

Compliant, Effective, Efficient.

Modeling Change in Personalized Medicine

Personalized medicine represents a paradigm shift from the "blockbuster" model in drug development that focuses on understanding and crafting treatments for specific diseases, not specific patients. Recent advances in science, genomics technologies, biomarkers, and drug development provide an opportunity to take an approach that is more personalized to specific patients.

View the full story [here](#).

Study Indicates Lower Risk of Death in Drug Coated Stent Devices

A team of researchers from Duke University, AHRQ and Kaiser Permanente have recently conducted a comparative effectiveness study of 262,700 Medicare patients. They've found that, compared with patients who received bare metal stents, those fitted with stents coated with medication, called drug-eluting stents, had an 18 percent better survival rate over the 30-month study period and were 16 percent less likely to suffer a heart attack.

Read the full guidance [here](#).

Introducing Core CAPA System for Quality and Compliance Personnel

The FDA reports that the leading cause of observations and warning letter issuance is deficiency within the CAPA system. Many organizations struggle with initiating, evaluating, closing and trending CAPA projects.

While there are many approaches that support individual CAPA procedures, most lack the complete system of elements that help manage and enable them. [The PathWise CAPA System is much more than a procedure-](#) it is a proven solution offering the tools necessary to build a compliant, effective and efficient CAPA system.

For more information, click [here](#).

PathWise, Inc.

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PATHWISE TRAINING AND DEVELOPMENT

Facing an uphill battle?

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

Documentation

Root Cause Analysis

Auditing

QSR

Upcoming Training Events

Effective CAPA Management

Bethesda, MD

April 24, 2009

Integrating ICH Q9 and ISO 14971 into the Quality System

Webinar

April 21, 2009

CAPA for the Life Science Industry

Dublin, Ireland

May 26-27

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