

27 May 2022 | **Analysis**

QUOTED. Dennis Gucciardo.

by

The FDA's proposed Quality Management System Regulation (QMSR) does not say if a regulation limiting the types of reports FDA investigators can review will be kept in place, which concerns some observers – including Morgan Lewis partner Dennis Gucciardo.

“If for some reason companies think that their management review records or internal audit records will be subject to inspection, I think that's a concern.” – Dennis Gucciardo, partner, Morgan Lewis

- Find out more: [FDA's QMSR: 3 Experts Read Draft Rule Comments So You Don't Have To. Here's What They Saw](#)

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