
DataFax Users Group Audit Report

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What is an Audit?

- Tied to vendor not version
- Focus on practices not product
 - You validate DataFax 3.5
 - You audit Clinical DataFax Systems, Inc.
- Audits focus on quality; validation focuses on function
- A quality development plan fosters creation of valid software.
 - But you still need to validate it in your computing environment

Why a User Group Audit (1)

- **Meet regulatory requirements**
21 CFR 11 (Electronic Signature Rule)
Document Quality Plan and Practices
- **Increases Credibility**
Multiple Needs and
a variety of opinions represented
- **At reduced cost to both customers
and CDSI**

Why a User Group Audit (2)

- **Share expertise and perspective**
We were able to evaluate concerns before
presenting them to the vendor
- **Shared Responsibility**
It's hard for one person to read 100 pages of
SOPs.
Then there are guidelines and logs, etc.

DFUG User Group Audit Process

- Presented at last year's DFUG
- Draft Audit Plans circulated by email to interested parties
- Discussion continued for months by phone and email
- Team members met in Hamilton on January 13-14, 2003

DFUG Audit Team Members

- **Lori Greulich**
Manager of GCP Compliance
Pharmacyclics
- **Rose Gonsalves**
Clinical Database Administrator
ALZA Corporation

DFUG Audit Team Members (2)

- **Chianne Chen**
Computer Validation Engineering Specialist
ALZA Corporation
- **Khursh Ahmed**
Consultant, Population Health Research Institute
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DFUG Audit Team Members (3)

- **Phil Kirsch**
System Administrator
Statistical Center for HIV/AIDS Research and
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Documents Reviewed

- Standard Operating Procedures
- Organizational Chart
- System Design Diagram
- Employee Confidentiality Agreement
- Guidance Documents (4)
- Logs (6)

Guidance Documents Reviewed

- Writing SOPs
- Version Control for CVS
- Coding Standards
- User Interface Guidelines

Logs Reviewed

- Hardware Configuration and Maintenance
- Software
- Backup
- Staff Training
- System Problem Report
- Requirements

Tour and Demonstration

- Version Control with CVS
- Sample Test Case
- Facilities, including server room

Key Findings

- SOPs and supporting documents demonstrate competence and commitment to quality
- Compliance with 21 CFR 11
- Clear links between requirements, specifications, test plans, test results and product release

Quality Commitment

- Established by the Computer Validation Policy Statement
- Facilitated by SOPs which require written procedures
- All of the above communicated to each employee as documented in training logs

Subcontractor / Supplier Management

- SOPs clearly call for changes only after testing by hardware vendor
- Offsite storage is a safe deposit box at a local bank.

Project Planning / Management

- Per SOP, CDSI defines and tracks
 - Unique ID
 - Purpose
 - Code
 - Status
 - Test Plan(s)
 - Test Results
 - Release Date

Software Development

- Per SOP, CDSI requires adherence to IEEE standards
- In practice, CDSI uses CVS and an internal web page to track software development

Security

- Outer office doors locked at all times
- Individual Accounts
- Virus Protection

Quality Control

- Regular internal audits
- Per PDA's Technical Report No. 32

Maintenance

- Hardware logs are kept

Disaster Preparedness

- Logs demonstrate regular testing of backups since April 1998
- Alternate facilities clearly identified

Training

- Training logs demonstrate regular review of SOPs.

Observations

- Records Retention
- Approval Process
- Server Room
- Reference 21 CFR 11

Conclusions

- Demonstrated Quality Commitment
- No unmanageable risks

Future Audits

- Every two years
- Interested organizations should send representative(s) to DFUG 2004 for the 2005 Audit