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Jacobs Institute lures major talent from FDA to Buffalo

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The Jacobs Institute has lured a major talent to Buffalo, and the institute's leaders say it is another sign of the project's uniquely exciting model in the med-tech space.

Carlos Pena started in December as chief regulatory officer of the Buffalo-based nonprofit. He heads its newly formed Office of Regulatory Services. He was previously director of the U.S. Food and Drug Administration's Office of Neurological and Physical Medicine Devices, part of the FDA's Center for Devices and Radiological Health.



JACOBS INSTITUTE

Carlos Pena, chief regulatory officer at the Jacobs Institute

As the Jacobs Institute seeks to support startups and corporate projects in the cardiovascular space, Pena will provide key insight and connections at the government level.

"This is another step in our efforts to let the world know that if you want to develop a medical device in the neuro and cardiovascular space, coming to Buffalo is a good

place to be," Jacobs Institute CEO [William Maggio](#) said. "It's not only a big win for the JI, but it's also enormous for the community to have an asset like this on the Buffalo Niagara Medical Campus."

Pena also served from 2012 to 2014 as assistant director of emerging technologies in the White House Office of Science and Technology Policy.

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At the FDA, his job had a national scope, yet he said the Jacobs Institute stands alone in the U.S. The institute is sandwiched in the middle of a \$291 million building that opened in 2012 to improve cardiovascular research and care in Buffalo.

The bottom floors are a hospital, Kaleida Health's Gates Vascular Institute, while the top floors represent high-tech medical research in the University at Buffalo's Clinical and Translational Research Center.

"I was surprised there was one site in Buffalo that had these multiple components," Pena said. "My heart is wanting to help patients, and this is the right place to continue my career in supporting medical device development, R&D and the financial side."

The institute debuted its signature commercialization program, Idea to Reality, in 2018. Last year, it took an ownership stake in two startups working on new products in the vascular space.

Pena is viewed as a crucial component of the commercialization process, which often involves heavy involvement from government regulatory entities. He plans to support services that assess the viability and risk of specific ideas, and to match up Buffalo-based researchers and entrepreneurs with their appropriate FDA counterparts.

The Jacobs Institute opened in 2013 and has received funding from a variety of sources, including a \$10 million pledge from [Jerry Jacobs](#) and his wife, Margaret, more than \$4 million of commitments through Empire State Development Corp., and a significant amount of local philanthropy.

"Carlos ran the neurological device division at the FDA for over a decade," said Dr.

Adnan Siddiqui, the institute's chief medical officer. "His insights and expertise will be valuable to all contemplating novel devices in the brain space for the foreseeable future. I expect (he) will drive a lot of new opportunities to Buffalo to be an incredible resource for UB, Kaleida and all our local and regional partners."

Dan Miner

Reporter

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