

PRIME PATH to the Weekend!

Vol. 5 | November 11, 2022

Good Morning and Happy Friday!

The weekend is finally here! Catch up on all the latest news and stories from this week, as well as updates from us!

Industry News



INDUSTRY BASICS WORKSHOP
Tuesday
November 15, 2022

CDRH Industry Basics: Understanding Risk with Medical Devices

The FDA is hosting a virtual workshop on November 15th about Understanding Risk with Medical Devices. Lots of reasons to tune in!

[Read more](#)
Source: U.S. Food & Drug Administration



Tempus begins study of AI-enabled predictive cardiology tests

Medical data company Tempus launched their first study that utilizes AI for predictive cardiology tests. Another example of how AI can be used in the medical world.

[Read more](#)
Source: Medical Device Network



5 takeaways from the FDA's list of AI-enabled medical devices

Speaking of AI, here's some analysis based on some of the AI based devices that the FDA has authorized so far.

[Read more](#)
Source: MedTech Drive



Medtronic Renal Denervation Study Misses Primary Endpoint (Again)

Medtronic announced that their RDN trial produced unsatisfactory results for the second time, but they still submitted their final module for FDA approval.

[Read more](#)
Source: MD+DI Online



Envoy Medical Early Feasibility Study of Breakthrough Fully Implanted Cochlear Implant Now Underway

Envoy Medical is developing a device that if approved by the FDA, would be the first cochlear implant that is designed to be fully implanted into the ear.

[Read more](#)
Source: Businesswire

Feel Good Stories



Lab-grown blood given to people in world-first clinical trial

Now here's a breakthrough. This lab grown blood could help create blood for donations without relying on people, and produce rare types of blood that are hard to find.

[Read more](#)
Source: BBC News



NYC jail complex to be restored into citywide green energy hub

Going green is always a good thing. This former NYC jail complex will be transformed to provide renewable energy for surrounding neighborhoods.

[Read more](#)
Source: Movement

Prime Path Weekly Blog



Annex 11 & Part 11: What's the Difference?

This week's blog talks about the difference between Annex 11 and 21 CFR part 11. While both are similar in their goals they are only relevant in their respective regions. Know what makes them different and how they may affect your development of a medical device.

[Read more](#)

Prime Path News

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