# Accelerating Biopharmaceutical Development

For the pharmaceutical industry, change is inevitable. Companies invest many years and many dollars in search of the next blockbuster drug, only to watch it disappear when the drug turns out to be ineffective. So how can this problem be resolved, and how can the development process be accelerated? This was the topic of discussion at the Society for Biological Engineering's (SBE) 1st International Conference on Accelerating Biopharmaceutical Development (Coronado, CA; Mar. 19–22, 2007).

Roger Perlmutter, executive vice president, research and development at Amgen, kicked off the meeting with an inspiring presentation titled "Conquering the Innovation Deficit in Drug Discovery." He noted that in the Jan. 4, 2007 edition of the *Star Ledger*, there was a headline blaring, "FDA Drug Approval at Lowest Rate Since VIOXX Withdrawal, Only 37 Treatments Received Federal OK." Perlmutter gave an even grimmer reality. "The truth is, there are only 16 new molecular entities." Yet, research and development investments have exponentially grown over the last decade. "The industry cannot continue down this path," proclaimed Perlmutter.

Unlike in the heyday of the pharmaceutical industry when there were "few interesting targets, room for many drugs and strong intellectual property, today's landscape is drastically different," said Perlmutter. Now, there are "thousands of targets, as well as rapid generic penetration. Furthermore, the industry is experiencing declining success rates and devastating product failures," he continued. Much of the fault lies in the ineffectiveness of preclinical trials. "Preclinical models, whilst informative with respect to biology, provide poor predictive information for human therapeutics," noted Perlmutter.

To conquer the innovation deficit, there must be a paradigm shift — different research priorities must be advanced. In particular, "we need to focus on grievous illnesses such as cancer and not just modest improvements," said Perlmutter. "We need to be prepared to exploit any treatment modality, such as proteins, small molecules, nucleic acids, cells. Furthermore, preclinical and clinical evaluation must be fully integrated, and human data needs to be brought to the forefront before we can truly achieve success," he advised.

In agreement with Perlmutter is Helen Winkle, the director of the Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA). In her presentation, "Regulatory Modernization," she noted that "little emphasis has been placed on manufacturing, even though it accounts for about 25% of expenses. Waste can be as high as 50%," she continued. Some of this waste, Winkle admits, is because the FDA assumed all responsibility for quality control, and may have set standards that are too restrictive.

But, the FDA is changing its ways. "Our desired state is to have a maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drug products without extensive regulatory oversight," said Winkle, quoting from Janet Woodcock, deputy commissioner, chief medical officer for the FDA. "Quality should be controlled by industry, while the FDA's role is to do an initial verification and subsequent audits," continued Winkle.

There are already drivers in place to make this "desired state" a reality. These include: Pharmaceutical Quality for the 21st Century Initiative; Critical Path Initiative; Quality by Design (QbD) Initiative; and Process Analytical Technologies (PAT) initiative.

While the industry appears ripe for change, care must be taken as to how much acceleration is possible, explained the conference's plenary speaker Anthony S. Lubiniecki, who serves as the vice president of technology transfer and project planning for Centocor R&D. "Much of accelerating development can be achieved by having a clear strategy that takes into account the tools available, the product needs, and the specific risks inherent in developing a given product by a given process for a set of indications," said Lubiniecki.

"Whether we work in large or small firms, we all need to master good development strategies, because in the final analysis, the patients are waiting for us to progress the products through development to make them available," he concluded.

## Call for Original Book Material

AIChE's New Books Subcommittee is looking for material for original books on chemical engineering and related fields, including bioengineering and biomedicine, nanotechnology, environment and sustainability, alternative energy technologies, microsystems engineering, and process safety and security. These books, if approved by the New Books Subcommittee of the AIChE Publication Committee in cooperation with John Wiley & Sons, will be published by the AIChE/Wiley Press.

AIChE's New Books Subcommittee, charged with acquiring, reviewing, and publishing original books on chemical engineering and related fields, is chaired by Dr. Joseph Alford, and its members consist of Drs. Thomas Edgar, Karl Schnelle, Patrick Mills, Jan Lerou, and Joel Fried, representing a broad spectrum of chemical engineering.

If you or any of your colleagues are interested, please contact Dr. Joe Alford at jmalford5@earthlink.net or Haeja Han at haejh@aiche.org.

## Sympathies for Virginia Tech

On behalf of the members and staff of AIChE, we extend our deepest sympathies to the families, friends, fellow students and faculty members of Virginia Tech. The tragic events of April 16, this unspeakable loss of so many lives, deprives us all of the talents and abilities these students and teachers brought to our world.

A tragedy such as this does not discriminate, but our profession especially mourns the loss of chemical engineering student Maxine Turner and the contributions she would have made. Let us honor Maxine and the other victims of this senseless act by renewing our commitment to work that improves the lives and well being of humanity.

**Larry Evans**
**AIChE President**

## Faculty Directory 2006–2007

**The Chemical Engineering Faculty Directory 2006–2007**

Developed by the AIChE's Chemical Engineering and Educational Projects Committee, this directory lists the most current mail and e-mail addresses, as well as phone numbers for all chemical engineering faculty members at nearly 500 universities and technical institutes worldwide. As a new feature in this edition, the research interests of each professor have been added to the directory.
*Published March 2007; 266 pages; ISBN: 978-0-470-14782-5; Price: $150; Members receive a 20% discount. To place your order online, go to www.wiley.com/go/aiche and use the discount code AIChE.*

## IN MEMORY OF ROBERT M. VILSACK JR.

The North Jersey Section of the AIChE mourns the loss of Robert M. Vilsack Jr. Bob passed away at his residence on March 12, 2007. He was 74. A former Chair of the North Jersey Section, Bob was also active in the New Jersey Section, a member of the American Chemical Society and the Montclair (New Jersey) Society of Engineers. Subsequent to graduation from Carnegie Technical School (Carnegie Mellon University) with a degree in chemical engineering, Bob served as an officer in the U.S. Army Corps of Engineers during the post war recovery in West Germany. In addition to obtaining an MBA from Rutgers University, he attended New York University and Stevens Institute of Technology for a variety of continuing education programs. At the time of his death, Bob was employed as an account executive and engineer for EI, Inc., located in Cedar Knolls, NJ. Prior to EI, Inc., Bob was employed by Bechtel, Rhodia, Shell Oil and Stauffer Chemical.

Bob was a "go to" man for the North Jersey Section. He could be counted on to provide dinner meeting topics, unique meeting locations, such as brewery tours, professional contacts, event sponsors, as well as employment advice and contacts for members. Additionally, Bob was responsible for recruiting many chemical engineers into active involvement in the AIChE.

Robert Vilsack Jr. was a rare type of individual who served as a model of Institute involvement, getting the job done with little fanfare and notoriety.

Bob is survived by Dolores Vilsack, his loving children, Barbara, Carol, Robert M., Christopher and grandchildren Clair and Frederick Meyer.

Those wishing to honor Bob are requested to send donations to:

**American Diabetes Association**
**1701 North Beauregard Street**
**Alexandria, VA 22311**

## AIChE Conference Calendar

For information and registration details, visit www.aiche.org/conferences or call Customer Service at 1-800-242-4363 or 1-203-702-7660 (outside the U.S.)

**SBE's 3rd International Conference on Bioengineering and Nanotechnology (ICBN)**
August 12–15 • Biopolis, Singapore

**2007 Ammonia Conference**
September 16–20 • Loews Lake Las Vegas • Henderson, NV

**2007 AIChE Annual Meeting**
November 4–9 • Salt Palace Convention Center • Salt Lake City, UT

**2008 SBE's International Conference on Stem Cell Engineering**
January 20–23, 2008 • Coronado Island Marriott Resort • Coronado, CA

**2008 Spring National Meeting**
April 6–10, 2008 • Hyatt Regency New Orleans • New Orleans, LA