Cultivating talent for Korea's biopharmaceutical industry

Eunjoo Pacifici, PharmD, PhD
International Center for Regulatory Science
University of Southern California
(http://regulatory.usc.edu/)

The Korean biopharmaceutical market is rapidly expanding and undergoing a transformation from an emerging market to a developed market [1]. In a similar fashion, Korea's biopharmaceutical industry is striving to transition from primarily focusing on generic products to discovering and developing innovative products. On the surface, this transition seems like a natural progression for a country that has been advancing rapidly on many fronts. Around the world, Korean cars roam the roads and highways and Korean appliances reside in homes and businesses. Domestically, Korean healthcare is the envy of the world and Korean students consistently rank at the top. However, this next evolution, to discover, develop and commercialize innovative medical products, poses new challenges that will require Korea to implement changes across a number of different areas, including a new approach in educating the next generation of professionals to meet the demands of this complex industry.

Follower to leader

Korean pharmaceutical industry has historically focused its efforts on manufacturing generic versions of products that were developed by foreign companies. This paradigm requires the industry to faithfully reproduce what has already been created by emphasizing quality and efficiency rather than creativity and innovation. For Korea to pivot its focus to usher in a new era of innovation in this field, it will need professionals who are creative thinkers and can navigate through the uncertainties of a high stakes enterprise that brings together science, law, and business.

To transition from being followers to leaders, Korean biopharmaceutical industry must have adequate access to the right talent. How is Korea positioning itself to develop the talent to meet this need? Does Korean educational system promote innovative thinking whereby students are exposed to diverse opinions, allowed to challenge the establishment, and encouraged to cultivate individual initiatives? Do Korean classrooms create a culture of interactive learning in which the students are taught to engage in professional exchange of ideas with their professors as well as with their peers? Are they given ample opportunity to collaborate on complex projects in groups that mirror cross-functional teams frequently seen in the industry? This horizontal or "flat" communication model, which may be in direct contrast to the vertical or hierarchical "Confucian" model that underpins many facets of Korean society, may be more effective in propelling the students to be engaged, collaborative, and creative.

Why is this industry different from others?

Fostering innovation in the biopharmaceutical industry requires the ability to operate at the frontiers of knowledge, where there are vast uncertainties and great number of failed programs. After all, most molecules, thought initially to be promising new drug candidates, fail at various points during the development process. Identifying the opportunities amidst this treacherous landscape requires certain level of courage and the ability to be relentless in the face of failure. Importantly, the ability to learn from these failures is an integral part of an iterative scientific process that is essential in order to elucidate the mechanisms of disease or optimize the design of the next experiment. Does Korean education system promote the concept that failure is an inherent part of an innovation process, or instead, does it cultivate an industrious but risk-averse environment? Although many have tried, scientific discovery cannot be industrialized. High throughput screening, combinatorial chemistry, and research automation can industrialize specific processes but the key scientific activities involved in research strategy, hypothesis formulation, experimental design, and data analysis require curiosity, critical thinking, and individual initiative. Moreover, many of these activities require working in a cross-functional interdisciplinary environment. Hence, the field needs individuals who can lead project teams that span across different functions and companies; and, in the case of global teams, different regions of the world.

The biopharmaceutical industry is highly regulated in almost all aspects of its business, from manufacturing and nonclinical studies to human clinical trials and marketing. Therefore, the work requires trained professionals with the regulatory knowledge and expertise to successfully navigate through a complex maze of international regulatory landscape. Increasingly, there is a convergence of regulatory strategy, business strategy, and scientific strategy, and, therefore, a leader in this field must be able to work across all three interfaces (Figure 1). An effective educational program must include cross training for individuals with a scientific background to become adept in business and

knowledgeable in regulatory [2]. The goal is to produce leaders who can translate scientific findings to clinical candidates and, ultimately, to commercialized products with desired benefit risk profiles that would meet the needs of patients. These leaders must be able to work within their own organizations as well as with outside entities including corporate partners, contract research organizations (CROs), non-profit organizations, academia, regulatory agencies, and payers. The necessary skillset goes beyond scientific proficiency, although this is important in an industry that embraces science as its core business. Increasingly, a high value is placed on those individuals that can network, collaborate, and cross-fertilize to bring a project forward by assembling and managing the right people. Being a brilliantly smart person is not enough to be successful in this industry, since no one person can take a molecule from discovery through development and commercialization. It takes teamwork. And success will follow those that can operate seamlessly within a wide network of specialists to orchestrate complex projects across different therapeutic areas, modalities, and platforms to develop products that meet scientific, regulatory, ethical, and business needs.

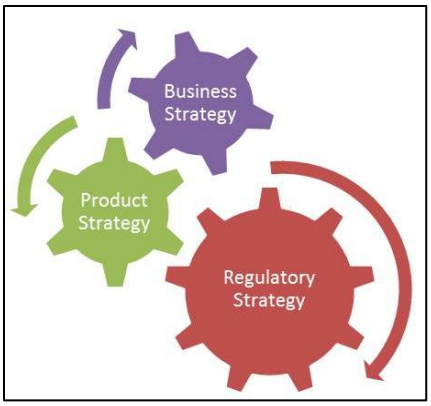

Figure 1. Role of regulatory science in product and business strategy

Need to innovate to survive

Having a finite patent life forces biopharmaceutical companies to innovate in order to replace the revenue that is lost following patent expiration of a marketed brand product. In United States, the steep "patent cliff" results in the precipitous erosion of a product's revenue within a short period. This is due to the presence of an abbreviated regulatory pathway for generics and the prevalence of generic substitution by pharmacists. A case in point is the 2011 US patent expiration of Pfizer's top selling product Lipitor®, which resulted in a loss of $5.5 billion in revenue during the first 9 months of 2012 [3]. A new product that receives regulatory approval has a limited period of market exclusivity during which time the company must maximize its sales, fill the pipeline with other promising candidates, and develop a life cycle strategy that may include second and third generation products.

Having a proper frame of reference

The Korean pharmaceutical regulatory history is relatively short, going back only about twenty years to 1996 when Korea Food and drug Safety Headquarter and six Regional Offices were established [4]. Being a latecomer has the advantage of learning from others that have already gone before and have laid down a path to be followed [5]. The downside is that the latecomer may be adopting systems that have been established by others without fully appreciating how those systems came about. For example, the United States Food and Drug Administration (FDA) has been in place for over a hundred years during which time key regulations were implemented as responses to now famous scandals: 1906 Food and Drug Act in response to adulterated and misbranded products that were widely available; 1938 Food, Drug, and Cosmetic Act in response to deaths that occurred following ingestion of sulfanilamide formulated in diethylene chloride; and 1962 Kefauver-Harris Drug Amendments in response to the Thalidomide tragedy. These events gave rise to the modern regulatory framework including Current Good Manufacturing Practices (cGMPs), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP).

As the regulatory landscape continues to evolve in response to changing public health needs, a thorough understanding of the past history as well as current developments in regulatory science is imperative and should include not only knowing "what" and "how" in terms of regulatory compliance but also understanding "why" various regulatory requirements were put in place. It would be helpful for Korean students and industry professionals to have a good working knowledge of the US regulatory framework since it is the oldest and is the basis for many others that are implemented around the world. Becoming proficient in the US regulatory system will enable the students to more fully grasp principles and concepts that are behind key regulations in Korea as well as in other countries.

Challenges of drug development

Biopharmaceutical product development process is often depicted as discreet sequential activities designated as discovery, preclinical, clinical (phases 1-3), and commercialization. But in reality, the process should be viewed more as a continuum. Innovation in this sector requires iterative cycles of scientific investigation, especially during the early, "proof-of-concept" phase when data are analyzed to gain greater understanding to inform the next iteration

(Figure 2). In challenging therapeutic areas, such as neurodegenerative diseases, there is much that is still unknown and, hence, the scientific inquiry must focus on gaining a deeper understanding of the mechanism of disease and potential points of intervention. Working in drug development is not for the faint-hearted or the impatient. The drug development landscape is scattered with product candidates that have failed across many therapeutic areas and all phases of development. The most expensive failures, those that fail during phase 3 or beyond, are the ones that are most difficult for the companies endure both financially and strategically. These scenarios are all too familiar to those who have been observing or working in the industry for many decades in US or Europe but may be new to those working in the Korean biopharmaceutical industry.

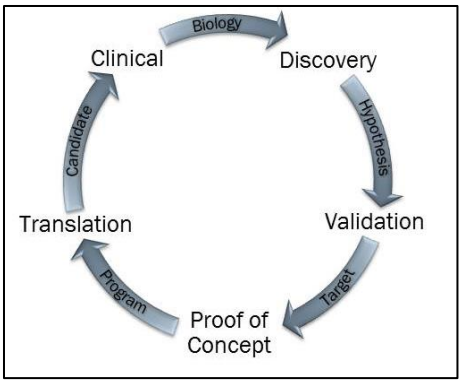

Figure 2. Drug development cycle (figure courtesy of Dr. Robert Pacifici)

The biopharmaceutical industry is a highly risky business but the potential benefits are immense for companies that are ultimately successful in developing innovative products and for patients who gain access to new therapies. Innovating in this space requires making decisions that are science-driven and patient-centered. Furthermore, it will require individuals with the knowledge, intellect, and interpersonal skills to lead project teams through uncharted territories, at the risk failing at every turn, while remaining focused and relentless in their quest.

Many companies are placing increased emphasis on external partnerships as they reengineer their R&D model. As such, talent development efforts in this new era need to consider the skillsets necessary to properly manage and evaluate projects involving multiple partners. This would be true for many Korean companies, where looking outward for product opportunities would make better sense than building large research and development capabilities internally.

Building an effective talent pipeline

So what would be the best way to develop the necessary talent pool to enable Korea's biopharmaceutical industry? I do not claim to have the solution. What I can provide is my perspective as an educator at the International Center for Regulatory Science (ICRS) at University of Southern California where our goal is to provide the next generation of regulatory scientists with knowledge, tools, and skills to expedite the development of innovative, safe, and effective biomedical products. Prior to entering academia, I worked in the biopharmaceutical industry, initially in the clinical research group managing US clinical trial sites and central laboratories before changing my focus to product development in the Asia Pacific and Latin America where I interfaced with local clinical and regulatory staff in Japan, China, Taiwan, Australia, Canada, and Mexico. When I was initially contemplating to work in a biopharmaceutical company, there weren't any academic programs designed for students interested in an industry career path. My training up to that point included basic research in an academic laboratory and clinical pharmacy in community and hospital settings. I had no idea about how a discovery generated in the laboratory would be translated into a therapeutic intervention in the clinic. Without an available academic program that addressed the needs of the industry, I obtained my training on the job. This was the case for most of my peers in the industry. Unfortunately, on-the-job training tends to be too narrow, focusing on the immediate workplace or project needs, rather than providing a broader context or interdisciplinary overview. However, my tenure in the industry did provide me with a great experience and an insight into all the career opportunities that are available in this exciting and rewarding field. Therefore, I was delighted to join as a faculty of ICRS to develop a tailored education to meet the needs of students who are choosing a career path in the medical product industry. It is gratifying to see our students receiving valuable training and then going on to secure positions and thrive in their careers. It is also reassuring to see the top two areas of our educational focus, interpersonal skills and regulatory science, recognized as those most needed by the industry [2].

Our Master of Science Programs in Regulatory Science and in Management of Drug Development are designed to prepare students for professions that depend on a blend of science, management, and law. Our students are a mix of those entering the regulatory science or drug development industry for the first time, usually out of a university environment, and those who are currently working in the regulated industry sector. We have considerable input from industry speakers who lecture in our courses and share current information and first-hand experience with our students. As a program geared to train the future professionals, great emphasis is placed in cultivating interpersonal

skills and both written and oral communication skills that will enable the students become effective in their work (Figure 3). Our courses provide comprehensive coverage of the field that will allow the individual to participate in the advancement of therapeutics (drugs, devices, and preventatives), clinical interventions, and behavioral modifications to improve health outcomes in a manner that is scientifically sound, ethical, and aligned with a clear regulatory strategy. We are also developing a new MS in Quality to address market needs for such a program and identified a large unmet need in the area of medical device and pharmaceutical quality for talented individuals with the potential to grow as leaders.

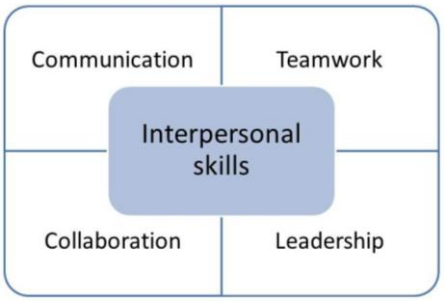

Figure 3. Essential skills for the biopharmaceutical industry

I look around my classroom and see a diverse population of students: working professionals from nearby and faraway companies, students who are just out of undergraduate education from colleges in US, India, Canada, China, Taiwan, Vietnam, Venezuela, etc., eager to learn and enter this exciting field. But, interestingly, I rarely see students from Korea. It is especially puzzling since I understand that Korea is working to transform its biopharmaceutical industry and, as such, a comprehensive education in regulatory science would be an important component in the process. It may be that there is a general lack of awareness of the regulatory science discipline. This is understandable since it is a new discipline and has only recently started garnering recognition in the US. It may also be that a Master's program geared to train student to work in the biopharmaceutical industry may not be as attractive as a Ph.D. program in the eyes of the Korean students and their parents. In reality, a Ph.D. education by itself may not be a good fit for many who lack the capacity or the interest to run a research laboratory as an independent investigator. On the other hand, students with educational background in life sciences, biomedical engineering, or health sciences could further their education in regulatory science and secure satisfying positions as professionals in the biopharmaceutical industry. The global biopharmaceutical industry generates a trillion dollar in annual revenue and the global medical device industry earns almost half of that at 500 billion dollars. When these figures are compared to the annual budget of the US National Institutes of Health, which has remained at around 30 billion dollars for many years, it is easy to see that career opportunities in the biomedical industry are far greater than those in the academic research. In fact, competition for talent is a critical issue for the top multinational biopharmaceutical companies with 51% of industry leaders reporting that hiring has become more difficult for them and only 28% expressing confidence that they will have access to top talent [2].

Building an effective talent pipeline to meet the needs of Korean biopharmaceutical industry will be key to its success. The Korean government can enable this process by identifying and implementing educational programs in areas that foster innovation. And it should include providing a select number of students and industry professionals with a fellowship abroad to obtain education in countries that have a mature regulatory structure. For this purpose, the US seems ideal in that it has the oldest and most established regulatory agency, is the largest medical product market, and is the center of biopharmaceutical innovation. Incorporating a year abroad would not only allow the students to become more knowledgeable in international regulatory science but would also immerse them in a multicultural classroom setting where they can gain valuable training in communication and interpersonal skills (Figure 4).

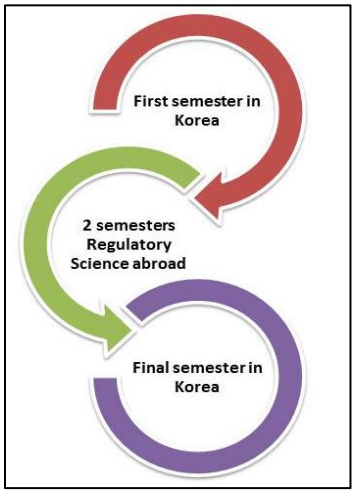

Figure 4. Incorporating regulatory science study abroad

Reference

1. Sackman, J.E., *Report from: South Korea.* Pharmaceutical Technology Europe, 2013. **25**(8): p. 18-19.
2. PwC Health Research Institute *New chemistry: Getting the biopharmaceutical talent formula right* 2013.
3. *Pfizer: Lipitor Vanishing Revenue*. Seeking Alpha 2012 [cited 2015 February 23]; Available from: http://seekingalpha.com/article/983801-pfizer-lipitor-vanishing-revenue.
4. Ministry of Food and Drug Safety. *About MFDS: History*. 2015 [cited 2015 February 27]; Available from: http://www.mfds.go.kr/eng/index.do?nMenuCode=9.
5. Johann, D., *The reconfiguration of a latecomer innovation system : governing pharmaceutical biotechnology innovation in South Korea*. Emerging markets studies. 2013, Frankfurt am Main: Peter Lang. 301 pages.