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MedTech Quality Journal

“A time of crisis is not just a time of anxiety and worry. It gives a chance, an opportunity, to choose well or to choose badly.”

- Desmond Tutu



As we publish this month’s newsletter, the novel coronavirus is rampant in over 150 countries across the world. There are more than 400,000 confirmed cases world-wide and the global death toll has surpassed 19,000. While social distancing is the new normal, it will take a theoretical “all-hands-on-deck” approach from government agencies and the entire healthcare sector to manage this crisis.

In our Feature Article this month, we explore how Medtech is rising to help combat the coronavirus pandemic. Under the Emergency Use Authorization (EUA), the FDA has rapidly approved several SARS-CoV-2 tests in the last two weeks. Testing is critical to identify infected individuals, isolate them and trace other potentially infected individuals. Increased testing will allow a more rapid, targeted response to the pandemic.

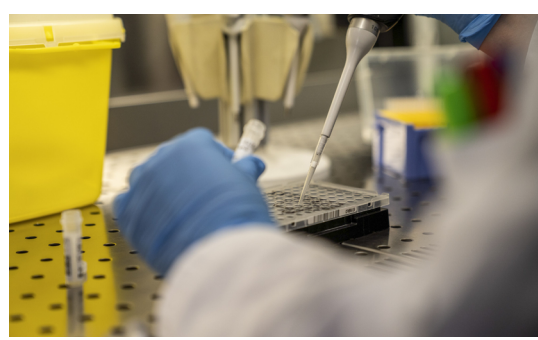
Fear, anxiety and uncertainty is everywhere, and no one knows how long this will last. It is important to stay calm and remember you are not alone. We can all do our part by practicing social distancing and staying up to date with the rapidly evolving reports on COVID-19. Stay safe and be well.

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

FEATURE ARTICLE

How MedTech is Rising to Help Combat the Coronavirus Pandemic



An overview of recently approved molecular diagnostic tests for the novel coronavirus.

Insight: Clear guidance from the FDA for test validation has been helpful.

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REGULATORY COMPLIANCE

FDA Guidance Provides Relief for MDR Reporting During a Pandemic



Certain 30-day MDRs can be held and reported after the pandemic.

Insight: Develop a continuity of operation (COOP) plan.

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INDUSTRY NEWS

How the Medical Industry Can Help Combat the Current Coronavirus Crisis



Emergency Use Authorization offers a pathway for quick FDA approval during a crisis.

Insight: Plan ahead by identifying potential product uses during an emergency.

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RISK MANAGEMENT

Regulatory Update on Medical Device Cybersecurity



A video update on cybersecurity activities at the FDA.

Insight: Regulatory policy for cyber security is still evolving. Stay tuned.

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