

FDA joins Purdue's Center for Pharmaceutical Processing Research

WEST LAFAYETTE, IN. —The Food & Drug Administration's recent initiative to implement real time quality testing methods during the manufacture of drug products represents a major change in how product quality is evaluated and should lead to a significant reduction in production related recalls, according to the head of a School of Pharmacy-based research program at Purdue University that recently welcomed the Food and Drug Administration as a voting member.

"Our partnership with the FDA allows pharmaceutical companies and the FDA to participate in a research environment focusing on innovations in the manufacturing process", said Dane Kildsig, Professor of Industrial and Physical Pharmacy at Purdue.

Kildsig heads the National Science Foundation (NSF) Center for Pharmaceutical Processing Research (CPPR), which is a non-profit center devoted to using the latest science and technology to understand and improve pharmaceutical manufacturing processes. The CPPR consists of 25 U.S. pharmaceutical companies, Purdue University and the Universities of Connecticut, Puerto Rico and Minnesota.

"This is a great opportunity for the branded and generic manufacturers to work together

with the FDA to better serve the public interest", Kildsig said.

"If a company can demonstrate that it really understands its manufacturing processes, the FDA can have more confidence in the results based on the underlying science, and the process should be at lower risk for failure," said Ken Morris, Professor and Associate Head of the department of Industrial and Physical Pharmacy. "This fundamental understanding allows the design of better controls and less trial-and-error development of new medicines."

The relationship with the FDA was established through the efforts of Ajaz Hussain, who is the deputy director of the office of pharmaceutical sciences at the FDA; Alex Schawartzkopf, the director of the NSF Industry-University Cooperative Research Program to which CPPR belongs; and Dane Kildsig, also NSF Center director at Purdue. The implementation of each CPPR project is determined by a vote of the membership, which now includes the FDA, and is executed by professors, advanced graduate students and an industrial mentor.

"The center has enjoyed significant successes in bringing to light underlying reasons for common issues in manufacturing and in designing and implementing improvements for existing processes," Morris said. "CPPR has numerous scientific publications to its credit and several patents are pending."

For example, the current emphasis on Process Analytical Technology (PAT) at FDA

and in the CPPR, led to the establishment of a PAT laboratory project in Morris' department. According to Morris, this will provide both student training on the cutting edge technology and opportunities for the members to make informed decisions on implementation of PAT.

PAT is the application of scientific knowledge to understand and advanced sensors to monitor and eventually control pharmaceutical processes for optimum performance.

"This could result in more efficient production, cutting costs and preserving important compounds where shortages or production failure could lead to dire consequences," Morris said.

Other contributions of the center focus on optimizing poorly understood processes that are common for many products. Morris said this effort is designed to reduce the regulatory burden, speed time to market, and reduce costs and is the heart of new FDA initiatives to foster better and more efficient interactions between the agency and industry.