MEDTECH INSIGHT
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02 Jul 2019 | **News**

QUOTED. 2 July 2019. Adam Saltman.

by

A mere two dozen quality-related warning letters were sent by the US FDA to device-makers in calendar year 2018 – the fewest ever issued to companies since the agency's Quality System Regulation came into force 23 years ago. See why FDA medical officer Adam Saltman believes the "big hammer" of enforcement isn't always needed.

"Using the big hammer [of enforcement] isn't necessary all the time. A lot of times there may an initial recommendation for a warning letter, but it ends up getting interpreted into an untitled letter or even a regulatory meeting to take care of the problem, the general idea being that a warning letter may not be necessary in all circumstances." – Adam Saltman, medical officer, the US FDA device center's Office of Product Evaluation and Quality

- Find out more: *A Record-Low 24 Warning Letters Were Sent To Device Firms In 2018. That's Because A 'Big Hammer' Isn't The Best Tool To Ensure Compliance, FDA Says*