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Device Week, 18 June 2021 – MDUFA V Update; FDA's Shuren Speaks; Harmonized QS Reg Almost Here?

by Shawn M. Schmitt

On this week's podcast we give an update on the Medical Device User Fee Amendments (MDUFA V) process. We also discuss US FDA device center director Jeff Shuren's comments about pre-submission meetings and IVD submissions during a recent podcast interview with AdvaMed. Finally, we talk about the FDA's latest scheduling of the release of its draft harmonized Quality System Regulation, due out this month.

Listen to the podcast via the player below:

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Medtech Insight articles addressing topics discussed in this episode:

- *MDUFA V: FDA Proposes New Program To Engage External Experts Early – But Industry's Skeptical*
- *'A New Kind Of Future'? FDA's Shuren Questions Whether Engagement With Industry Will Change Post-Pandemic*
- *IVDs: 'Every Non-COVID Premarket Submission That Was Held Up Is Moving Forward' Soon, FDA's Shuren Vows*
- *After 3 Years Of Work, FDA Says It Will Release Its Revamped Quality System Regulation This Month*