

January 08, 2010

2010-01-08: Ensuring pharmaceutical quality

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Recommended Citation

Fodrowski, Samantha, "2010-01-08: Ensuring pharmaceutical quality" (2010). *News@Northeastern*. Paper 487. <http://hdl.handle.net/2047/d20001730>

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Ensuring pharmaceutical quality



Dr. Graham Jones and Dr. Barry Karger photo by Craig Bailey

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Northeastern University and the U.S. Food and Drug Administration (FDA) have signed a partnership agreement to advance methods of analysis for developing safe, complex protein-based drugs known as biological drugs.

The agreement establishes a research collaboration, along with educational, training and outreach programs for members of the FDA, industry and academia in the areas of biotechnology and analytical chemistry.

Northeastern's Center for Advanced Regulatory Analysis, housed within the Barnett Institute of Chemical and Biological Analysis, will lead the research projects, which include the development of

methods that assess the structural attributes, safety and efficacy of biological drugs.

The center will also develop critical new technology to analyze these drugs and support the development of biological products.

"Northeastern has the unique expertise and state-of-the-art equipment to test and analyze the most complex samples and find toxic impurities that could otherwise remain hidden even through clinical trials," explains Barry Karger, director of the Barnett Institute.

"Our partnership with the FDA will ultimately help enhance and accelerate clinical trials, introduce safe and effective new drugs, lower prescription costs, and save lives," Karger continues. "We hope to strengthen this relationship with the FDA and find new opportunities for collaboration."

As part of the agreement, Northeastern and the FDA will develop joint research programs and training activities for partners in industry and academia. They will also seek to enhance the visibility of their work through training activities, meetings and symposia.

The collaboration with the FDA builds on Northeastern's goals of developing programs and training that advance the field of regulatory science. The University plans to unveil a professional science master's degree in regulatory science later this year.

To learn more about the Barnett Institute of Chemical and Biological Analysis at Northeastern University, visit: <http://www.northeastern.edu/barnett/>

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