
User Group Audits

Theory and Recommendation

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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 conduct an Audit?

- Regulatory agencies are increasing their scrutiny of Data Management systems.
- You can't 'validate' software if you don't control the source code.
- You can check to see that the developer did.

Auditors Ask

- Does this organization have written procedures that will enable it to create 'valid' software?
- Is there *written* documentation that the organization trained its staff to follow the procedures staff actually followed the procedures

'Validation' does NOT mean

- The software is perfect
- No installation testing is needed on the client's system
- No user requirements are needed

'Validation' MEANS that the vendor

- Developed the software to meet a specific list of requirements
- Documented how the software was constructed to meet the requirements
- Test results demonstrate that the software met requirements *or*
- Exceptions were noted and followed appropriately

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 what you needed it to do?”

Why a Group 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, experience and effort will increase 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 can 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

Potential Challenges for DFUG

- Varied audit practices
- Varied document formats

Approaches

- Identify contacts at each organization
- Compare requirements by
 - Conference call
 - Email
- Submit for approval in each organization
 - Audit procedures and checklists
 - Nominees resumes
 - Document formats

Auditors should include experience in

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

Auditors could include

- Auditing professionals from larger organizations
- Contract auditors paid by the user group

Phases

- **Organization (Audit Steering Committee)**
 - 6 to 8 months phone, email or face-to-face contact
 - Identify auditors
 - Create an audit plan
 - Agree on formulas for sharing expenses
 - Obtain management buy-in from companies / organizations
- **Audit**
 - 3 to 5 days in Hamilton
 - Findings written and provided to CDSI and participating companies/organizations
- **Follow-Up as appropriate**

An Audit Plan should identify

- Documents that should be reviewed
- Questions that should be asked

Possible Outcomes

- No follow-up necessary
- Corrective actions requested, such as
 - Improved documentation
 - Revised procedures
- If corrective actions are requested follow-up would be necessary to
 - Review CDSI's response
 - Ensure documentation of any changes made in response to the audit

Timing

- Prior to release of DataFax 4.0
- Sufficient time for preparation of a solid audit plan
- Convenient for all involved

If you are interested

- Please mark the interest sheet as it is passed
- Talk with me
- Stay tuned for the panel discussion
- Consider participation in a DFUG Audit Steering Committee

Who should join the DFUG Audit Steering Committee

- Able to join conference calls 2 to 3 times per month
- Willing to share what you know
- Willing to learn from others
- Willing to approach your company / organization about financial participation

This is your opportunity to

- Gain a broader industry perspective
- Contribute to industry standards
- Give your data management system a quality edge

You've devoted your career to
ensuring the scientific integrity of
clinical data.

Don't ignore the details of the
computerized system you've
created to manage it.