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# QUOTED. 22 July 2019. Ben Dastoli.

by

When US FDA investigator Ben Dastoli inspects a medical device company, he typically sees firms making the same process validation mistakes over and over, including failing to identify all processes that require validation activities. Check out his comments here.

"As we as investigators are doing our facility walk-through, we're reviewing manufacturing instructions and we're looking at different processes that may require validation. Processes that seem to be commonly missed are gluing, layer-crimping and reagent-mixing. And keep in mind that if destructive testing is the only way to verify that specifications are met, then it's most likely a process that requires validation." – Ben Dastoli, investigator and medical device specialist, US FDA

- Find out more: *Compliance Corner: These Are The 6 Top Process Validation Mistakes Made By Firms, According To An FDA Investigator*