exeed™ Medtech Quality Journal

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"The ASR Program allowed the FDA to more efficiently review reports of well-known, well-understood adverse events, so we could focus on identifying and taking action on new safety signals and less understood risks."
- Statement from Dr. Jeffrey Shuren MD JD, Director CDRH, FDA

A good idea with unintended consequences! The Alternate Summary Reporting (ASR) program started in 1997 and millions of adverse events were reported in an aggregated, summary form over a period of 20 years. There was a lot of concern that this data was "hidden" from public view since it was not available in the MAUDE database. As a result, there was a widespread perception that many unsafe devices continued to be marketed without proper oversight. The FDA has now ended this program and all data files are available. In our feature article this month, we provide an interactive dashboard of 2018 ASR
reports and a summary of key insights. Take a look and let us know your questions about this data source.

Check out the latest industry news in less than 15 minutes. Please let me know if there are future topics you would like discussed by contacting me here.

– Naveen Agarwal, Ph.D

FEATURE ARTICLE

Lifting the Curtain on Alternate Summary Reports

FDA is ending the ASR program and data is now available.

It is time to take a look.

Question: Have you been including ASR data in your post-market safety surveillance reviews?

Read More >>>

PERSPECTIVE

Risk is a Personal Thing

Research shows that individual perception of risk varies broadly. Here are a few considerations to drive consistency in your risk management system.

Question: How do you ensure consistency in risk assessments while recognizing individual perspectives?

Read More >>>

RESOURCES

Lifecycle Risk Management of Combination Products

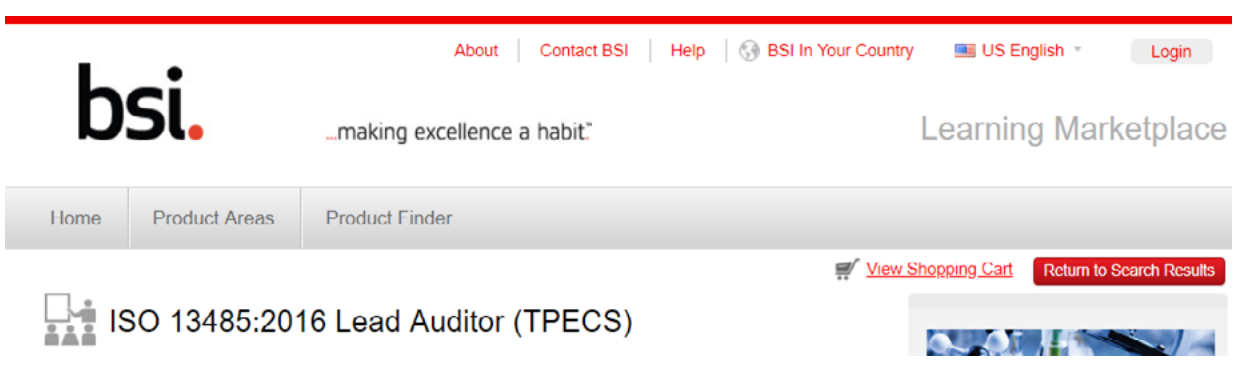
Slides from our presentation at the 2nd Annual CPLM summit in Boston.

Download Now >>>

EVENTS

Lead Auditor Training for ISO 13485:2016

We are conducting a Lead Auditor training for ISO 13485:2016 on behalf of BSI in Atlanta, GA. **Contact us** if you would like a customized training session for your team.



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