



INGENUITY SYSTEMS AND FDA ENTER 3-YEAR, \$6 MILLION COLLABORATION TO ENHANCE REGULATORY REVIEW PROCESS

Redwood City, CA – November 27, 2007 – Ingenuity Systems, the leading provider of information solutions to help life science researchers generate insights from biological and chemical information, is pleased to announce that it has entered into a Cooperative Research and Development Agreement (CRADA) with the Food and Drug Administration. Under the collaboration, Ingenuity and FDA will use IPA, Ingenuity's pathways and content solution, to facilitate the FDA's regulatory review of biomarker, pharmacogenomic, and toxicogenomic data.

Under the terms of the CRADA, Ingenuity Systems and the FDA will expand Ingenuity's content and software solutions and further enable the research and regulatory review of biomarker, pharmacogenomic, and toxicogenomic data.

The collaboration directly relates to the FDA's need to identify biomarkers in order to monitor drugs for early signs of toxicity and to identify individuals at high risk for serious side effects from drug treatment. Ingenuity Systems, a member of the [Biomarkers Consortium](#), recently launched its unique [IPA-Biomarker™ solution](#) within IPA, which has been widely cited as enabling diagnostic, drug response, and toxicity biomarker discovery in diseases such as autism, Alzheimer's disease, diabetes, schizophrenia, Crohn's disease, and over a dozen different types of cancer ([see Ingenuity publications](#)).

"To clearly visualize and understand biological relationships embedded in the regulatory data, we required a solution that helped us make connections between drugs and potential mechanism of action and mechanism of toxicity. We believe IPA will help identify new functional pathways which can be adapted to describe drug-centric or disease-centric pathways of specific regulatory interest," commented a senior FDA official. "In addition, IPA's dynamic, graphical depiction of relationships between genes in different networks could allow for the identification of potential genomic 'fingerprints' that could be used to quickly and easily compare genomic data from submissions of drugs in the same class."

"IPA has become an industry standard for the search, visualization, and analysis of biochemical pathway data, and we're excited about the opportunity to work with the FDA to further develop our technology and content platform for the regulatory review of voluntary genomic data submissions (VGDS) datasets," stated Jake Leschly, CEO of Ingenuity Systems.

About Ingenuity Systems®

Ingenuity Systems is a leading provider of information solutions to help life science researchers generate insights from biological and chemical information. Ingenuity Systems is recognized as a technology leader, providing complete solutions for researchers to better understand the complex systems foundational to human health and disease. Today, Ingenuity's solutions are used by thousands of researchers at hundreds of leading pharmaceutical, biotechnology, and academic research institutions worldwide. Ingenuity was founded in 1998 and is headquartered in Redwood City, California with offices in Germany, Switzerland, France, the United Kingdom, and Japan. www.ingenuity.com.

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