

FEBRUARY 2019

Medtech Quality Journal

“Quality is doing it right when no one is looking” - Henry Ford

In our Feature Article this month, we offer a business case for creating a [Culture of Quality](#) to sustain a truly high performing organization. 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

Business Case for Quality Culture



The business case for achieving a true culture of Quality in the medical device industry is strong! It is not just about cost savings, but also increasing revenues through real improvement in product quality and customer experience. When everyone in the organization is focused on Quality, remarkable results are possible.

Are you ready to renew your commitment to Quality?

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REGULATORY NEWS

FDA is Raising the Bar for Medical Devices

Did you know that FDA is slowly eliminating older devices for use as legal predicates in 510(k) submissions? Check out new policy objectives recently announced by the FDA Commissioner. The shift in FDA’s regulatory decision-making approach is raising the bar for medical devices.

The question: How can you strengthen your Quality Management System to meet higher expectations?

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PERSPECTIVE

3 Important Questions for AI in Healthcare



Artificial Intelligence is a hot topic!

But there are no good answers to these 3 important questions...

What you need to think about before rolling out an AI project in your organization.

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RESOURCES

AI Revolution in Healthcare Quality

Here are slides from my presentation at ASQ Houston last month. We talked about how AI is transforming the rough and heavily regulated landscape of Helathcare and how the FDA is responding.



Download this complimentary January 2019 presentation from the ASQ Greater Houston Meeting.

[Download PDF >>>](#)

EVENTS

February 11th ASQ Meeting at Asheville, NC



We are speaking at ASQ section meeting in Asheville, NC! Slides will be posted on the website. [Contact us here](#) to request a speaking engagement.

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