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QUOTED. 21 May 2020. Blea Vuniqi.

by

Manufacturers participating in a pilot program to streamline the CAPA process closed 74% of open CAPAs within 90 days, data from the US Food and Drug Administration show. Agency biomedical engineer Blea Vuniqi said the program was successful in other ways as well.

“In terms of cycle time of completing and closing CAPAs, ...baseline versus pilot CAPA, there is an overall huge reduction in cycle time to address issues that are identified, ...focusing on the issues that are higher risk that may take additional time, versus those that are lower risk [or] medium risk, that can be addressed quicker.” – Blea Vuniqi, biomedical engineer, US FDA

- Find out more: [Device Makers In Joint FDA/MDIC Pilot Closing CAPAs Faster, Agency Reports](#)

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