in the life sciences clusters across Indiana and, more specifically, the kind of coursework employers report is needed to address them. Within the life sciences industry, education and training programs have lagged vis-à-vis the innovations that are occurring in the industries surveyed. The many fine colleges and universities operating in Indiana are well positioned to provide innovative educational initiatives which can close the current talent gap. However, they need to develop a more comprehensive view of education and credentialing. The life sciences industry is one of Indiana's strongest sectors. It employs thousands of individuals, and it is poised to be a growth sector, creating new jobs and new wealth for the state. However, for life sciences companies to grow and prosper they need to be able to tap into a talent pool which possesses college-level education as well as practical industry-related skills. In the life sciences, knowledge of where science and technology are going, the new developments in healthcare delivery and patient care, regulatory issues facing the development of drugs and devices as well as the delivery of care are essential to successful industry growth. Currently, undergraduate and graduate degree programs rarely provide courses with industry-specific information that is relevant to life sciences employers. If Indiana's local colleges and universities can begin to develop credentialing and certificate programs that are professionally-focused, then those courses would serve as a bridge for the individual from a general education to a specific job. Local employers would benefit from a range of skills and knowledge that they need to be competitive.

Interviews and surveys with companies large and small in Indiana reveal a significant need for employees who are competent in FDA regulatory issues, project management, drug and device financing and business models, technical writing, and product design. We know from regions of the United States such as Seattle, Washington; San Diego, California; and Boston, Massachusetts that community colleges and university extension divisions are valuable sources for the types of bridging credentials that are needed in Indiana. The University of California in San Diego, one of the largest hubs of pharmaceutical and medical device companies in the United States, has a very diverse range of courses and certificates for individuals working in the local cluster which could potentially be relevant to Indiana. The extension service provides education in regulatory affairs, clinical research and

drug development, clinical trials management, medicinal chemistry, biotech manufacturing, developing markets for high tech and life sciences products, and project management in life sciences companies. The list could go on and on. The curriculum making up these programs is built on the practice-based knowledge of advanced professionals working in research laboratories, drug development, and production companies across southern California. They work collaboratively with university faculty to define the core knowledge and skills that are needed and to identify appropriate instructors. Typically, a college graduate enrolled in these courses can, over a 12- to 18-month period, successfully complete six to eight courses which will introduce him or her to a whole new world. Educational institutions across Indiana need to begin innovating in their curriculum and responding to employer needs in a more nimble and imaginative way, if Indiana is to develop the talent pool it needs not only to grow life sciences businesses, but to retain them in the region.

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USING POST-BACCALAUREATE EDUCATION AS A COMPETITIVE ADVANTAGE FOR INDIANA'S LIFE SCIENCES INDUSTRY

Indiana's Life Sciences Industry

Indiana is home to an outsized proportion of a highly diversified set of major life sciences companies with both strong research and development and manufacturing operations. Companies such as Biomet, Cook Medical, Covance, DePuy Orthopaedics, Dow AgroSciences, Eli Lilly and Company and Roche Diagnostics have themselves invested, collectively, over $3.2 billion in expanded operations and facilities over the last ten years. In the 2012 Biotechnology Industry Organization-Battelle report on the United States' life sciences industry, Indiana is one of only five states ranked "First Tier" (others include California, Massachusetts, New Jersey and North Carolina) for every significant indicator of life sciences industry strength, including concentration of companies, number of companies and total number of bioscience industry jobs.

The life sciences industry is comprised of four distinct, but interrelated sectors - agricultural feedstock and chemicals, medical devices and equipment, drugs and pharmaceuticals and research, testing and medical laboratories. In 2011, more than 47,000 Hoosiers at 877 establishments worked in these four life sciences sectors. Each of the four sectors is well represented in the state. Agricultural feedstock and chemicals employs over 4,000 workers, while medical devices and equipment stands as the largest sector, with over 20,300 employees. Drugs and pharmaceuticals employ more than 14,600 employees and nearly 8,400 workers are employed by research, testing and medical laboratories. There are important synergies and links among and between these industry segments, with Indiana having nationally recognized strengths in three of the four sectors. Indiana's life sciences firms increased their employment by nine percent between 2006 and 2011, and the number of life sciences establishments in Indiana has grown by 50 percent since 2006. Indiana life sciences workers, on average, have a wage differential which pays them more than twice the average private sector job in the state – nearly $89,367 compared to $40,272 – a differential of $49,095. These jobs are geographically dispersed throughout the State – from Bloomington, Seymour and Spencer to Gary, Indianapolis, Warsaw and West Lafayette.

All of these factors contribute to a uniquely strong Indiana economic asset, a rising industrial sector that today represents a third of the State's $29 billion in annual exports of manufactured goods ($9.3 billion in 2011) and delivers a total $44 billion economic impact to the State.

Industry Challenges

While Indiana's life sciences industry is a national leader in exports and has a significant impact on the State's economy, there are now headwinds facing the industry that may limit its ability to grow in the future if nothing is done to limit their effects. Challenges include the following:

- Regulatory hurdles for product approval by the U.S. Food and Drug Administration (FDA) are becoming increasingly more stringent due to concerns about patient safety;
- Payers – both public and private – are becoming increasingly reluctant to purchase products which do not have a clear and compelling clinical advantage over existing therapies;
- Increasing pressure from government payers to decrease product prices due to the rising number of patients covered by government-funded programs such as Medicare and Medicaid;
- Capital markets are increasingly risk averse and interested in investing in new technologies only after they have shown promise in human clinical trials; and
- Increasing competition from companies located in China, India and Brazil, whose countries have growing markets for pharmaceutical and medical device products.

The industry faces increased costs to commercialize products, longer timelines to bring these products to market, potentially lower revenues upon product launch and increased competition from overseas competitors. Those who work in this industry – or hope to – must be prepared to meet the challenges of an increasingly dynamic sector.

Understanding Employer Needs

BioCrossroads interviewed 24 Indiana-based life sciences companies, representing a cross-section of employers from the four industry sectors, and involving multinational, small and medium-sized enterprises, to understand the industry-specific knowledge that would better prepare and assist new college graduates and non-life sciences professionals for this highly regulated and complex sector. Company representatives defined and illustrated the types of professional coursework that would help current and future employees increase their knowledge of industry-specific priorities and requirements.

The results of those discussions are summarized as follows:

- Companies expressed a high level of interest in having academic institutions develop and teach post-baccalaureate coursework that would enable current and future employees to increase their knowledge of industry-specific topics, especially since many of these companies today lack the type of in-house management training programs that were formerly made available to new entrants.

- The companies believe that they can add value in the development and delivery of newly-prepared coursework programs through subject matter expertise and as a source of potential "adjunct faculty".

  Employers had the most interest in courses such as:

  - FDA regulations, including Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), quality systems and Quality Assurance (QA);
  - Project management;
  - An overview of the pharmaceutical and medical device industry; and
  - An overview of the U.S. healthcare delivery system.

- In several cases, the companies noted that many of their existing employees – in addition to new personnel – would benefit from these kinds of courses.

- Several suggestions specifically targeted liberal arts degree graduates:

  - Project management;
  - Writing for the life sciences industry;
  - An overview of the healthcare delivery system; and
  - Process improvement concepts.

- Professional coursework would bring ancillary benefits beyond job readiness. Employers cited improved employee retention, professional development, increased opportunities for trailing spouses and credibility with clients as additional benefits of this kind of professional education program.

The following "course descriptions" were identified by employers as particularly promising post-baccalaureate curricula for people entering the life sciences industry:

Life Sciences Industry Survey

This course will provide a general overview of the life sciences industry – broadly defined as pharmaceuticals, medical devices, agricultural biotechnology and research and testing laboratories – to individuals new to the industry. Topics for participants will include a description of industry segments, the business models, regulatory requirements and interaction with customers, patients and clinicians. In addition, the course will provide an example of how a pharmaceutical and a medical device are discovered, commercialized and utilized in the healthcare delivery system. Experts from the industry will teach the course and will describe how new trends and technologies such as personalized medicine, gene therapy and regenerative medicine will impact the delivery of care in the future. Finally, participants will visit a research laboratory and manufacturing facility to learn how modern life sciences companies discover, develop and deliver these valuable products to patients.

Food and Drug Administration Overview

As the U.S. regulatory body for the life sciences industry, the FDA is one of its most important stakeholders. It is critical that current and future employees are aware of the FDA's regulations and how they impact the operations of life sciences companies. This course will provide an overview of the FDA's mission, organizational and divisional structure and policies and procedures. Industry professionals will describe how life sciences companies must organize their businesses to ensure compliance with the FDA's rules and ensure that managerial systems are in place to maintain compliance.

Good Laboratory Practices

This course will address basic compliance principles of the FDA's current GLP regulations and will demonstrate how these rules impact the conduct of non-clinical laboratory research. Participants will study the management controls for research laboratories that allow for the consistency, reliability, and integrity of non-clinical safety tests. The course will describe FDA inspections, current inspection trends, required GLP documentation, and the role of the quality assurance unit, study director and control articles.

Good Manufacturing Practices

Course participants will learn about the FDA's GMP regulations, which ensure pharmaceutical and cosmetic products are consistently produced and controlled to quality standards appropriate for their intended use. Topics include the Food, Drug and Cosmetics Act, the regulatory structure of the FDA and rules specific to the manufacture of pharmaceuticals. The coursework will also describe the quality systems and manufacturing rules enacted by the Safe Medical Devices Act. Participants will discuss federal regulations and FDA site inspection trends. Experiential learning will include reviewing and responding to an FDA warning letter.

Health Information Technology Overview

This course will provide an overview of healthcare information technology (HIT) systems and concepts to software engineers and business professionals. The course will describe the HIT systems utilized in a healthcare environment such as patient registration, laboratory, imaging, billing and enterprise resource planning. Discussion topics will also include the HL7 coding language and health information exchanges. In addition, local health and IT experts will give seminars on policy and industry developments affecting HIT systems such as ICD10 conversion, healthcare delivery quality measures, the rise of accountable care organizations and data mining.

Healthcare Delivery System Survey

This course features a comprehensive review of the current healthcare delivery system covering the roles and responsibilities of various stakeholders (patients, providers, healthcare professionals (HCPs) and insurance companies), as well as the data generated and maintained by each group through patient – HCP interactions and medical terminology. Topics will also include an explanation of the financing mechanisms for healthcare (public and private), the role of government in regulating this industry and how medical technology is assessed and utilized in clinical practice. Finally, the course will highlight projected changes in the industry business model such as the development of accountable care organizations, the growing trend toward direct employment of physicians by hospitals and the on-going consolidation of healthcare systems.

Process Improvement

This course will provide an overview of process improvement principles, methodologies, and tools for enhanced effectiveness and efficiency of processes. Topics include a basic framework to guide improvement efforts from planning to implementation and tools to understand current processes and possible improvements. Participants will learn essential skills to lead efforts that are data-driven and performance-oriented. Application of knowledge will be stressed through interactive learning experiences. At the end of the course, participants will identify a process, perform an assessment, and draft a proposal for improvement.

Project Management

Project management is the process of planning, organizing, monitoring and controlling resources to achieve specific goals. Participants in this class will gain the knowledge and tools necessary to plan, execute and complete complex projects within various types of organizations within the life sciences sector. The curriculum includes an in-depth study of the elements essential to initiate, execute and complete a successful project, including the development of interpersonal skills critical to conducting work in a team environment. Students will apply the tools and skills learned through a comprehensive "capstone" experience at the conclusion of the course.

Quality Assurance

This comprehensive course focuses on the quality requirements for the production and control of pharmaceuticals and medical devices. It highlights the importance of implementing and maintaining a quality system during the early stages of product development, including the documentation and processes necessary to make a system effective per FDA guidelines. Participants will learn how to draft, issue and control standard operating procedures (SOPs), manufacturing instructions and how to review and archive relevant documents used in a quality system. Students will learn how to perform and/or respond to facility inspections and vendor audits, and will compile, write and archive audit reports.

Quality Systems

This course will provide professionals with the basic knowledge and skills needed to develop a quality system program that conforms to the FDA's Quality System regulation, including the required organizational structure, procedures, processes, and resources for implementing quality management. In addition, this course covers acceptable compliance practices, recognizing that quality system requirements may differ based on medical device classification and company size. Upon completion of this course, the participant will have completed a portion of the FDA's training criteria for its Accredited Persons Program.

Writing for the Life Sciences Industry

Technical communications, also known as technical writing, is a field in which writers translate complex scientific or technical information into content that a general audience will easily understand. Technical writing for life sciences companies includes drafting instruction manuals, standard operating procedures, responses to regulator and customer inquiries and other supporting documents that require industry-specific knowledge of a scientific, medical or engineering subject. This course will focus on writing techniques and strategies that will help an audience of general readers understand scientific and medical information. Students will read and analyze a wide array of contemporary science topics and perform both in-class and outside writing assignments.

Regulatory Affairs Survey

Regulatory affairs personnel are the first-line assurance that company products and documentation are in accordance with regulatory bodies worldwide. This course provides training to manage these activities and reviews FDA regulations, Good Pharmaceutical Practice principles and ethical considerations covering the development of drugs and dossiers for clinical trials and licensure. Coursework for the class will also describe the related functional areas of clinical research, product and process development, manufacturing and supply chain, and quality and compliance.

A Strategy for Increasing Worker Knowledge and Productivity

For many years, a bachelor's degree has been adequate for many entry-level positions within the life sciences industry. However, because of accelerating changes in scientific fields and the shifting requirements of customers and regulators, companies will need future workers to be better educated on industry-specific issues and processes so that they will become more productive, more quickly in their new positions. Feedback from local employers indicates that post-baccalaureate, industry-directed coursework would be an effective strategy for increasing employee knowledge and productivity. BioCrossroads recommends a concentrated effort to deliver a new type of life sciences-related professional coursework. The coursework, developed and delivered by higher education institutions with direct input from life sciences companies, would provide Indiana professionals with the subject matter expertise they will need to be equipped to enter and grow in this promising industry.

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