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QUOTED. 19 September 2019. Jeff Shuren.

by

Device-makers with less-than-stellar compliance history may soon be able to join a variation of the program by the US Food and Drug Administration that assesses a company's manufacturing maturity and quality. See what Jeff Shuren, who leads the FDA's Center for Devices and Radiological Health, said about it here.

"If struggling firms "are part of the appraisal program and we have a good plan for improvement and oversight, we might be a lot softer in the more traditional enforcement actions we take." – Jeff Shuren, director, US FDA Center for Devices and Radiological Health

- Find out more: *FDA Mulls Variant CMMI Maturity Model Program For 'Struggling' Device Companies*