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Device Week, 12 June 2020 – New Insights Into FDA’s Quality System Reg Rewrite

by [Shawn M. Schmitt](#)

On this week’s podcast we discuss some recent news out of the US FDA about its efforts to harmonize its Quality System Regulation with international quality systems standard ISO 13485.

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Medtech Insight articles addressing topics discussed in this episode:

- [*Q&A: New Details Emerge From FDA About Long-Delayed Draft Rule That Harmonizes Quality System Reg With ISO 13485*](#)
- [*For FDA, The Third Time Wasn’t The Charm For Releasing A Draft Of Its Harmonized Quality System Reg*](#)
- [*FDA’s Retooled Quality System Regulation Coming ‘Sometime This Year,’ CDRH Chief Shuren Says*](#)