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QUOTED. Jan. 30, 2018. Connie Hoy.

by

Check out what Cynosure's Connie Hoy had to say about how an intrusive US FDA facility inspection – and audits from Japanese, Korean and Brazilian regulators, all within one year – pushed her device firm to use the Medical Device Single Audit Program (MDSAP).

"It was particularly difficult [in 2014] to be in the quality department at Cynosure because all we did was get audited. It did not stop. We had regulators in from Japan and Korea. We had three Brazilian audits – one for our site and at our two OEMs [original equipment manufacturers]. We also had two FDA audits related to IDE [investigational device exemption] devices. And we had an FDA quality systems inspection. That FDA inspection really made me want to get Cynosure involved in MDSAP because I cancelled a vacation to Indonesia to stay behind for that inspection." –Connie Hoy, executive VP of clinical development and regulatory affairs, Cynosure

> Find out more: *'We Survived MDSAP': Cynosure Aces Single-Audit Program Twice; Tells How Your Firm Can, Too*

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