GOOD AUTOMATION

USE CASE: Test Set Validation for Medical Devices

Are you sure your test systems and validation will pass FDA inspection scrutiny?

Perhaps you recognize some of the warning signs:

- Your templates have changed since your last test validation...whenever that was.
- Your company has been acquired and you've put off updating validations and testers.
- Your test systems have become obsolete in need of new features added.
- You know you have to upgrade, but you're worried it's going to be a massive effort.
- Most of the time you can handle regulatory changes. This time, it's driving you batty.
- Last month you got blindsided by a 483. You definitely don't want to go through that again.
- You've never heard anything scarier than "Consent Decree."

Here's what it sounds like:

Knock knock.

Who's there?

It's the FDA.

Are you really ready for that inspection?

"I hope so," you say.

What do you do when hope never holds off a 483.

Here's where to focus:

- It's dangerous to go alone. Get that extra set of expert eyes so you can be more certain you won't see that 483.
- Whether you go it alone or get help, make sure your test systems are actually validated. Far too many cut corners on this critical step!
- Remember, in test validation stacks, quality is often inversely proportional to size.
- No matter what you do, get ownership of all IP and source code, documentation, etc. No one wants to be held hostage by vendors!

Want help? Give us a shout.

At Good Automation, we believe writing and running good, validated test systems shouldn't be as difficult as learning to play ukulele by 2pm this afternoon.

ABIOMED

"Good Automation has helped us with several projects and has done a great job. They were able to work remotely to modify and write new LabVIEW software for our medical device and complete all the validation tasks as well. We could not find a better partner to help us."

— Jacob Spector, Manager, NPI & Lifecycle Engineering, Abiomed