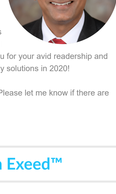
exeed™ Medtech Quality Journal

DECEMBER 2019

MedTech Quality Journal



What a year 2019 has been! I want to thank you for your continued interest in Exeed™. It is my commitment to provide highly effective solutions for your Quality organizations. With the proper resources and timely updates, you can achieve your business objectives through effective compliance and superior product quality. The MedTech Quality Journal allows me to keep you up-to-date with the ever-changing medical technology industry.

To reflect on the end of a decade, I wanted to re-visit the resources that you, as readers, found the most useful. The following featured resources are the Top 5 articles on our website this year. Thank you for your avid readership and eagerness to learn. I look forward to another year of sharing Quality solutions in 2020!

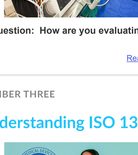
Stay updated on the latest industry news in less than 15 minutes. Please let me know if there are future topics you would like discussed by contacting me here.

– Naveen Agarwal, Ph.D

Top 5 Articles of 2019 from Exeed™

NUMBER FIVE

When a Warning Fails



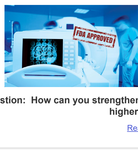
Instead of using warning letters to drive compliance, FDA is focusing more on helping device companies improve the quality of their corrective action plans.

Question: How can you take advantage of this changing mindset at the FDA?

Read More >>>

NUMBER FOUR

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 the effectiveness of risk management?

Read More >>>

NUMBER THREE

Understanding ISO 13485:2016

Exclusion vs. not applicable?

How to make the right decision for your Quality Management System (QMS).

Insight: Define the scope of your QMS carefully.

Read More >>>

NUMBER TWO

FDA is Raising the Bar for Medical Devices

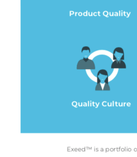
Did you know that FDA is slowly eliminating older devices for use as legal predicates in 510(k) submissions? The shift in FDA's regulatory decision-making approach is raising the bar for medical devices.

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

Read More >>>

NUMBER ONE

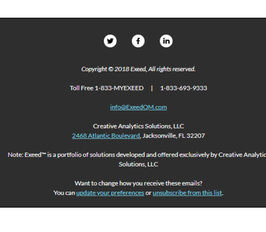
FDA Recognizes It's Time for QSR 2.0



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?

Read More >>>



We hope your holiday season is filled with Quality time with loved ones and we wish you the very best in 2020.

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