
Strategies for Streamlining DataFax Validation

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Would You Feel Safe Here?



What Happened?



Sometimes Things Fall From The Sky

- September 11, 2015
- Sandra Dwyer
- Chelyabinsk
- But we think more about the weather



What Matters?

- If SOPs keep you from thwarting hackers
- Are the interests of the current investigators more important than an ability to compare the data to similar trials in the future?
- If you worry about everything you will accomplish nothing.

Not Everyone Enjoys Baseball



Enforcement Discretion

- Freedom to decide
- Wisdom about disclosure
- Understanding limits
- Evaluating risks

FDA Must Choose

- Who to inspect
- When to inspect
- What questions to ask
- How to grade findings
- Who to trust

Principles

- Better is an enemy of the best.
- Computerized systems are dynamic; what works today will fail tomorrow.
- Not all requirements are created equal; but each has a cost.
- Computers are good at recognition; wise people understand context.
- Testing can be programmed if systems are planned.

Better Is An Enemy Of The Best

- Early marine biologists killed specimens by trying to purify their aquariums.
- CRF Monitoring has been documented to introduce as many discrepancies as it finds.
- The known bugs in existing software are a greater risk than those which have yet to be discovered.
- Statisticians have proved the introducing errors does not always change results.

Computerized Systems Are Dynamic

- Drives get full and wear out.
- Power goes out.
- Users accidentally delete things.
- Networks fail.
- Hackers disrupt.

Not All Requirements Are Created Equal

- It is easy to confuse:
 - Requirements with design
 - “Should” with “want”
 - What we are worrying about with what we actually care about
- The key question is “What will happen without it?”

But Validated “Requirements” Cost \$\$

- Each requires test
 - Planning
 - Coding
 - Execution
 - Documentation
- Each is a potential failure
 - Instructional and typographical errors
 - Bugs that don't actually matter
- So each one needs to prove its worth

Computers Are Good At Comparing; People Understand Context

- “diff” quickly compares thousands of lines.
- People often miss capitalization.
- Spell checkers catch errors people often miss, but sometimes change the meaning of sentences.
- If people type something twice, the second entry frequently does not match the first.
- The more paper you hand an auditor, the less likely they are to find an error.

Testing Can Be Programmed If Systems Are Planned

- SAS has a test suite that produces hundreds of pages of output in a matter of minutes because they have pre-defined expectations.
- The DataFax Acceptance Test kit functions on the same principles at a smaller scale.
- Google can program computers to drive cars because there are clear rules about where cars should go.

Strategies

- Clearly Defined Goals
- Risk Assessment
- Change Management
- Vendor tools
- Checklists
- Automated checks
- Virtual Systems

Defining Goals Clearly

- Purpose
- Process
- Costs
- Benefits
- Never lose sight of the big picture
- Always ask “Why can’t we get rid of this requirement?”

Risk Assessment

- Likelihood
- Severity (impact on requirements)
- Detectability
- Mitigation
- Overall score after mitigation

Change Management

- If nothing has changed ...
 - Test plans can be reused.
 - Retesting is sometimes unnecessary.
- If something has changed, what new risks are introduced?
- If a test worked for the last version and the release notes don't indicate this aspect of the program has been revised, the same test will probably work again.

Vendor Tools

- When the vendor provides tools, there is a good chance someone else will find the problem before it affects you.
- Vendor tools reduce the time required to write test plans.
- Vendor tools often support automated execution.

Checklists

- Easy to use
- Avoid forgetting something important
- Promote consistency
- Good for both training and documentation

Automated Checks

- When the computer checks itself, it can evaluate more detail more quickly.
- When notices are delivered via email there is additional evidence that network resources are functioning properly.
- Once automated checks are set up, little time or effort is required.
- Output can be saved to verify function over time

Virtual Systems

- If the server is nothing more than a file, it is easy to make a copy.
- Virtual systems ensure congruence between test and production.
- Virtual systems make destructive testing possible.

Discussion

- What is the difference between a functional requirement and a user requirement?
- How can one test be used to document multiple requirements?
- When can retesting be avoided?
- What test plans should be repeated for each version of DataFax?
- What evidence needs to be saved every day to document that DataFax is valid?

As A Wise Man Once Said ...

“Woe to you, teachers of the law and Pharisees, you hypocrites! ... You blind guides! *You strain out a gnat but swallow a camel.*”

-Matthew 23:23, 25