



MASTERS of Their FATE

Working professionals enhance their futures with School's online MS programs in regulatory science and pharmacometrics

BY RANDOLPH FILLMORE

Designed for working professionals from government, academia, and industry, two new Master of Science programs at the School of Pharmacy — developed over the past several years and now running full speed — are preparing students to play greater roles in the global pharmaceutical, biologic, and medical device industries and at regulatory agencies.

Graduates of the two programs will not only influence drug development, testing, and therapeutic decision-making worldwide by taking new skills and greater capabilities back to their employers. They also will be uniquely positioned to meet new and global challenges in pharmaceutical regulatory issues — from drug discovery, to drug development, and into clinical trials — and conduct research and analyses that will enhance the quality, safety, and efficacy of the industry.

Both programs, conducted 100 percent online, were created to be flexible and available to prospective students who are professionals in the industry and government. The programs each accept 20 to 30 students, but draw up to three times as many applications.

“The University of Maryland School of Pharmacy is uniquely positioned to offer these programs,” says James Polli, PhD, the Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutical Sciences in the Department of Pharmaceutical Sciences, co-director of the University of Maryland Center of Excellence in Regulatory Science and Innovation, and the School faculty member who developed and directs the MS Program in Regulatory Science. “We have not only the experts to serve as faculty in these programs and the technological resources, but we also have the ability to access expertise from nearby government agencies, such as the Food and Drug Administration [FDA], and industry, so that students can partner with professionals working in either regulatory science or pharmacometrics.”

The Master of Science Program in Regulatory Science provides students with the knowledge and skills necessary to professionally contribute to drug regulation and pharmaceutical product life cycles. The Master of Science Program in Pharmacometrics prepares students for scientific leadership

through mastery of quantitative disease, drug, and trial models to influence key strategic decisions during drug development to clinical trials and beyond.

REGULATORY SCIENCE

“Students are coming to the Master’s in Regulatory Science program from diverse educational and professional backgrounds,” says Polli. “Prior to the start of our program, there was a dearth of education in this area. We are filling emerging needs for an industry that is increasingly global and complex in nature.”

In many cases, students had a vision of what they wanted to do, but needed to find just the right program.

For example, John Montgomery, a student in the program’s inaugural class, has been working in biopharmaceutical development for the last 15 years. His interest in regulatory science was suddenly sparked after attending a meeting where FDA and international regulators discussed issues in regulatory science. Initially, he did not know where to go to get the training necessary for entering the field.

“I found that the University of Maryland School of Pharmacy MS Program in Regulatory Science offered a number of unique advantages over other programs across the country,” Montgomery says. “The School’s partnership with the FDA creates opportunities for students to interact with its experts, other government agencies, and pharmaceutical companies. I’m very excited about the potential in this emerging field.”

Kimberly Updegraff, BSP, MS, who graduated from the University of Maryland School of Pharmacy in 1991, has been practicing pharmacy in a variety of settings. However, while working on her MS in Public Health, she became interested in drug development.

“Regulatory science was a natural fit for me,” she says. “But I did not have any formal training in the field. This program covers major areas of drug development from preclinical to clinical trials and beyond, and it will enable me to combine pharmacy, science, and public health.”

Polli emphasizes that students come to the program not only from a great variety of backgrounds, but that, because of the nature of regulatory science, the coursework touches on many disciplines and professional areas that enhance their fund of knowledge. Chemistry, manufacturing, controls, clinical research, pharmacovigilance, Phase IV research, and drug discovery are included.

“Graduates will be able to develop new tools, standards, and approaches to assessing such things as drug safety, efficacy, quality, and performance,” explains Polli. “Critical methods of risk assessment, drug utilization, and post-marketing surveillance are included in regulatory science.”

Terrence Clemons works as a human research protections administrator for the Office of Naval Research. He enrolled in the program to further his research interests that contribute to new technologies.

“My experience with the Navy has helped me recognize the critical role that regulatory science plays in developing medical products for the military,” explains Clemons. “The program has given me the opportunity to develop a greater understanding of regulatory science, which is essential to my work in protecting human subjects who are participating in research.”

Currently working at Merck in vaccine manufacturing, Shay Wingate was admitted to the MS Program in Regulatory Science with a goal already in mind.

“My goal is to determine why some medications are more efficacious than others,” says Wingate. “Ultimately, we need to reduce the severity and frequency of adverse events caused by less effective drugs while maintaining the safety and efficacy of those products.”

Among the courses that will help him realize those goals are “Drug, Biologic and Device Regulation” aimed at, among other issues, ethical issues in drug development. “Clinical Research” is designed to orient students to important issues in clinical trials, including study design and regulatory issues.

“In previous studies, I was often told what to do, but not told the why,” recalls Wingate. “In this program, I am learning the why.”

What is Regulatory Science?

“We use the FDA’s definition of regulatory science. It’s the science of developing new tools, standards,



and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated drugs. We also address biologics, diagnostics, medical devices, and nutritional products.”

—JAMES POLLI

PHARMACOMETRICS

After 12 years at the FDA as a scientist and developer of a pharmacometrics program for the agency, Joga Gobburu, PhD, MBA, FCP, came to the School of Pharmacy in December 2011 to accomplish a number of goals, both personal and professional. One goal was to start a program in pharmacometrics.

For Gobburu, who is director of both the MS Program in Pharmacometrics and the School’s Center for Translational Medicine, pharmacometrics is “a young discipline” that helps professionals in the industry make more efficient drug development decisions. He admits that pharmacometrics is his passion and he

What is Pharmacometrics?



“Pharmacometrics is a disciplined approach to drug development, regulatory, and therapeutic decision-making, and is not about number crunching.”

—JOGA GOBBURU

works to instill that same passion in his students.

“By the time they graduate from the pharmacometrics program, our students will be able to frame the key questions correctly, conduct a complex data analysis independently, and communicate with interdisciplinary scientists effectively,” he explains.

That statement fits the kind of involvement in drug development that was appealing to Renae Chavira, MS, currently enrolled in the MS program.

“I have always found drug discovery and development fascinating,” says Chavira. “I knew that I wanted to pursue formal education in pharmacometrics, but as a full-time working professional, my options were limited. However, the design and flexibility of the program has made it possible for me to continue working while doing the coursework, which is so relevant that I have already been able to apply many of the concepts in my current work.”

Among the courses offered in the eight-semester pharmacometrics program are those teaching modeling and simulation through advanced tools. “Basic Pharmacometric Tools” introduces students to software for importing and restructuring data and performing statistical analyses. “Basic PKPD Modeling” provides an overview of pharmacokinetics (PK) and pharmacodynamics (PD) and offers training in modeling, such as in dosing, and modeling for decision-making related to drug development.

Those courses are among the ones that attracted Tim Cacek, PharmD, a current student who works as a clinical hospital pharmacist and a pharmacometric consultant.

“I realize how important it is to stay on top of the latest innovative techniques for assessing drug action,” explains Cacek, whose emphasis is in toxicokinetic and population modeling. “The MS Program in Pharmacometrics offers me that opportunity and has exceeded my expectations.”

In addition to drug development, the MS Program in Pharmacometrics prepares pharmacists for clinical research and practice. “Drug, dose, and regimen selection are key parts of clinical therapeutics,” says Gobburu. “The MS Program in

Pharmacometrics, combined with knowledge from the PharmD program, will prepare pharmacists to lead therapeutic decisions in a clinical setting.”

According to both Polli and Gobburu, the two Master of Science programs will provide professionals with not only the knowledge to become experts in these emerging fields, but will place them in a position where they will be highly sought after by pharmaceutical companies, regulatory agencies, and research organizations around the world.

“The programs, and the students who graduate from them, will have a global impact,” concludes Polli. ☀

TWO CENTERS SEEK AND DRIVE EXCELLENCE

M-CERSI

Funded by a \$1 million grant from the U.S. Food and Drug Administration (FDA), the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) — a collaborative partnership between the University of Maryland, College Park, and the University of Maryland, Baltimore — aims to modernize and improve the ways drugs and medical devices are reviewed and evaluated.

Researchers from both campuses, with leadership from Polli at the School of Pharmacy, work with FDA personnel to support the development of new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.

Through M-CERSI, researchers, regulators, and industry professionals can learn from one other in an effort to develop regulatory science practices that promote innovation in medical devices and pharmaceuticals, while also addressing critical safety concerns.

CTM

The goal of the Center for Translational Medicine (CTM) at the School of Pharmacy is to use the knowledge and skills of its expert faculty and staff to develop future quantitative translational scientific leaders as well as decision-making tools for drug development.

For more information on applying to the Master of Science Program in Pharmacometrics or the Master of Science Program in Regulatory Science, visit www.pharmacy.umaryland.edu/academics.