MEDTECH INSIGHT
CITELINE COMMERCIAL

21 May 2021 | **Analysis**

Device Week, 21 May 2021 – QSR Harmonization, Recalls, And More In MedCon Spotlight

by Elizabeth Orr

In this week's podcast we round up news from this year's MedCon medical device conference, sponsored by the US FDA and Xavier University. Key topics include Quality System Regulation harmonization, product recalls, a new FDA Inspectional Affairs Council, and the agency's breakthrough devices pathway.

Listen to the podcast via the player below:

Click here to explore this interactive content online

- *After QSR Delays, 'It's Full-Steam Ahead With That Proposed Regulation,' FDA's Shuren Vows*
- *FDA's Shuren: 'Senior-Level Folks' Will Take Part In New Inspectional Affairs Council*
- *Sprinting To Approval: Insider Tips On FDA's Breakthrough Devices Program*
- *FDA eSTAR Update: 51 Submissions, No Manufacturer Complaints*
- *Success Of Case For Quality Program Triggers 'Culture Shift' At FDA's Device Center, Officials Say*
- *Q1 Recalls Snapshot: It's A Mixed Bag As Device Recalls Fall 10% But Recalled Units Rise 3%*
- *FDA Warns Industry: We're Looking 'Closely And More In-Depth At Class II Recalls'*