MEDTECH INSIGHT
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22 Aug 2018 | **Analysis**

Device Week, Aug. 22, 2018 – Quality System Regulation + ISO 13485 = ?

by Shawn M. Schmitt

On this week's podcast, *Medtech Insight*'s Shawn M. Schmitt talks about his recent reporting on US FDA's plans to merge its bedrock rule for manufacturing safe and effective devices in the United States with international quality systems standard ISO 13485.

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Medtech Insight articles addressing topics discussed in this episode:

- *QSR Author Kim Trautman Predicts What A Mash-Up Of FDA's Quality System Regulation And ISO 13485 Might Look Like*
- *The QSR/ISO 13485 Maze: How FDA's Satellite Device Rules Will Complicate A Quality System Regulation Rewrite*
- *US FDA Commissioner: Agency Will Propose New Rule That Blends Quality System Regulation, ISO 13485*