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QUOTED. Nov. 7, 2018. David Boudreau.

by

David Boudreau, chair of the committee that oversees the Medical Device Single Audit Program (MDSAP), believes "instability" could come to the device industry if international quality systems standard ISO 13485 is retooled right now. See what he wrote to the International Organization for Standardization (ISO) here.

"If changes are implemented to ISO 13485:2016, the Audit Model for MDSAP, which was just recently revised, will have to be completely revised, training of the auditing organizations will need to be conducted, and transition periods will need to be implemented, leading to instability in the MDSAP at a critical time." –David Boudreau, chair, MDSAP Regulatory Authority Council

- Find out more: *'An Unnecessary Editorial Revision': In Letter, MDSAP Council Rails Against ISO's Push To Change 13485 Quality Standard*