Data Integrity Training Lessons Learned & Case Studies

Monica J. Cahilly, M.S.
Green Mountain Quality Assurance LLC
www.greenmountainQA.com

OUTLINE

• What is “Data Integrity”?
• Good Documentation Practices
• Data Life Cycle
• Quality Management Systems
• Management Governance
• Data Integrity in a Global Context
• Case Studies
Is ‘Data Integrity’ a ‘New’ Regulatory Expectation?

- Evolving Business Models
- Increasing Globalization
- Evolving Documentation Practices
Current Environment--Risk Factors for Data Integrity Issues

• Overseas Testing and Manufacturing
• Supply Chain
• Out-sourcing of Operations (e.g., QC Labs, Manufacturing)
• Economic Stressors—*cutting corners*
• Data Review Practices

*Continued…*

Current Environment--Risk Factors for Data Integrity Issues

• Increasing use of Electronic Systems without commensurate understanding and implementation of risk-based controls for Electronic Data Integrity
  – Controls to *Prevent* Data Integrity Issues
  – Controls to *Detect* Data Integrity Issues
Data Integrity—A Growing Concern

• Data Integrity (MHRA)* = The extent to which all data are complete, consistent and accurate throughout the data lifecycle.

  – *Data integrity arrangements must ensure that the accuracy, completeness, content and meaning of data is retained throughout the data lifecycle.*

*MHRA Data Integrity Definitions and Guidance March 2015
What Assures Data Integrity?

• Good Documentation Practices
  – A = Attributable
  – L = Legible
  – C = Contemporaneous
  – O = Original
  • or Certified Copy of Original
  – A = Accurate

What is data + “metadata”?

Result Fails with 3.15…

3.15g

2.89 g
MC 28Sep15 entry error

Result Passes with 2.89…
Original:

- Original = Includes source capture of the data and all data needed to fully reconstruct conduct of activity
- Must Review the Original Records
- Must Retain the Original Records or a ‘Certified Copy’ of the Original Records

Potential Pitfall: “We Consider Printouts to be the “Raw Data” / the ‘Official Record’”
Part 11 Paradigm Shift

Applying the “Predicate Rule” to Electronic Data: Inside the “Black Box”

The Paradigm Shift

- How do we think about “data” and how do we design our business processes?
- How do we validate systems that generate source data with direct impact on patient safety, product quality, application integrity...?
- How do we manage risks across the entire DLC?
Data Life Cycle

- Do I have all my data?
  - Design of data collection: protocol, process, method
  - Data Life Cycle controls for data + metadata
- Has my data been objectively processed?
  - Controls to Prevent & Detect Testing Toward Outcome
- Am I reviewing all my data?
  - Printouts versus Source Electronic Records
  - Review of Audit Trails
- Am I reporting all my data?
  - Controls to Prevent & Detect Selective Reporting
What is the relevance of Data Integrity?

*Impact on:*

- Patient Safety
- Product Quality

Risk Management Methodology

- Risk Management Programs—ICH Q9
  - Risk Assessment
  - Risk Mitigation and Control
  - Risk Communication
  - Risk Review
Data Life Cycle = Business Process + Data Flow

Create Data → Process Data → Review Data → Report Data

Create Data → Transfer Data → Store Data → Retrieve Data

By: Monica Cahilly
Risk-Based Approach to Data Review

• “Critical” Thinking Skills for Data Reviewer
  – What are the reviewer’s “blind spots”?

Risk-Based Approach to Data Review

• “Critical” Thinking Skills for Data Reviewer
  – What about ERROR PATTERNS?
    • Frequency
    • Pattern
    • Determinate or Indeterminate
    • Failure Mode
    • Failure Effect
Data Life Cycle = Business Process + Data Flow

Preserving Relationships between Data + Data Attributes (‘Metadata’) throughout Data Life Cycle

6.5

Who?  When?  Why?

What?
Risk Management of Data Transfer and Storage

What is Goal of Data Process Mapping?

- Process Understanding.
- Knowledge Management.
- Quality Risk Management.
- Business Process Improvements:
  - Efficiencies, Effectiveness, Cost Reductions

Deming: “Quality costs less not more.”
Population of GxP Data:
Meaningful Decision-Making

External Environment:
Economic, Societal, Political, Legal, etc.

Internal Environment:
Quality Management System
Management Culture & Governance

Data Life Cycle

Good Documentation Practices

By: Monica Cahilly
Quality Management Systems Key to Data Integrity

- Training Program
- Risk Assessment & Management
- Validation (*Computer, Method, Process*)
- Data Life Cycle
- Investigations Program
- Data Review Program
  - Critical Thinking Skills

Quality Management Systems Key to Data Integrity

- Quality Audits & Inspections
- Vendor/Contractor Management
  - Agreements
  - Monitoring
- Management Culture & Controls
  - Transparency & Accountability
  - Tracking and Trending
  - Risk Profiling
“The Fraud Triangle”*

*Source: Occupational Fraud and Abuse, by Joseph T. Wells, 1997; reference to work of Donald Cressey, American Criminologist

**Incentive / Pressure**
Incentives or pressures on management or other employees to materially misstate the truth

**Attitude / Rationalization**
An attitude, character or set of ethical values that allows one or more individuals to knowingly and intentionally commit a dishonest act, or a situation in which individuals are able to rationalize committing a dishonest act (e.g., the environment imposes sufficient pressure on them to meet certain goals or targets).

**Opportunity**
Circumstances that provide an opportunity to carry out a material misstatement

Creating a Management Culture to Assure Data Integrity

• Transparency
• Accountability
• **Lead by Example**
  • Staying Continuously & Actively Involved
  • Process Ownership / Personal Responsibility
  • Set **Realistic** Expectations
  • **Fair and Just** Consequences & Rewards
  • Collaboration and Team Camaraderie
  • Staying “Current” with the “C” in CGxPs
Keys to a Successful Data Integrity Assurance Program

• Management Commitment & Governance
• Quality Risk Management
• Critical Thinking Skills
• Embracing Innovation

Win-Win!

Global Community for Healthcare: Medicines for All

• Safe
• Effective
• Quality
• Affordable
• Accessible
• Ethically Produced
What are Your Next Steps?

- Accuracy, reliable design, consistent intended performance of record systems, both paper document systems and computerized systems
- Data Controls (both paper and electronic) to ensure authenticity, integrity, confidentiality, readily retrievable, accuracy, consistency, completeness throughout Data Life Cycle
- Signature Controls (both hand-written and electronic) to ensure legally-binding
- Quality Systems and Management Governance in place to assure data integrity

Questions / Comments

Monica J. Cahilly, M.S.
Green Mountain Quality Assurance LLC
mcahilly@GMQA.net
www.greenmountainQA.com