
2013 User Group Audit

Phil Kirsch

DF/Net Research, Inc.



History

- Proposed in 2002
- Conducted roughly every other year beginning in 2003
- Most recently May 23-24, 2013

2013 Audit Team

Phil Kirsch, Quality Manager,
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Janet Chien, Principal, Dyad
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Sandra Oyola, Clinical
Scientist, Inovio Pharmaceuticals,
Blue Bell, Pennsylvania, USA

Bob Lucchesi, Vice President
and SME, Life Sciences, USDM Life
Sciences, Santa Barbara,
California, USA, under contract to
Inovio Pharmaceuticals

17 Findings

- 5 major
- 10 minor
- 2 comments
- A complete copy is available upon request

Key Recommendations to the Company

- We suggest CDSI continues working towards ISO 9001:2008 Certification which contains all the necessary components of a QMS
- Identify staff members responsible for each audit, and ensure that no one is auditing their own work

Recommendation to the Community

DataFax version 4.3 was released with a satisfactory level of quality for application in clinical operations governed by GCP and other applicable regulations

Since May 2013

- ISO Certification achieved
- DF/Net purchased the assets of Clinical DataFax Systems, Inc.

ISO 9001:2008

Craig Dilks

DF/Net Software ULC



What is ISO?

- ISO is the International Organization for Standardization
- An ISO International Standard represents a global consensus of the knowledge of a particular subject or process, be it the state of the art in that subject, or what is good practice

What is ISO 9001:2008

- International standard that gives the requirements for quality management systems
- Used in 176 countries over a wide variety of business sizes and sectors

What is ISO 9001:2008

- A framework for continual improvement and customer satisfaction
- Provides assurance about quality in supplier customer relationships
- Promotes good managerial practice
- Encourages the rise of services

Why Certify?

- ISO 9001:2008 can be used by internal and external parties to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements
- Provides evidence to customers and potential customers of what your organization can do for them

ISO 9001:2008 Requirements

- Scope
- Normative references
- Terms and definitions
- Quality management system
- Management responsibility
- Resource management
- Product realization
- Measurement, analysis and improvement

What We Did to Certify

- ISO awareness training for all staff (1 day – June 2013)
- Established a QMS that met the standard
- ISO internal auditor training for 1 staff member (November 2013)
- Two external certification audits performed by an ISO approved auditor (certified 23 July, 2014)

What's Next?

Craig Dilks

DF/Net Software ULC

Phil Kirsch

DF/Net Research, Inc.



Options

- New volunteers lead the DFUG audit
- Each company or organization accepts ISO certification or audits as needed