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Meditech Quality Journal

“Putting out fires is not improvement of the process.” – Dr. W. Edwards Deming



In our Feature Article this month, we offer a going-back-to-basics approach to help achieve business growth. Just as Dr. Deming said, we can't be continuously fighting fires. We must focus on consistently improving [Product Quality](#), not just driving Compliance. We are also discussing how FDA is shaping its policy for software modifications and why Risk Management is critical in light of the recent Boeing 737 Max crashes.

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

Renew Your Focus on Product Quality to Drive Business Growth



Medical Device companies are facing two competing challenges as they seek new growth— how to grow their core product sales while also innovating to bring new products in adjacent or entirely new market segments. Going back to basics will help sustain market leadership.

Question: How are you driving Product Quality improvements in your organization?

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PERSPECTIVE

27 Billion Reasons to Get Serious About Risk Management



One high-tech aircraft. Two fatal crashes, 346 dead. \$27 billion of market value lost in two days. Risk Management can no longer be a paper exercise to satisfy regulators.

Question: What can MedTech learn from these failures to renew its focus on patient safety?

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REGULATORY NEWS

Regulatory Policy in the Age of Artificial Intelligence

AI is enabling rapid innovations in MedTech. How should FDA respond? In a recently released discussion paper, FDA is proposing a risk-based policy for review of software modifications.



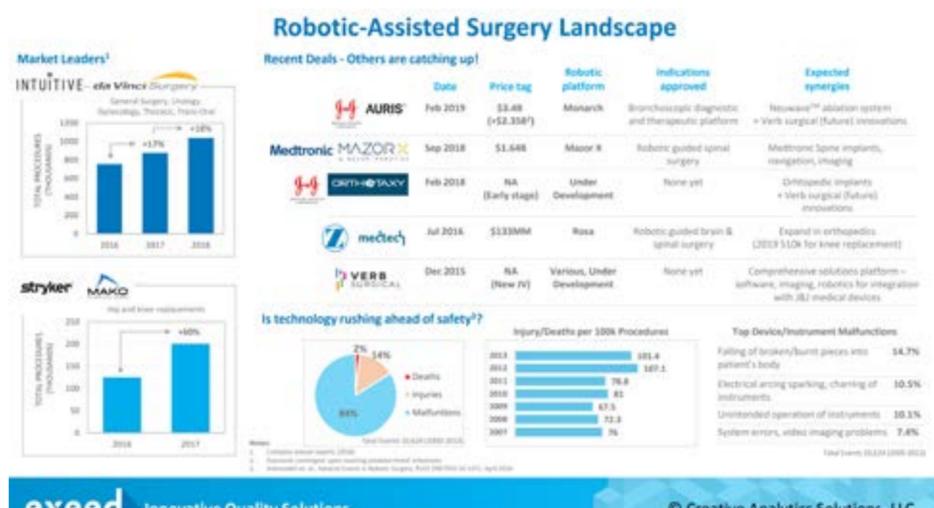
Question: Does your regulatory strategy for AI-based devices include a change control plan?

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RESOURCES

Robotic-Assisted Surgery Landscape

Intuitive Surgical and Stryker have dominated the market for several years, but now the robotic-assisted surgery landscape is heating up with a couple of multi-billion dollar deals. Here is an overview of the industry, market leaders, recent deals and safety record of this technology.



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EVENTS

Baldrige Award Examiner Training

I have been selected to join the Baldrige Board of Examiners. I will be attending the New Examiner Training this month. Stay tuned for updates.



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Toll Free 1-833-MYEXEED | 1-833-693-9333

info@ExeedQM.com

Creative Analytics Solutions, LLC
 2468 Atlantic Boulevard, Jacksonville, FL 32207

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