

## Improving Quality and Compliance.

### FDA Increases Regulation of Diagnostic Tests and Services

Recent regulatory developments from the FDA have indicated a significant increase in the regulation of two categories of diagnostic products- analyte specific reagents (ASRs) and in vitro diagnostic multivariate index assays (IVDMIA). These categories potentially encompass many genetic-based tests and other cutting-edge diagnostic products and technologies that have previously been unregulated or minimally regulated by FDA.

Read more about the increased regulation [here](#).

### The Gateway: A Risk-Based Filter for Effective CAPA Management

Many organizations in the Life Science industry today are suffering from "Death by CAPA," using a funnel-based approach to quality issue prioritization. Under this system, some non-conformances are categorized as higher or lower on the priority scale but eventually everything becomes a CAPA. This industry practice has made it difficult for quality professionals to manage their quality system.

In recent years, the FDA has stressed a risk-based approach to managing quality systems. In response, PathWise has developed a risk-based filter, which handles quality issues based on risk to the end-user. This method, known as "The Gateway" effectively teaches QA/QE individuals, investigators and other quality professionals to determine which non-conformances should become a CAPA and which should remain in their respective areas of the quality system. This approach enables the CAPA system to be more manageable and easier to learn from.

Learn more about [The Gateway](#) in this upcoming webinar.

### Operator Error: Is it Really the Root Cause of Performance Problems?

More often than not, the root cause of a performance problem is documented as "operator error," and the corrective action is retraining. But is this really the case? Find out how to avoid management and training program scrutiny and identify what's really causing your nonconformity. Read the complete story [here](#).

### Risk Management for FDA Regulated Industries - A PathWise/Master Control Webinar

Effective Risk Management is essential to a product's development and post-production success, as well as being a critical process for those under increased regulatory scrutiny. Recent medical device and pharmaceutical regulation increases have now, more than ever, increased the need to have solid risk systems in place.

In this webinar, industry expert Ed Bills offers an overview of risk management, where listeners can become acquainted with industry standards and regulations to better improve their risk management system.

A free copy of this webinar will be available on August 7. [Download here](#).

PathWise, Inc.

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#### 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 Courses

<b>The Gateway: A Risk-Based Filer</b>	<b>Documenting &amp; Conducting CAPA Investigations</b>	<b>Risk Management</b>	<b>CAPA for the Life Science Industry</b>
<a href="#">Online Webinar</a>	Washington, DC	Chicago, Illinois	Costa Mesa, California
August 27	September 9-10	October 9-10	December 8-9

Enroll online at [www.PathWise.com](http://www.PathWise.com) or call 866.580.PATH for more information.