

Pfizer CRADA

As part of the annual progress report and implementation plan for the CGMP initiative, “Pharmaceutical cGMPS for the 21st Century — A Risk-Based Approach,” the Agency announced the development of a Cooperative Research and Development Agreement (CRADA) with Pfizer, Inc. The purpose of the collaboration is to investigate the utility of chemical imaging in the measurement, evaluation, and control of various pharmaceutical processes. Recent advances in chemical imaging technology make it possible to acquire and analyze high-resolution chemical images rapidly. Chemical imaging can now be applied to process monitoring and control. Such modern chemical-imaging tools can offer novel, efficient approaches to ensuring pharmaceutical quality.

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The FDA is collaborating with the National Science Foundation's Center for Pharmaceutical Processing Research (CPPR) in support of the objectives of the PAT and cGMPs initiatives. The mission of the Center for Pharmaceutical Process Research is to foster an interdisciplinary approach to pharmaceutical processing-related research, to catalyze interaction between industrial and academic scientists, and to make the application of a basic science approach to formulation manufacture of drug products an integral part of pharmaceutical education. This collaboration is intended to expand the Agency's scientific foundation in the area of innovative pharmaceutical manufacturing technology. We believe this collaboration will help the Agency develop and implement sound, science-based policies with regard to the review and inspection of current and innovative systems for monitoring and controlling pharmaceutical manufacturing.