

09 Jan 2018 | Analysis

QUOTED. Jan. 9, 2018. Mark Durivage.

by

Check out what QA/RA expert Mark Durivage had to say about device-makers that are "afraid" to perform process validation activities.

"I've seen so many times in companies I've worked in that they were afraid to do validations. Quite honestly, if you're afraid to do a process validation and you don't know your process, there's a good chance you're going to put discrepant products on the market. Personally, I love the challenge of process validations and doing DOEs [design of experiments], and learning the stats behind all of it. But if you don't plan your validation activities properly, you're going to hate it, because it's not going to work for you." –Mark Durivage, managing principal consultant, Quality Systems Compliance LLC

> Find out more: [Compliance Corner: When Should Your Firm Revalidate Under Process Validation? An Expert Explains](#)

[Click here](#) for a free trial of *Medtech Insight*