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Speaking Of Medtech, Ep. 3: FDA Quality System Regulation Harmonization

by [Steve Silverman](#)

On this episode of Speaking Of Medtech we talk about arguably one of the biggest regulatory changes to come down the pike in decades: the ongoing harmonization of the US FDA's QSR, which is going to broadly change the way the agency handles medical device quality oversight.

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Medtech Insight articles addressing topics discussed in this episode:

- [*QSR Author Says FDA – Not Industry – Will Need Most Time To Adapt To New Quality System Reg*](#)
- [*QSR Q&A: 5 Top Medtech Experts Answer 6 Burning Questions About FDA's Coming Quality Reg Redo*](#)
- [*FDA's Draft QSR: 'Lucy' Pulled The Football Away. Again*](#)