

Improving Quality and Compliance.

Fitting Human Factors in the Product Development Process

The FDA has recently stated that more than one third of medical device incidents involve use error, and more than half of device recalls for design problems involve the user interface. These statistics have prompted the agency to strengthen its initiative requiring medical manufacturers to conduct appropriate human factors studies, analyses, and tests.

Manufacturers seeking FDA approval for new devices must submit evidence of systematic human factors analysis of use errors and how they will be controlled throughout the product development process.

View the full article [here](#).

An Overview of Quality System Regulations

If you think the FDA's quality system regulations for medical devices can be a bit overwhelming, you're not alone. 21 CFR 820 alone has over 15 subparts that are applicable to the production of medical devices, each with their own separate guidances.

In this complimentary webinar, former FDA field investigator Lisa Hornback sorts through the regulations and clarifies the issues. In today's regulated medical device industry, it is imperative to understand quality system requirements to ensure quality and avoid penalties.

View the webinar [here](#).

What's Going On? Why Do We Have So Many Repeat Investigations?

Repeat CAPA investigations are arguably one of the largest areas of concern for quality managers today. Despite many firms taking the recommended corrective action, repeat investigations throughout the industry have accounted for as many as 30% of all open investigations- or 1 in every 3. What's going wrong? Why is this happening to so many of us?

There are many reasons this phenomenon occurs; the majority of which are occurring because of mistakes taking place in the initial steps of the investigation process.

Read the full article [here](#).

Kennedy-Grassley Bill Aims to Increase Regulation of Medical Devices and Pharmaceuticals

Read the proposed regulation [here](#).

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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

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Online Webinar

November 18 – 10:00 am PDT

CAPA for the Life Science Industry

Costa Mesa, California

December 8-9

CAPA for the Life Science Industry

Dublin, Ireland

May 18-19

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