

## Improving Quality and Compliance.

### FDA Waiting on “OK” to Open China Offices

In one of many efforts to increase safety monitoring of food and medicine destined for the United States, the FDA is currently negotiating a presence in China.

The plan to open three offices in the country is being postponed by Chinese bureaucracy, a top health office said last week. Although the Chinese government supports the U.S. plans, China is still in the process of approving FDA employee visas. The offices, located in Beijing, Shanghai and Guangzhou, would employ thirteen FDA employees with the goal of increasing consumer product quality.

Recent safety issues involving the blood thinner, food and other products imported from China has put pressure on the FDA to act. "This is about giving them better capacity to reach their most important consumer market," said Mike Leavitt, secretary of the Department of Health and Human Services. "I think they can see that."

View the complete story [here](#)

### New Efforts Help Improve Medical Products for Patient Safety and Quality of Medical Care

In a white paper released by the FDA last month, the agency describes plans for the Sentinel Initiative, which includes the development of a new electronic system that will enable FDA to query a broad array of medical information.

The Sentinel System is an important example of how electronic health records and other electronic health information, such as the Medicare data, can help move the nation toward a system that delivers safer and better quality health care.

View the complete story [here](#)

### PathWise Participates in AAMI’s Annual CAPA Conference

Each year, the Association for the Advancement of Medical Instrumentation hosts a 2 ½ day course on the essentials of a Corrective and Preventative Action system. This year, [Dave Baldwin](#), Senior Partner of PathWise, Inc., was a featured speaker, guiding a 1 ½ day workshop on Analytical Problem Solving and Identifying Root Cause. Mr. Baldwin received excellent feedback from the 55 course participants by providing quality and conformance procedures to positively impact their CAPA systems.

PathWise, Inc.

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Pathwise, Inc. offers training and development for medical device and pharmaceutical companies in the areas of quality and compliance. We help our clients to develop and implement standards that improve the manufacturing process for products that serve citizens around the world.

#### CAPA

Risk Management

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QSR

## Upcoming Training Courses

<b>CAPA for the Life Science Industry</b>	<b>Documenting &amp; Conducting CAPA Investigations</b>	<b>Risk Management</b>	<b>CAPA for the Life Science Industry</b>
Salt Lake City, Utah	Washington, DC	Chicago, Illinois	Costa Mesa, California
July 18-19	September 9-10	October 9-10	December 8-9

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