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QUOTED. Aug. 21, 2018. Kim Trautman.

by

When FDA rewrites its Quality System Regulation, it will have to consider satellite device rules that address complaints, product recalls and traceability – just to name a few – to make sure those requirements will still be met by device-makers. So says Kim Trautman, who wrote the QSR in the 1990s. See what she said here.

"When ... the team at FDA takes this project on, it's not going to be just about looking at Part 820 [the QSR] by itself. A lot of other regulations will also have to be considered, because there are ties – there are ties in the actual words. There are definite linkages within 820 that tie to other regulations that FDA has that will have to be thought through." –Kim Trautman, executive VP of medical device international services, NSF International

- Find out more: *The QSR/ISO 13485 Maze: How FDA's Satellite Device Rules Will Complicate A Quality System Regulation Rewrite*

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