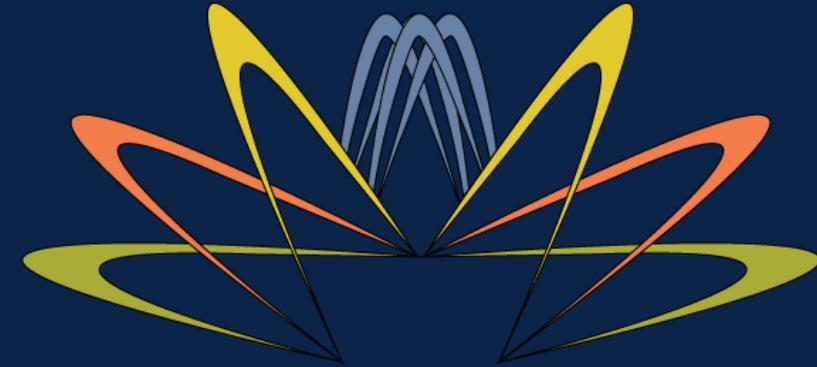




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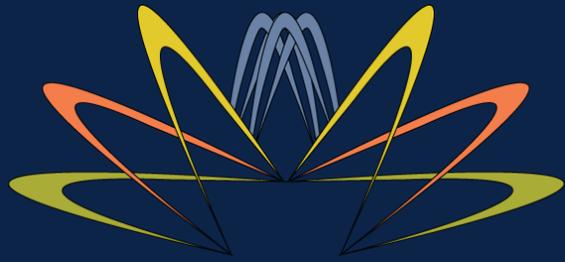
South Africa

DFUG 2016

DFUG 2015 Audit Report

Michael Holdsworth

Phil Kirsch



Overview

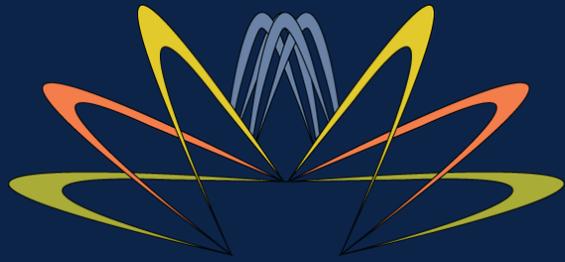
The DataFax User Group (DFUG) vendor audit is a combined user group audit that allows DataFax users to determine whether DF/Net Research (as the vendor of DataFax software) has the necessary procedures and documentation to comply with industry standards and regulations.

The 2015 DFUG Audit was announced to the User Group by mailing list (dfug@datafax.com) on the 14 September 2015.

The audit was conducted on Monday the 5th and Tuesday the 6th of October at the offices of DF/Net Research.

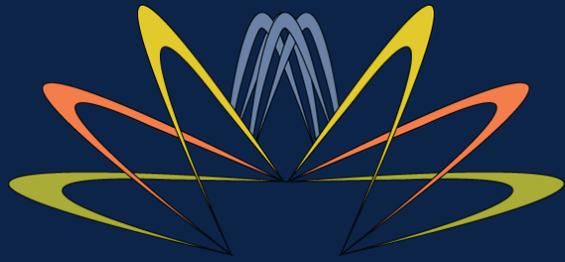
The Audit Report was published in early December 2015.

The audit team concluded that DF/Net Research does have the necessary procedures and documentation to comply with industry standards and regulations.



Regulatory and Industry Standards

- Code of Federal Regulations, (CFR) Chapter 21 Part 11 (Electronic Records and Signatures), Part 50 (Protection of Human Subjects), Part 312 (IND), Part 314 (NDA), and Parts 600/601 (Biologics General and Licensing).
- ICH E6: Good Clinical Practice and Q9: Quality Risk Management.
- Good Clinical Data Management Practices (Society for Clinical Data Management, October 2013).
- PDA Technical Report # 32: Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations.

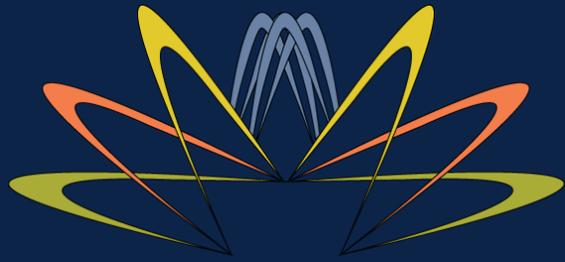


Audit Plan

In preparation for the on-site audit, an Audit Plan and Checklist were developed.

The Checklist was based upon the PDA Technical Report 32.

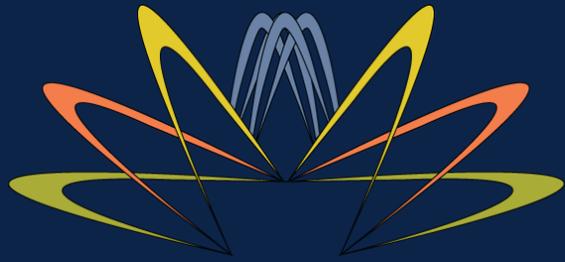
This Audit Plan was distributed to the entire user group before the audit for review and comment.



Audit Team

Michael Holdsworth, Senior Data Analyst, National Institute of Allergy and Infectious Diseases, Rockville MA, USA.

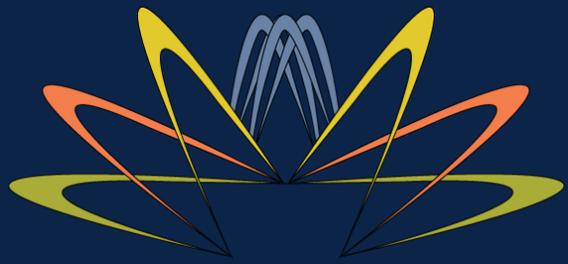
Manisha Thakur, Validation Specialist, Population Health Research Institute (PHRI), Hamilton, Canada.



Audit Focus

The audit reviewed documentation, inspected processes and interviewed staff members related to the following DataFax relevant activities/processes:

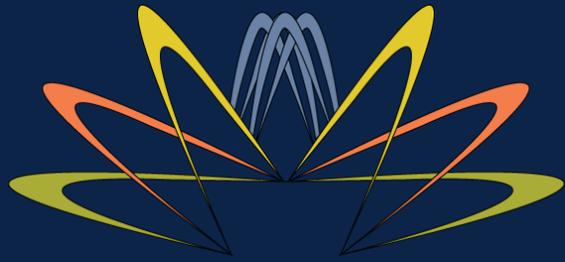
- Overall quality management
- Personnel qualification and training
- Software development methodology
- Supplier and sub-contractor management
- Project management
- Quality control processes
- Quality assurance processes
- Merger management
- Security
- Disaster preparedness
- Physical server and file rooms
- Financial stability
- Outcomes from other audits and regulatory inspections
- Follow-up from previous DFUG vendor audits



Summary of Findings

A total of twelve (12) observations were made:

- 0 critical findings
- 2 major findings
- 4 minor findings
- 6 comments



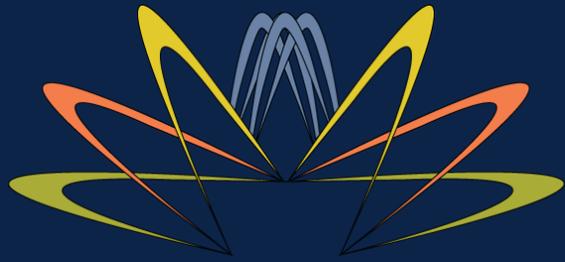
1st Major Finding

OBSERVATION:

The CVS system (used for managing and documenting the SDLC), the CR system (used for managing and documenting Change Requests) and the electronic SOP system are all very well established systems, which have been used successfully for over 20 years. However, despite the success and effectiveness of these well-established systems, regulations and best practices do require validation documentation.

RECOMMENDATION:

The auditors recommend that DF/Net Research establishes and maintains validation documentation for these systems.



2nd Major Finding

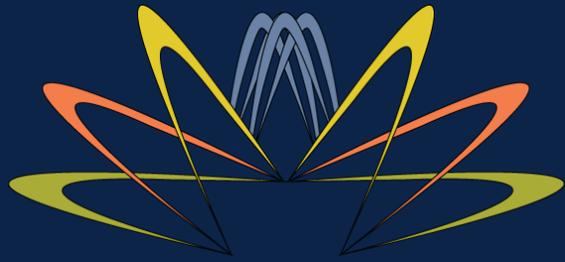
OBSERVATION:

SOP-QM003 “Purchasing” contains information about the co-location services used by DF/Net Research. However, the SOP does not discuss in detail how vendors are evaluated, qualified, monitored and managed over time.

Although the co-location services used by DF/Net are recognized, well-established, world-class facilities, regulations. Best practices do require that there are documented procedures for the management of vendors. Even though DF/Net has audited the co-location facilities and does manage these vendors (to some extent), these procedures are not documented in the SOPs.

RECOMMENDATION:

The auditors recommend that DF/Net Research either rewrites SOP-QM003 or develops a new SOP that details procedures on how vendors are evaluated, qualified, monitored and managed over time.



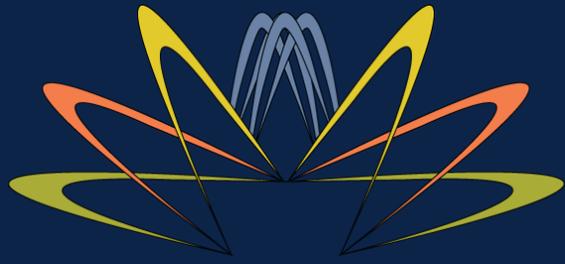
1st Minor Finding

OBSERVATION:

The training records (for all staff involved in the DataFax SDLC) were reviewed in detail. Some staff members have not been trained on the latest version of the SOPs and some staff members are missing training records. These training record discrepancies are detailed in Appendix C.

RECOMMENDATION:

The auditors recommend that the training record discrepancies, detailed in Appendix C, be suitably addressed.



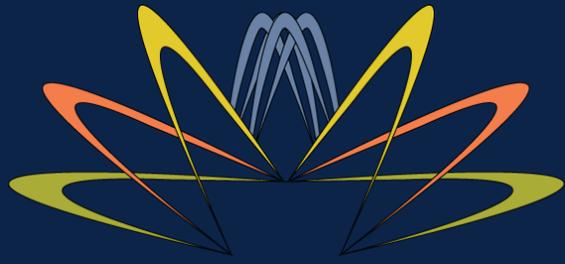
2nd Minor Finding

OBSERVATION:

Various SOPs refer to the roles "Director of Operations" and "QA Manager". However, these roles are not represented in the organogram.

RECOMMENDATION:

The auditors recommend that roles referenced in the SOPs (and other documentation) should be harmonized with roles depicted in the organogram.



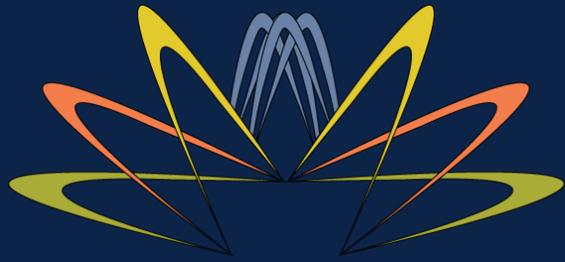
3rd Minor Finding

OBSERVATION:

One of the staff member's training logs does not reference SOP version numbers.

RECOMMENDATION:

The auditors recommend the following two actions: firstly, that the staff member's existing training records are updated to include SOP version numbers and secondly, the Training log/form is updated to include a column for version number.



4th Minor Finding

OBSERVATION:

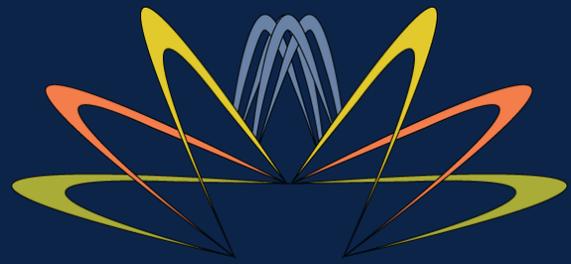
SOP-PR004 “21 CFR part 11 Training” says: “It is the responsibility of every supervisor to ensure that their staff have read and understood the 2 reference documents...”

The 2 reference documents refer to the FDA’s 21 CFR part 11 regulations and to “DataFax’s Compliance with 21 CFR part 11”.

However, training records only show that staff members have been trained on the FDA’s 21 CFR part 11 regulations. But there is no evidence that staff members received training on “DataFax’s Compliance with 21 CFR part 11”.

RECOMMENDATION:

The auditors recommend that DF/Net ensure that all staff are trained on “DataFax’s Compliance with 21 CFR part 11” and that the training logs are updated accordingly.



Questions
