NIPTE

National Institute for Pharmaceutical Technology and Education

The goal of NIPTE will be to become the pre-eminent interdisciplinary national resource for research and education on science and engineering based understanding of pharmaceutical development and manufacturing. Scientists, researchers and engineers from academia, the FDA and the industry will collaboratively engage in developing state-of-the-art science and technology to enable the pharmaceutical industry to develop products faster, and at a significantly lower cost with less variability and higher predictability of performance.

Major Focus Areas
Pharmaceutical Development
Pharmaceutical Manufacturing
Process Analytical Technologies
Modeling and Informatics
Regulatory Science
Education

NIPTE The National Institute for Pharmaceutical Technology and Education
Improving Quality and Lowering Costs of Pharmaceuticals
The pharmaceutical industry, a sector in which the U.S. remains a global leader, is at a critical juncture. As costs in healthcare rapidly accelerate and the size of uninsured and underinsured populations continues to increase, the issue of drug prices has been moving to the center of the public agenda in America.

Development and manufacturing processes have become so complex that it is not feasible for the industry to provide drugs at significantly lower prices. A recent FDA report (FDA White Paper; March 2004) estimates that the cost of bringing a new drug to market can be as high as $1.7 billion, a 50% increase in just five years. During the same period, the number of new drugs submitted for FDA approval has declined by 50%. The industry increasingly concentrates on drugs with potentially high market return; many therapies of proven medical efficacy never reach the market if the target disease affects a small population (orphan/legacy drugs). Similarly, therapies for the Third World diseases receive a low priority.

While drug discovery engages the most sophisticated research tools and technologies, drug development and manufacturing paradoxically do not. Furthermore, due to the high cost of FDA re-approval and inadequate understanding of pharmaceutical materials and manufacturing steps, once approved, the manufacturing processes often remain unchanged.

Recently, the FDA has unambiguously identified inadequate drug development and manufacturing as the key causes of “an impending crisis in public health.” (FDA, 2004) Unless this situation is changed, safety concerns will not allow FDA regulatory practices to change and the current trend will continue for years to come.

Once the new drug discovery is made, product development and manufacturing are left to traditional “tried and true” practices because of the enormous business driver to rapidly bring the new drug to market. Furthermore, the interplay of tight FDA regulation to insure product safety, the high cost of re-approval of process innovations and inadequate science-based understanding of pharmaceutical materials and manufacturing steps insures that once a manufacturing process is approved, it is left substantively unchanged for the duration of the product life. As a result, the beneficial learning curves and associated progressive reductions in costs typical of products sold in unregulated markets do not occur. Instead, product costs only increase as energy, input materials, marketing and labor costs rise.

Finally, the results of this national research effort will be translated into educational programs and materials that will prepare the next generation of pharmaceutical scientists and engineers as well as regulatory staff who will lead in the transformation of the pharmaceutical industry to the benefit of all stakeholders.
What is NIPTE?

The National Institute for Pharmaceutical Technology and Education will address the current challenges in pharmaceutical development and manufacturing through a multi-university research partnership with the FDA and the pharmaceutical industry to dramatically change the way in which pharmaceutical products are developed and manufactured. The research program, executed in multidisciplinary teams of engineers, industrial pharmacists and scientists, will involve the following thrusts:

1) The development of science-based understanding of pharmaceutical materials and manufacturing processes.

2) The development of a cradle-to-grave approach to understanding of the factors that affect pharmaceutical product design and development, scale-up, performance, quality, and variability in manufacturing.

3) The creation of tools for model predictive-based methods for drug formulation and manufacturing process design.

4) Studying the pharmaceutical development and manufacturing process for the active pharmaceutical ingredients and the different types of dosage forms and drug delivery systems.

5) The development of novel manufacturing technologies that allow flexible manufacture of multiple products in the same device, in contrast to the dedicated, often batch-wise operated traditional devices.

6) The invention and demonstration of new sensing technologies that allow key product characteristics, sterility, and purity to be monitored continuously and controlled automatically.

7) Working closely with scientists in safety and medical utility to jointly develop the knowledge and strategies needed to reduce time to market throughout the entire drug development process.

8) Developing and providing a suitable educational program for scientists from the FDA and industry in the above areas.

The successes achieved in this research program will allow the design of pharmaceutical products and processes to achieve levels now experienced in other regulated industries such as the aircraft industry where entire aircraft is designed efficiently using predictive computer-aided design tools with minimum of trial and error. As a result, drugs will be brought from discovery to the patient requiring the therapy in dramatically reduced time and with significant cost savings. The coupling of science-based understanding of materials and processes with on-line sensing and control technology will enable consistent production of a high quality product while allowing processes to undergo continuous improvement and cost optimization. Furthermore, successes in the development of new flexible, multipurpose manufacturing technologies, will permit cost effective production of small volume “orphan” or “designer” products.
Our Vision

NIPTe will be the pre-eminent non-profit multi-university consortium for interdisciplinary research and education in pharmaceutical science, technology and engineering, with the goal of developing, manufacturing and delivering high quality pharmaceutical products faster, and at a significantly lower cost to the patient.

Our Strategy

1. Establish a multi-university organization in collaboration with the FDA with strong research programs in drug development, pharmaceutical manufacturing and regulatory science.

2. Establish a distributed network of Centers of Excellence at the participating universities. Many of these centers will be nucleated from already established centers or research concentrations.

3. Establish an administrative core to coordinate academic, industry and government activities.

4. Develop synergistic research programs in the areas of drug development, drug manufacturing, process analytical technologies, modeling and informatics, and regulatory science involving the universities and FDA employees.

5. Administer competitive peer review research funding programs.

6. Promote educational programs in all phases of pharmaceutical sciences, engineering and drug related regulatory affairs.

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