
DFUG 2009 Audit: Purpose, History, Opportunity

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Just to review ... What is an Audit?

An audit is an independent review
of procedures and documentation
which demonstrates that software
was developed according to
acceptable industry standards.

Why Audit a Software Vendor?

- Regulatory agencies are have the authority to audit Data Management systems.
- You can't 'validate' software if you don't control the source code.
- But, you can check to see that the developer followed generally accepted practices.

Auditors Ask

- Does this organization have written procedures to guide its work?
- Do those procedures contain "best practices"
- Is there *written* documentation that the
 - organization trained its staff to follow the procedures
 - staff actually followed the procedures

A successful Vendor Audit does NOT mean

- The software is perfect
- Installation testing is unnecessary
- Customers can forego
 - End user requirements
 - SOPs
 - Training
 - Backup
 - Etc.

Key Auditor Interests

- Documented commitment to quality
- Which translates into
 - SOPs
 - Training
- For which there is documented evidence of compliance

The goal is practical application of the Scientific Method

- Requirements become the hypothesis or endpoints for the software development process
- SOPs become the protocol
- Testing verifies that an expected outcome was achieved

An audit

- Along with
 - User requirements
 - Installation testing
 - Appropriate training and
 - Operational procedures
- Provides documentation to answer the question, “How do you know this software did (*or will do*) what you needed it to do?”
 - Whenever a regulator or prospective client asks
 - Often long after the data has been collected

Why a Group Vendor Audit?

- Vendor Audits are expensive for both client and vendor
- These costs can be reduced by focusing the resources of the user group on a single audit.
- The sharing of knowledge and experience from a variety of perspectives increases the value of the audit.

Client Costs

- Travel Expenses
 - Transportation
 - Food and Lodging
 - Time away from the office
- Document Preparation
 - Audit Plan
 - Findings

Vendor Costs

- Preparation time
- Hosting
- Response to findings

Multiple Resources Improve Quality

- Auditors need to understand both
 - How to conduct an audit, and
 - How the software is supposed to work
- Each organization has strengths and weaknesses in their auditing practices
- It is easy for any single individual to overlook an important issue

Previous DFUG Audits

- Were conducted in
 - January 2003
 - November 2004
 - April 2007
- Consisted of
 - 2 Days in Hamilton
 - Several conference calls to create and finalize the report
- Use PDA Technical Report 32
- Begin with SOP Review
- Proceed to documentation

Reporting Process

- A tentative list of findings is provided during the wrap-up meeting.
- A draft report is presented first to the vendor.
- The final report includes the vendor's response to each finding.
- Follow-up varies depending on the nature and severity of the findings.

Ground Rules

- Each organization pays the travel expenses of auditors they send.
- The final audit report is available free of charge to any DFUG member.
- Auditors are free create independent reports according to the requirements of their own organizations.

We look for Auditors with experience in one or more of these areas:

- Regulatory Affairs
- DataFax Data Management
- DataFax System Administration
- Software development
- And should represent a variety of companies and organizations

The Next Audit

- April 28-29, 2009
- Currently 5 auditors are committed
- 2 additional auditors are possible
- No additional auditors are required, but reasonable attempts will be made to include all interested parties.
- A completed audit report should be available to all DFUG members by the end of 2009—probably sooner.

If you are interested

- Review the 2007 report
(*You can find it at DFquality.org*)
- Talk with me
- Watch for the 2009 Audit Report
- Consider participation in a future DFUG Audit