USC pharmacy program targets drug development

By Laura Sturza, October 2, 2012

If you’ve ever had sticker shock at the pharmacy, you may have wondered why the price was higher than a pair of tickets to a Trojan football game.

And if you purchased a new drug, it probably took about 15 years to bring it to market, following an expensive, rigorous path from new idea to clinical testing, Federal Drug Administration (FDA) approval, and, finally, reaching the public.

The escalating investment in time and resources needed for successful discovery and development of new medications is a serious unmet medical need, demanding professionals to ensure a safer, faster and better course to bring new drugs to the patients who need them.

To educate these professionals, the Regulatory Science program at the USC School of Pharmacy has launched the MS in Management of Drug Development (MDD), a novel degree program designed for students with a background in preclinical biological and pharmaceutical science.

Since it can cost a billion dollars or more to develop one drug, and those that are tested are more than 90 percent likely to fail, “there’s an urgent medical/business need for professionals adept at innovating this process,” said Daryl Davies, MDD program director. “Our unique program will make people highly employable.”

The MDD is ideal for people with a background in science or those already working in the pharmaceutical industry who want to advance their careers.

“They want to be team leaders, they want to drive research,” Davies said. “They are the people who can put regulatory and basic science together.”

MDD students take on projects, such as working for a mock company and following a drug’s development from conception to market — if it makes it to market. The teams also explore the potential hurdles they’ll jump with real-world employers.

Once a drug’s basic structure is developed, the real work begins. People graduating from the MDD program will be ready to discover how a new drug works in the lab and on people, the safest ways for it to be ingested and how the drug compares to other drugs on the market.

Since students in the program are at different points in their careers, they experience the everyday life of someone working as a drug development manager; someone who oversees people just out of school and those who have worked in industry for years. In addition, they interact with classmates studying on a distance basis, another real-world experience they will encounter at current and future jobs.

Megan Yardley is a dual degree student pursuing both the MDD and the PhD in Molecular Pharmacology and Toxicology at the School of Pharmacy. She initially thought she would stay on the research side of things, but said she realized that while a lot happens during the research stage, “so much happens afterwards.”

Yardley was referring to the steps that usually follow research, including protecting the research with patent laws, applying to the FDA for approval and conducting market research to reach those who will benefit from the new drug.

“PhD students don’t always think about the bigger picture of what needs to be done five to 10 years down the line,” Yardley said. But in her studies toward the MDD, her classmates have included people employed by Pfizer and Allergan, who keep her apprised of that bigger picture. They tell her about their daily work and their excitement about it, she said.

Since she is also pursuing the PhD, Yardley’s studies include research on a new drug, a project with Davies and a multidisciplinary team of researchers.

“The knowledge Megan brings to our laboratory discussions regarding the regulatory pathways that will need to be traveled to get our discovery into humans would not be happening without the training she received in the MDD program,” Davies said.

Yardley is realistic about the time needed to make progress on this project, and she knows that all of her goals for the development of the drug won’t be reached before she completes her PhD. However, “long term you hope what you are doing can make a difference,” she said. “I hope I’m in some way pushing the field forward.”

Photo: Daryl Davies serves as director of the MS in Management of Drug Development Program.