

CASE STUDY: PFIZER



OUR CLIENT

Founded in 1849, Pfizer is dedicated to better health and greater access to healthcare for people and animals. Every day they help 38 million patients, employ 100,000 colleagues, utilize the skills of more than 12,000 medical researchers, and work in partnership with governments, and individuals for healthcare to treat and prevent illness

WHY THEY CAME TO US

For drug makers and others in the life science industry, any software changes that impact product quality, safety, or identity require validation in the eyes of the FDA or other regulators. Computer System Verification (CSV) requirements have become increasingly more rigorous since validation moved from the Lab and process systems to the IT department in the 1980's, and the cost of being accountable continues to escalate.

Mandated by FDA compliance regulations, Millennium Software, an bespoke software house in Cork who develops software for Pfizer, are required to test software changes or additions in line with FDA and industry guidelines. This was taking them hours and hours detailing the results of manual software tests on green screen programmes that they wrote and maintained.

Now, this tedious, costly and time consuming process has been automated with Original Software's TestBench solution.

WHAT WE DID

Throughout the testing process, Millennium technicians use TestBench to record procedures and results. Since the level of software quality and verification documentation is so good, Pfizer technicians can spend less time verifying these results before placing the modifications and enhancements into production.

Pfizer also have a copy of TestBench, which they use to verify Millennium's testing procedures. Brendan McMahon, MD of Millennium Software explains, "They can actually walk through our testing process and verify what we've done. They can use TestBench files as evidence later if they are audited."

HOW IT WORKED OUT

Brendan Murphy, Team Leader of Manufacturing Systems for Pfizer comments, "We are able to depend on the validation that Millennium produces. We have the same version of TestBench as they do, so when they restore onto our system we actually have access to the tests that they carried out. This is very handy".

Streamlining the testing and CSV process with TestBench has allowed Millennium to pare down costs to Pfizer by reducing the amount of work involved, says McMahon. "Part of the whole rationale of getting TestBench was that we would be able to share the testing data and eliminate duplicate testing. The reduced testing saved Pfizer a lot of money. Because we could be talking about multiple large projects, you get a quick payback on TestBench."

"We have also saved by not having to keep a million screen prints stored here in fireproof safes," adds McMahon. "We have to keep CSV records essentially forever. We have five safes full of test evidence, but we would have 50 if we didn't have these things electronically stored."

"TestBench is essential for anyone doing bespoke development. There is no better way to do this as far as I can see."

Brendan MacMahon
MD, Millennium Software