UNIVERSITY of MARYLAND BALTIMORE

UMB Champions of Excellence

Ensuring Prescription Drug Quality for All Patients

James Polli, PhD | University of Maryland School of Pharmacy

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Growing up, James Polli, PhD, thought everyone worked in pharmaceuticals. After all, his father was a longtime researcher who developed medications, and the young Polli spent his summers working on research projects at Pfizer and Merck. “To me, that was pretty normal,” he says with a shrug.

Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics, Polli has been part of the University of Maryland School of Pharmacy faculty for 25 years. In that time, he’s devoted his career to two main research interests — maximizing oral drug availability, and developing public quality standards for oral dosage forms.

“The Food and Drug Administration [FDA] talks about safety, efficacy, and quality. I’m interested in quality — quality medicine,” Polli says.

How medications are designed and manufactured isn’t something the public fully appreciates, he says. “I make sure a drug is designed to be absorbed not only on a chemical level but also from a tablet and capsule point of view,” Polli says. “There are lots of challenges to maintaining drug product quality over time.”

Ranked in the top 10 nationally, the School of Pharmacy partners with numerous organizations to enhance product quality. For instance, Polli and his team collaborate with the FDA on research initiatives to help understand how to maintain drug product quality for complex formulations.

“We’re interested in drug product quality,” Polli says, “but we’re also interested in not having regulations be overbearing. We just want to know what risks there are, and how to mitigate those risks.”

They do this in part through the Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), a collaborative partnership between the University of Maryland, Baltimore (UMB) and the University of Maryland, College Park (UMCP).

As M-CERSI co-director, Polli helped to secure a $3 million grant from the FDA to develop the education and research program focused entirely on regulatory science — the first of its kind to an academic institution (it’s since been replicated at other prestigious universities, including Johns Hopkins, UCSF/Stanford, and the Yale/University Mayo Clinic).

M-CERSI trains the next generation of regulatory scientists, working from both UMB and UMCP to develop new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of products regulated by the FDA. These revolutionary professionals are modernizing and improving the way drugs and medical devices are reviewed and evaluated.

Currently, researchers are looking at the safety of e-cigarettes, evaluating the metal ions found in their aerosol condensates. One M-CERSI project is predicting the toxicity of certain cardiovascular drugs; another is improving communication between elderly women and the FDA regarding FDA-regulated products.

Under Polli’s leadership, each year M-CERSI hosts symposiums, conferences, and workshops on regulatory science issues. One recent workshop attracted nearly 300 attendees to Pharmacy Hall and was highlighted by a keynote address from Janet Woodcock, MD, director of the Center for Drug Evaluation and Research at the FDA.

In fall 2018, M-CERSI, the Center on Drugs and Public Policy at the School of Pharmacy, and the Center for Devices and Radiological Health at the FDA will host a one-day workshop on best practices for patient engagement in the National Evaluation System for health Technology (NEST). The workshop will focus on how patients are engaged with real-world evidence generation for medical device or device and drug combination evaluation.

“M-CERSI would not exist without Dr. Polli’s leadership,” says Paul Shapiro, PhD, professor and chair of the Department of Pharmaceutical Sciences at the School of Pharmacy and M-CERSI researcher. “Under his guidance, M-CERSI has brought together leaders from academia, biopharmaceutical industry, and government agencies to develop better approaches to improve the safety and efficacy of drugs regulated by the FDA. Regulatory science students have the opportunity to meet with these leaders and learn about the issues that affect health care.”

M-CERSI’s not only improved collaboration and communication with the FDA — it’s also led to the development of an online master’s of science in regulatory science program, also directed by Polli.

Launched in 2014, the part-time, two-year program is one of the school’s first online degree programs. With an emphasis on drug discovery, drug development, clinical research, and post-approval drug regulation, the program provides additional learning and training for people who currently work or would like to work in drug regulation and biologics development.

“About 20 percent of students in the program actually work at the FDA,” Polli says, with others attracted from academia (including other schools at UMB), industry, and federal government. The program is entirely online, though students work in groups on team projects and presentations.

To date, the program has enrolled 120 students. The first cohort graduated in 2015. In May 2018, Polli graduates the fourth class, the latest students who will continue his legacy of looking beyond efficacy to research and provide quality medicine.