

26 Jan 2018 | Analysis

QUOTED. Jan. 26, 2018. Kimberly Lewandowski-Walker.

by

Check out why US FDA's Kimberly Lewandowski-Walker says she has faith in the Medical Device Single Audit Program (MDSAP) and believes it will fare better than other third-party audit programs that went "up in a puff of smoke."

"I'm part of the team that developed [the MDSAP] program from scratch. To be brutally honest, I wanted to be involved in MDSAP because I had been at FDA long enough to see other third-party audit programs go over like a lead balloon. But with MDSAP, I got the feeling that this was different – that this was the real deal. I had seen these other programs kind of go up in a puff of smoke and never really materialize, but that's not the case with MDSAP." –Kimberly Lewandowski-Walker, senior regulatory officer, US FDA Office of Regulatory Affairs

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