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QUOTED. April 29, 2019. Melinda Plaisier.

by

In a new draft guidance, US FDA is offering device-makers step-by-step advice on how to recall a problem product, from general preparations to the development of correction and removal initiation procedures – and much more. See what the agency's Melinda Plaisier said about it here.

"For a recall to be effective and timely, it's crucial that companies be prepared in advance to take all necessary steps for when a recall is initiated. [The guidance will] provide industry with clear information on ways to prepare, plan and work with the FDA to ensure voluntary recalls are initiated properly and promptly." – Melinda Plaisier, associate commissioner for regulatory affairs, US FDA

• Find out more: <u>Device-Makers Can Be 'Recall Ready' With This New Step-By-Step Guidance</u> From FDA

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