DataFax User Group Vendor Audit Report

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Purpose

User group audits …

- Reduce the burden to the vendor
- Promote communication between
  - User Organizations
  - Quality and IT

Purpose (2)

Software vendor audits …

- Do NOT remove the need for validation in a local environment
- Provide only a snapshot of the vendor
- Can be skewed by bias and miscommunication

Purpose (3)

But, are required by regulatory agencies because they do provide important checks and balances.

Scope of Audit

- Software development processes
- GxPs
- FDA Guidances
- Company SOPs

Outside Scope

- Business risks
- Vendor financials
- Corporate governance
- Organizational risk

History

- First proposed at DFUG 2002
- Five have been conducted:
  - January 2003
  - November 2004
  - April 2007
  - April 2009
  - May 2011

Ground Rules

- Each participant covers own expenses
- 5 to 7 team members is an ideal size
  - Only 1 auditor per organization is allowed unless total would be less than 6.
  - All interested organizations can send at least 1
- SOPs are only available on-site
- The final report is freely available upon request to any member of the user group.

Traditions – not necessarily planned

- Announced at DFUG and via the DFUG mailing list.
- Audits limited to 2 days.
- The same reporting format has been used since November 2004.
- Where applicable, focus has been on the most recently released version of DataFax.

Variations

- The regulatory experience of auditors has varied widely.
- Key issues have varied according to the needs of each organization.

2011 Audit Team

- Phil Kirsch, *Quality Manager, DF/Net Research, Inc., Seattle, Washington, USA*
- Janet Chien, *Principal, Dyad Systems, LLC., Cambridge, MA, USA*
- Janette Panhuis, *QA Director , Population Health Research Institute, Hamilton, Ontario, Canada*
- Christina Ma, *Clinical Research Unit Manager, Hotchkiss Brain Institute, University of Calgary, Calgary, Alberta, Canada*
- Dina Jarrar Kittani, *Senior QA Specialist, Teikoku Pharma USA, Inc, San Jose, CA, USA*
- Marni Meredith, *Research Data Coordinator, Abbott Nutrition, Columbus, OH, USA*

The audit team concluded that DataFax version 4.1 was developed and manufactured with an adequate level of quality for application in clinical operations governed by applicable regulatory and industry standards.

2011 AUDIT CONCLUSION

Summary of Observations

- 0 - Critical
- 3 – Major
- 11 – Minor
- 2 – Comment

Background on Observations

- Some minor issues were deemed major because they have persisted through multiple audits, including
  - Linking roles to names. (Clear to members of a small organization, but not clear on paper alone.)
  - Integration Testing (Unit test documentation has always been strong, but an overall requirements list was not published until after the 2011 Audit.)
- The relationship between attention to detail and a Quality System remains an outstanding point of disagreement.

Major Observation 1

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There is no list of what staff members are approved to fill the roles defined in the Organiza-tional Chart.

Company Response

Each role and the SOP training requirements for them are clearly tabulated in SOP PR002.

Major Observation 2

Observation 11

- The Quality Assurance function does not have the dedicated resources required to support software quality.

Company Response

… we feel that we currently have adequate resources devoted to the QA function.

Major Observation 3

Observation 15

Because the ATK covers only major functions of the software, and is not reviewed prior to every release, there is no evidence that the ATK is a sufficient integration test.

Company Response

- … while the ATK is part of integration testing it comes only as a final step after all individual CR integration testing has been performed. We will revise the SOPs to make this clearer.
- They also added requirements to the ATK.

Key Points

- The company is committed to excellence and compliance.
- There are differences of opinion which remain unresolved, and additional input from the user community or independent observers could be helpful.
- Each customer organization still bears primary responsibility for documenting that their use of the software meets their requirements and applicable regulations.

Future Considerations

- Are there ways to facilitate a remote audit without compromising confidential or proprietary details?
- Are there other ways to engage more user regulatory departments?
- Are the current criteria appropriate?
  - Is the current checklist appropriate?
  - Are the current observation grades helpful?
- Could the existing Beta program be expanded to supplement existing QA/QC?

This process is what you contribute to it

- It is important that each user organization think carefully about what they need to meet their regulatory obligations.
- There are significant issues which will require the careful and creative input of smart people to resolve.

For more information contact

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