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QUOTED. May 23, 2018. Becky Fitzgerald.

by

US FDA is working with device firms and outside experts to adopt new tools for appraising companies' manufacturing capability and maturity, leveraging the Capability Maturity Model Integration (CMMI) approach. See what CMMI appraiser and consultant Becky Fitzgerald said about one of FDA's key focus areas for the program here.

"How capable [a company] is to detect that it has a problem and to address it rapidly, and to effectively respond – that's the capability that the FDA is very interested in." – Becky Fitzgerald, principal and cofounder, Two Harbors Consulting

- Find out more: [*Chasing Quality Isn't Easy. But An FDA Pilot Aims To Boost Quality By Appraising The Capability Of Manufacturing Sites*](#)

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