exeed™ Medtech Quality Journal

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MedTech Quality Journal

"The objective of this rule is to reduce the number of fatalities and injuries attributable to defective medical devices."
- FDA final rule on implementation of the medical device QSR in 1996

It doesn't seem to have worked out that way! 22 years later, MedTech continues to have a Design problem! This month, we examine why design and development continues to be a challenge for the industry, and a key driver of FDA warning letters and recalls. We are also exploring how FDA's plans to modernize the QSR may impact your Quality Management System (QMS) in the future.

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

Can Your Risk Management Prevent a Recall?

Medical device recalls are costly and damage trust in your brand.

Effective risk management can help.

Question: How are you evaluating effectiveness of risk management?

Read More >>>

REGULATORY NEWS

FDA Recognizes It's Time for QSR 2.0

22 years after it became effective, FDA's current Quality System Regulation for medical devices is ready for a makeover. FDA is announcing plans to harmonize the QSR with ISO 13485.

Question: Are you aware of gaps and redundancies in your QMS?

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PERSPECTIVE

MedTech Has a Design Problem

Design issues top the list of reasons for Medical Device Recalls and FDA Warning Letters. Why does MedTech continue to struggle with Design Control?

Question: What are the top opportunities for improvement in your Design Control process?

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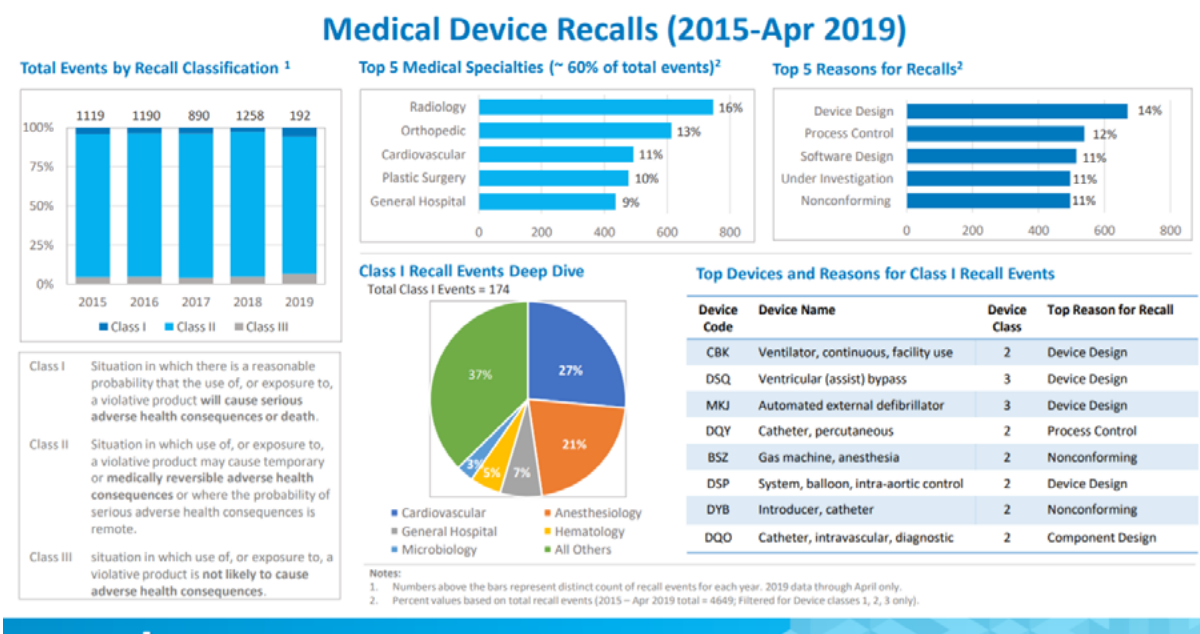
RESOURCES

Medical Device Recalls (2015 - Apr 2019)

Device Design issues are the top driver of Medical Device Recalls based on our analysis shown below. Here is a quick overview of recalls since 2015.



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EVENTS

2nd Annual CPLM Summit

We are leading a hands-on workshop in life-cycle risk management of drug-device combination products. Slides coming soon.

Learn More >>>

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