According to the Bureau of Labor Statistics, the number of jobs in clinical research and pharmaceuticals is expected to increase by 24 percent from 2006 to 2016.Demand for this industry's products is expected to remain strong.

Bringing Drugs to Market

In an industry where time can translate into big financial gains, clinical trial specialists know how to move new therapies from the lab to the marketplace more effectively.

WORDS BY EVE JACOBS / PHOTOGRAPH BY JOHN EMERSON

Moving a new drug or medical device from the laboratory to the marketplace takes from five to 15 years, an average estimated cost of $800 million plus, and a host of clinical research professionals with the expertise to complete the work.

With potentially big profits at stake, and the drug and device development industries in full throttle, the need for highly trained and knowledgeable professionals to do the work is growing. This recognition was the impetus for a unique collaboration between UMDNJ's School of Health Related Professions and Merck to develop and launch a post-baccalaureate Web-based certificate program to better train those already working in clinical trial sciences and to prepare those thinking of entering the field. The initial certificate program — in recruitment sciences — enrolled its first 11 students, all from Merck, in 2006. According to Barbara Gladson, MS, PhD, director of the BioPharma Educational Initiative at UMDNJ, two additional certificate programs, in regulatory affairs and clinical data management, were launched in 2007. In 2009, the University began offering a master's degree, with specialization tracks in clinical trials management and recruitment sciences, clinical trial informatics and regulatory affairs.

Many of the program's faculty members work in industry, according to Gladson. "They bring their specialties to the table. Also, as regulations change, the faculty changes the content of the courses—keeping everything up-to-date. They can also guide students in their job search," she says. Gladson and Admissions Director, Robin Ratkowski, MSJ, also teach courses.

Taking new drugs and medical devices from the laboratory to the marketplace is an industry that has quietly been gaining momentum in New Jersey, the country and globally. The hoped-for result—a new and better medical therapy — is the end point of a long process that starts with a scientific finding, which is then tested extensively in a laboratory using animals and human cells, and finishes with large-scale human trials to prove the value and safety of the new drug or device. On the way, reams of data are collected, analyzed and interpreted; study design is drafted and revised, often multiple times, to ensure the safety of participants and the quality of the collected information; governmental regulations must be followed and stages of approval met; and appropriate research participants need to be recruited within a defined time period and maintained in the study. A misstep can prove extremely costly and even deadly.

CenterWatch — the largest online database of clinical trial s—lists "more than 80,000 active clinical trials seeking volunteers each month," according to its Website.

For each of these, several phases of human clinical trials must be completed, ranging from Phase 1, involving just 20 to 100 volunteers, to Phase 3, which often lasts years and can involve thousands of participants at multiple sites across the country or world. Each phase must be completed, and the data submitted to the FDA and approved, before the next segment can be started.

"Word of mouth keeps students coming here," says Ratkowski, who is an assistant professor of clinical trial sciences. "In this economy, in order to move up or even keep your job in this field, you need to be competitive." Among the pharmaceutical companies whose employees have found value in the certificate and master's programs are Imclone, Regeneron, Johnson & Johnson, Merck, Celgene, Sanofi, and Daiichi Sankyo. From 2010 to 2011, the number of students doubled from 35 to 72.

"There is no magic background for someone interested in this field," says the admissions director. GREs are not required, but a goal/mission statement, a resume, and reference letters from employers must be submitted. "We look at the undergraduate degree, but many of our applicants went to college years ago. Work experience is very important."

The majority of students have studied biology, but others have degrees in such areas as psychology, nursing, public health, engineering and medical/technical writing. "Strong science training is a plus but not required. Nursing is a good background for this work," comments Ratkowski. Although the majority of students are New Jersey residents, others are from California, North Carolina, Boston, Philadelphia and Canada.

"There are a variety of positions available in the clinical trials field," she states. "Entry level jobs command a salary of $65,000 to $85,000, similar to some other entry level allied health positions. One of our current MS students in Regulatory Affairs, who is close to completing her degree but has no prior industry experience, was just hired for an entry level position as a Regulatory Affairs Specialist at a medical device company in southern New Jersey."

Students who complete one of the 15-credit certificates can apply all of those credits towards the master's, moving them a giant step closer to attaining a graduate degree. That's what Lisa Palladino Kim did. With an undergraduate degree in psychology from West Chester University in Pennsylvania, she worked in the mental health field for five years before joining Merck's Clinical Neurosciences Department in Pennsylvania about 12 years ago. During those 12 years, she gained experience primarily from three departments: clinical, data management and operations. Currently, as a Global Trial Operations Specialist (formerly called a Patient Recruitment Specialist), her focus is creating strategies and tactics for patient recruitment and retention, as well as managing a group of consultants who provide operational feasibility, and she describes herself as largely "self-taught," that is until she heard about the UMDNJ program.

(L – R) ADMISSIONS DIRECTOR **ROBIN RATKOWSKI** AND **BARBARA GLADSON,** DIRECTOR OF THE BIOPHARMA EDUCATIONAL INITIATIVE AT UMDNJ

It took her two and a half years, basically one course at a time, to complete a certificate in patient recruitment, which she found "very helpful for my position." She is applying the credits from her certification towards a master's degree in clinical trial sciences and will have seven courses completed by January. The online program demands "a big time commitment," she says, but she can log on from home when her life gets quiet, rather than traveling to attend scheduled lectures.

"I learn more and retain more from online courses because of the scheduled online discussion sessions; I think the actual demands on my time are greater in terms of reading and posting to the Web," she states. Kim hopes to finish her graduate degree in two years.

Most of Kim's current work actually takes place prior to the first volunteer being entered into the clinical trial. She collects input from investigators around the world on how the protocol is written and if the trial will actually work given the demands on patients. "For instance, we may need to determine if we can recruit patients to go through five lumbar punctures or whether that is too excessive," she says. "What we find can change the study design—how the trial is conducted. Or we might address how to recruit volunteers faster, thus condensing the overall recruitment timelines." She has been involved in creating an "Investigator Consultation Network for submitting operational feedback prior to protocol approval."

Kim describes the content of the UMDNJ certificate program as "dead on" in terms of teaching her what she needs to know to do her job. "But this program is not like other company certificate programs, which are more basic," she says. "This is a very intensive program and requires a real commitment."

Patient recruitment and clinical operations are at the heart of a clinical trial's success or failure. "Determining protocol feasibility is crucial," Kim states, "so there is definitely a market for what I do, but the competition for jobs is strong." Her graduate education should position her to excel in this rapidly developing field.

For more information on this program, call: 973-972-6482 or email: biopharma@umdnj.edu. Or go to the Website: http://shrp.umdnj.edu/dept/biopharma/ ■