COMMENTARY

The Future of Pharmaceutical Engineering

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Received 25 April 2003; revised 7 August 2003; accepted 11 August 2003

The healthcare industry is changing. Unmet medical needs, an aging population, rising healthcare costs, and sparse pharmaceutical pipelines are forcing healthcare companies to reevaluate their competitive strategies. Also, consumers are playing a larger role in healthcare. Patients are more knowledgeable and assertive regarding their individual healthcare decisions and are putting additional pressure on the industry to lower cost through innovation.[1] The healthcare sector, comprised of pharmaceutical, biotechnology, medical device companies, government agencies such as the Food and Drug Administration (FDA), healthcare providers, insurers, and consumers, is a dynamic and unique entity, rapidly moving towards highly automated and electronic environments in which the storage, management, and use of complex information is essential for success.

Pharmaceutical companies lie at the center of America's healthcare debate. In response to market and regulatory forces, the industry is restructuring, consolidating, and reevaluating their competitive strategies. The cost to bring a single new drug product to market has steadily increased to \$500–\$800 million.[2,3] As much as 75% of the total cost of each marketed drug is attributed to high failure rates of other candidates due to efficacy and safety problems.[4] The high risk of drug development places increased pressure on all levels of the organization to reduce cost and increase productivity. From identifying candidate failures sooner in the research and development (R&D) process[5] to maintaining manufacturing compliance with federal regulations and improving efficiency, pharmaceutical companies are actively searching for innovative solutions to these complex problems. Decreasing a promising candidate's time to market in drug development is especially important due to dwindling patent protection, increased generic competition, and early introduction of competitor's "me-too" products. Increasingly, technical and scientific decisions are coupled with business, legal, and marketing priorities. Corporate strategy, generally aimed at identifying and producing blockbuster drugs, may be shifting toward strategies targeting smaller patient populations with safer and more effective medicines through pharmacogenomics.[1,6] Genomics and other biotechnology tools are beginning to find their way into large pharmaceutical companies as biotech products start to compose a significant portion of many companies' pipelines.[7] However, the integration of biotechnology with the pharmaceutical industry will require significant changes in R&D and manufacturing strategies.[4]

Industry experts cite the need for quality and efficiency to be built into each area of drug discovery, development, and manufacturing. New FDA initiatives are promoting quality and efficiency by implementing a risk approach through continuous assurance programs. To help prevent the production of poor quality products, programs such as quality manufacturing operations, risk assessment, and risk management are being implemented.[8,9] The integration of discovery, development, and manufacturing and increased interaction among industry, academia, and government are avenues to improve efficiency within the healthcare sector.[5] This drive for improved product

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Journal of Pharmaceutical Sciences, Vol. 93, 235–238 (2004)

quality and process efficiency within the industry is increasing the demand for new crossfunctional scientists and engineers to tackle difficult and complex problems. Today's pharmaceutical scientists and engineers are found working in the pharmaceutical, biotechnology, and medical device industries. Informatics, high-throughput screening, simulations, and process analytical technologies (PATs) are some examples of current and new science and technology tools that are affecting the way in which discovery, development, and manufacturing of therapies, diagnostics, and devices are performed.[5,8]

Developing new and innovative graduate research and training programs in Pharmaceutical Engineering is necessary to educate and train the healthcare industry's future technical leaders. Such programs are a means to provide the foundation for developing crossfunctional skills in engineering, life sciences, regulations, and management as applied to the pharmaceutical, biotechnology, and medical device industries. Through academic and practical training, students should be exposed to different aspects of the healthcare industry early in their careers by providing them the opportunity to learn from members of industry, academia, and government. This exposure will allow students to better understand the complexities involved in this constantly changing, technology-driven environment. Students can enhance their technical knowledge within pharmaceutical and biotechnology industries through practical training in discovery, process development, formulation, and manufacturing. Additionally, they can gain knowledge in social, regulatory, legal, and business aspects of the healthcare industry through formal and informal active participation in frequently held discussions. Interdisciplinary programs emphasizing the development of crossfunctional skills will give students the education and training needed to succeed in bringing innovative and practical solutions to the future healthcare industry.

In the true spirit of crossfunctional training and learning, programs should be available to eligible students from a variety of undergraduate backgrounds with solid fundamental engineering and science training. In a properly structured and demanding environment, diverse backgrounds foster innovative and "out-of-the-box" thinking among students. For the successful implementation of a strong, interdisciplinary degree program in Pharmaceutical Engineering, a three-tiered approach may be used. First, a strong engineering and scientific foundation will provide the backbone to each individual student's course of study. Second, additional academic courses in statistical analysis, risk assessment, intellectual property, corporate business strategy, and technology development will elaborate on the student's academic core. Knowledge gained from these courses will be crucial components for decision making at all levels of an organization. These classes, coupled with several seminar/lecture series on current health science and engineering-related topics will create a solid platform from which the student can advance into the third and final component of practical training. Hands-on industry experience will pull together the students' prior studies and experiences to instill the foundation for advanced crossfunctional thinking. To develop the future technical leaders for the pharmaceutical and life science industries, new Pharmaceutical Engineering programs should emphasize the development of both technical and "soft" skills to prepare the students for a competitive and teamwork-driven environment. Universities with strong engineering, pharmacy, medical, business, and law colleges are ideal institutions to administer such strong interdisciplinary graduate training and life-long learning programs. Successful programs should incorporate collaboration with industrial partners who are willing to provide technical and financial resources along with practical training opportunities for students. Recruitment of students should come from both undergraduate science and engineering programs and industry. Recent graduates will benefit significantly from a learning environment that includes working professionals with varied educational backgrounds and experiences.

Figure 1 illustrates the broad realm of disciplines involved in pharmaceutical discovery and development. In the past, more traditional curricula in Pharmaceutical Engineering, or Industrial Pharmacy, have been narrowly defined, focusing education and training on the late-stage development and manufacturing processes. Future pharmaceutical engineers should be trained more broadly, learning the roles they can play as crossfunctional technical leaders and managers in a variety of job functions depicted on this pharmaceutical and biopharmaceutical discovery and development process flow diagram. This includes pharmaceutical/clinical development and manufacturing, as well as discovery and early-stage development operations. The need for well-trained engineers in all disciplines of pharmaceutical discovery and development is increasing as the scope

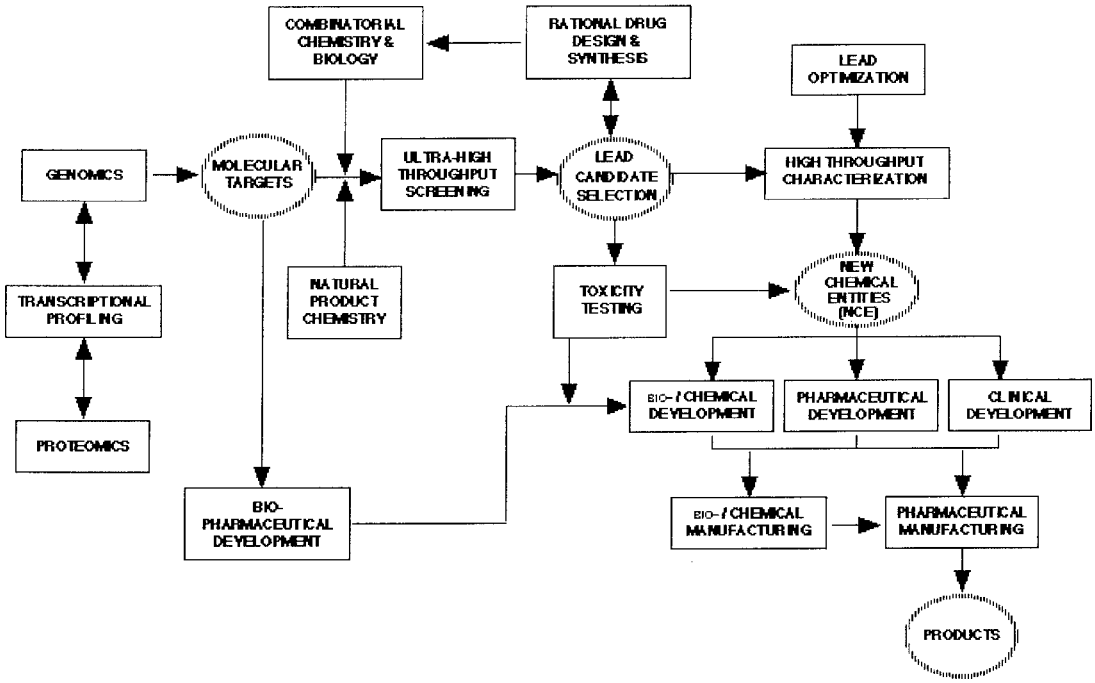

Figure 1. Modern pharmaceutical discovery and development process.

of therapeutics expands beyond small molecular weight compounds to new and more complex biopharmaceuticals and combination therapies. The convergence of the biomedical device and drug markets has led to the development and manufacture of innovative products such as drug eluting stents for cardiovascular disease treatment. The possibilities of combination products and therapies are endless as healthcare companies move from disease treatment toward disease management.[1] The increased complexity in healthcare products has further emphasized the demand for crossfunctionally trained and technology-driven professionals.

Upon graduation, new pharmaceutical engineers may find themselves supporting drug discovery and/or development with high throughput screening (HTS) procedures, total quality management (TQM) to reduce false positive and false negative results, and developing computational tools in bioinformatics or cheminformatics. Examples of specific projects in pharmaceutical/biopharmaceutical development that may be led by pharmaceutical engineers include the development of experimental and computational tools for biopharmaceutical and pharmacokinetic parameters (ADME) and toxicology evaluation to reduce drug candidate failure. These pharmaceutical engineers may also be involved in developing quantitative models and process analytical technology (PAT) tools for evaluation and scale-up of pharmaceutical solids and semisolids unit operations. In the areas of pharmaceutical and biopharmaceutical manufacturing, pharmaceutical engineers will be concerned with current Good Manufacturing Practice (cGMP) compliant operations, as well as the introduction and implementation of robust PAT tools for process and product validation and continuous improvement. In addition to quality management, Pharmaceutical Engineering graduates may also use their knowledge and expertise to participate with policy-making and regulatory agencies such as the FDA.

As the healthcare industry continues to face significant challenges, pharmaceutical companies in particular have an increased demand for technically competent leaders throughout the entire discovery, development, and manufacturing processes. This complex and evolving industry requires innovative technologies and improved knowledge of cutting-edge science to overcome the challenges ahead. New interdisciplinary Pharmaceutical Engineering graduate education and training programs have the potential to produce tomorrow's leaders with the technical knowledge and skills needed to meet the challenges presented by the evolving healthcare industry. It is these leaders who will define the Pharmaceutical Engineering discipline and ultimately help to shape the future of the healthcare industry.

REFERENCES

1. Pharma 2005: Marketing to the individual. IBM Business Consulting Services; 2002.
2. Pharma 2005: An industrial revolution in R&D. IBM Business Consulting Services; 2002.
3. Tufts center pegs cost of a new prescription medicine at $802 million. Tufts Center for the Study of Drug Development; 2001.
4. A revolution in R&D: How genomics and genetics are transforming the biopharmaceutical industry. Boston Consulting Group; 2001.
5. Pharma 2010: The threshold of innovation. IBM Business Consulting Services; 2002.
6. Outlook 2003. Tufts Center for the Study of Drug Development; 2003.
7. Pharma 2005: Silicon rally: The race to e-R&D. IBM Business Consulting Services; 2002.
8. Pharmaceutical cGMPs for the 21st century: A risk-based approach. US Food and Drug Administration. http://www.fda.gov/cder/gmp/index.htm.
9. Process analytical technologies (PAT) initiative. US Food and Drug Administration. Center for Drug Evaluation and Research. http://www.fda.gov/cder/OPS/PAT.htm.