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# QUOTED. July 26, 2018. Sean Boyd.

by

US FDA's Sean Boyd wants device-makers to provide the agency with clear, well-organized responses if they're hit with observations following a facility inspection. See what he said about it here.

"Your responses should enable the reviewer or the compliance officer to locate the evidence or the exhibits that you're providing to us that show what corrections you've made, what additional steps need to be taken and what timeline that will be taken on. So, providing even a simple outline or an index that points to exactly where we can find the answer to the question, or the solution to the problem identified, would really help facilitate our reviews." –Sean Boyd, deputy director for regulatory affairs for the Office of Compliance, US FDA's Center for Devices and Radiological Health

- Find out more: *Compliance Corner: FDA's Boyd Gives 4 Pointers For Engaging With The Agency Post-Inspection*