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 accidently 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
“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.
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?
“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