



Data Integrity Training Lessons Learned & Case Studies

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OUTLINE



- What is “Data Integrity”?
- Good Documentation Practices
- Data Life Cycle
- Quality Management Systems
- Management Governance
- Data Integrity in a Global Context
- Case Studies



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Is 'Data Integrity' a 'New' Regulatory Expectation?

NO

- 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

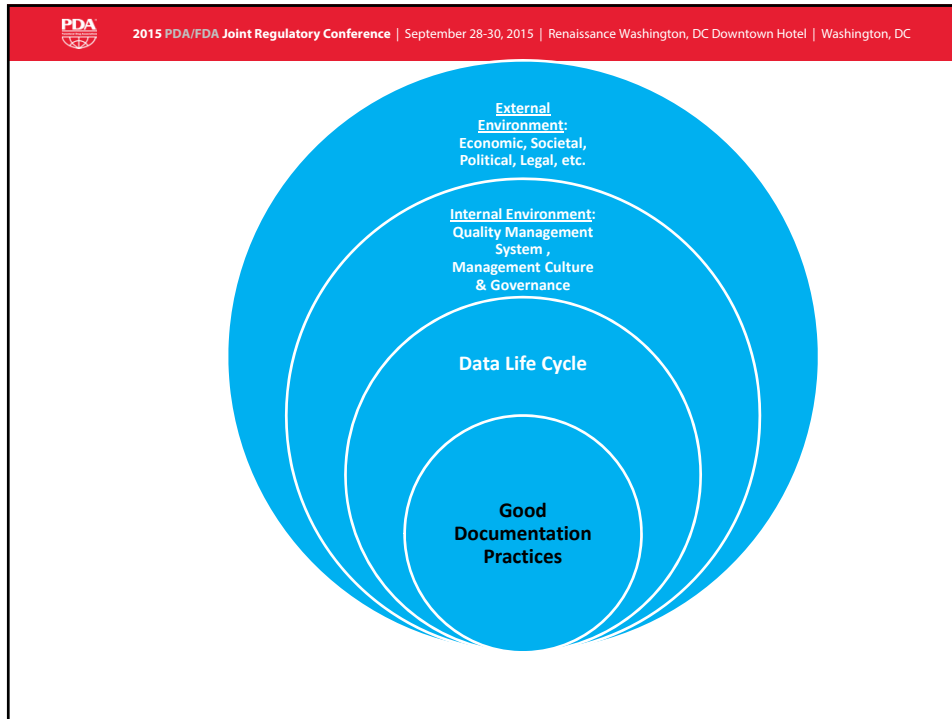
Continued...



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





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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...

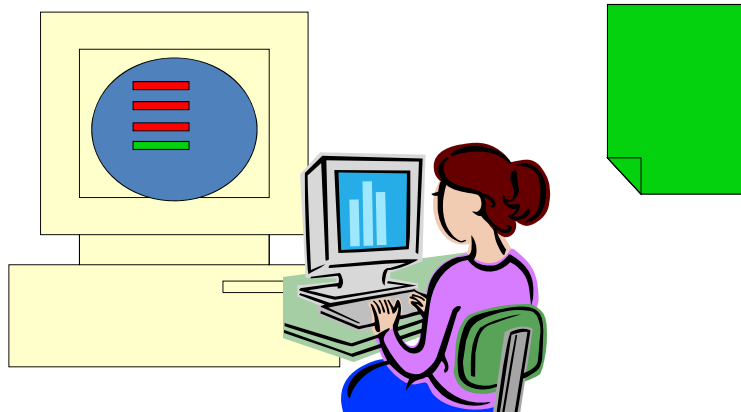


Original:

- 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

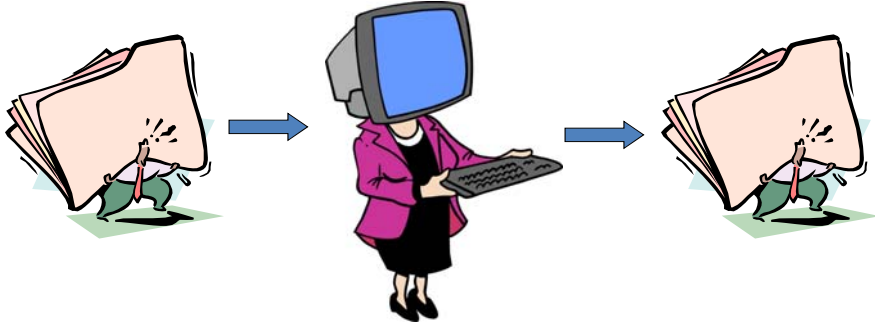


Potential Pitfall: *"We Consider Printouts to be the "Raw Data" / the 'Official Record'"*



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Part 11 Paradigm Shift




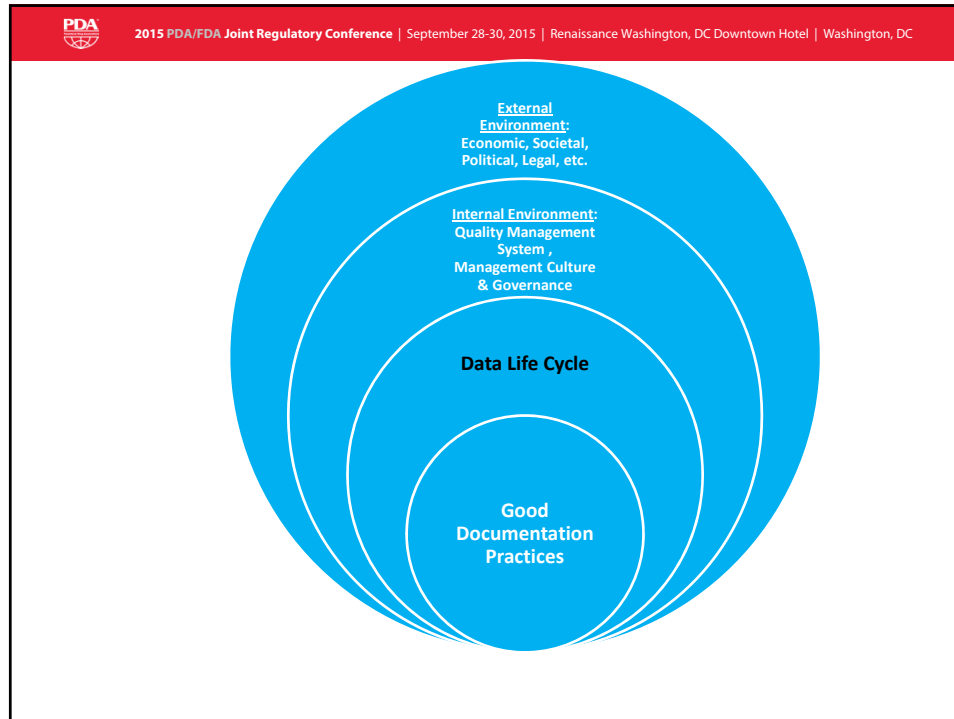
Applying the "Predicate Rule" to Electronic Data: *Inside the "Black Box"*

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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?





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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:

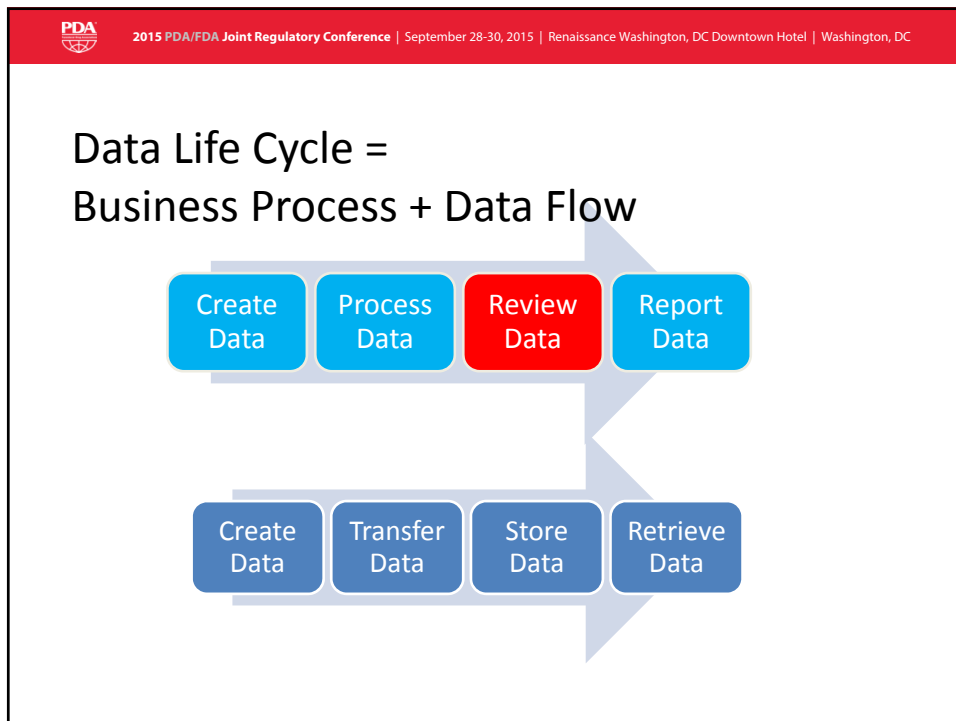
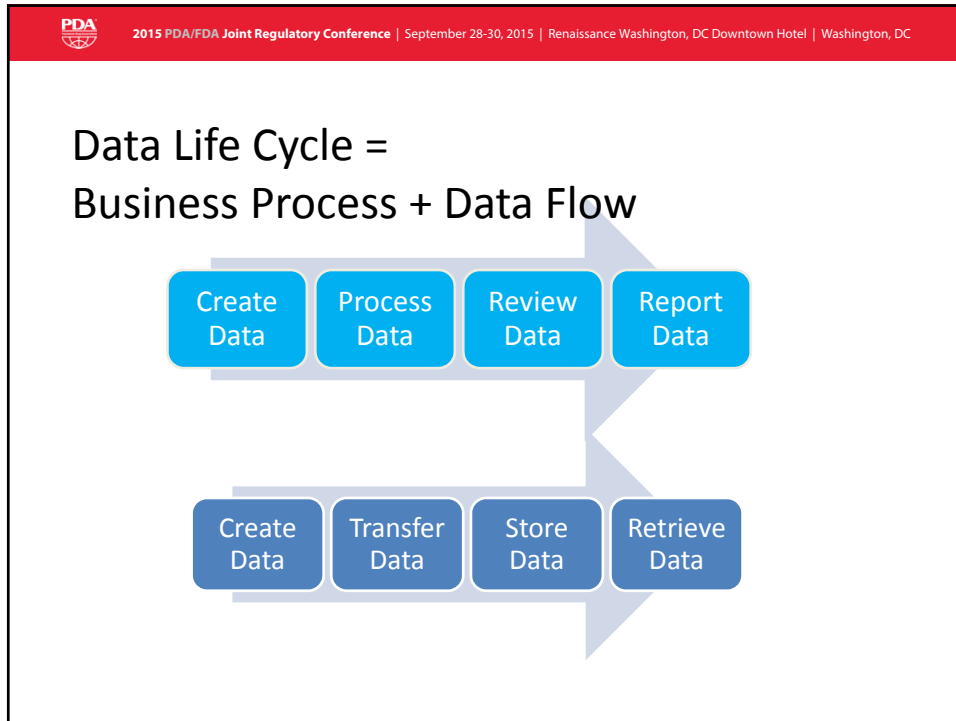
- Patient Safety
- Product Quality



Risk Management Methodology

- Risk Management Programs—ICH Q9
 - Risk Assessment
 - Risk Mitigation and Control
 - Risk Communication
 - Risk Review







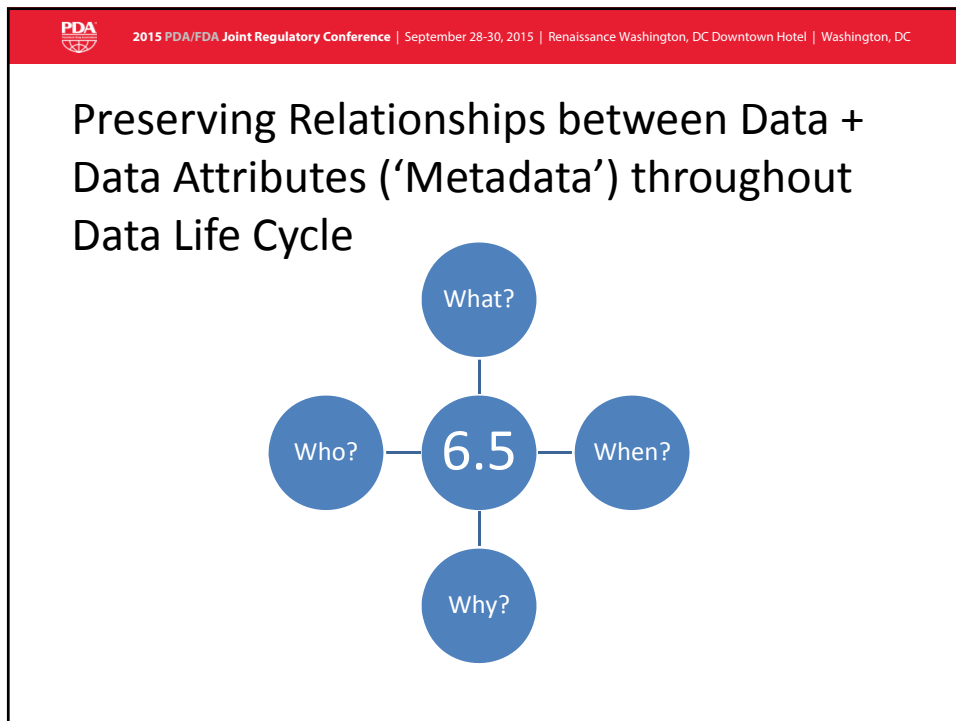
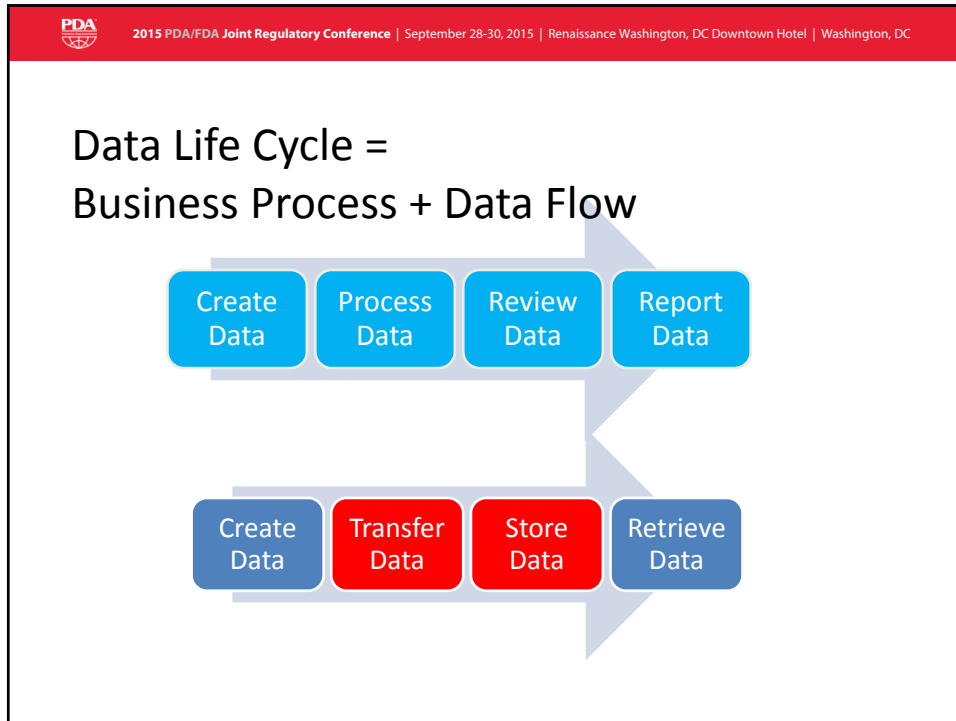
Risk-Based Approach to Data Review

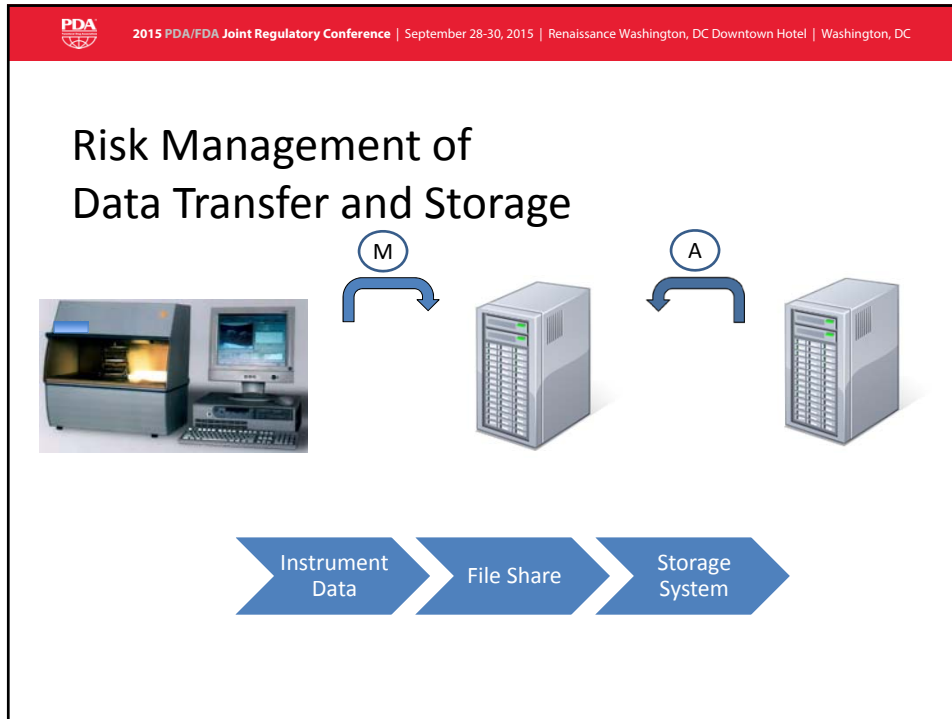
- “Critical” Thinking Skills for Data Review
 - What are the reviewer’s “blind spots”?



Risk-Based Approach to Data Review

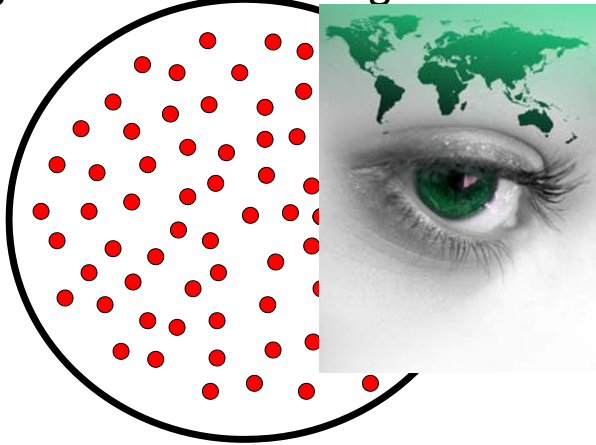
- “Critical” Thinking Skills for Data Review
 - What about ERROR PATTERNS?
 - Frequency
 - Pattern
 - Determinate or Indeterminate
 - Failure Mode
 - Failure Effect





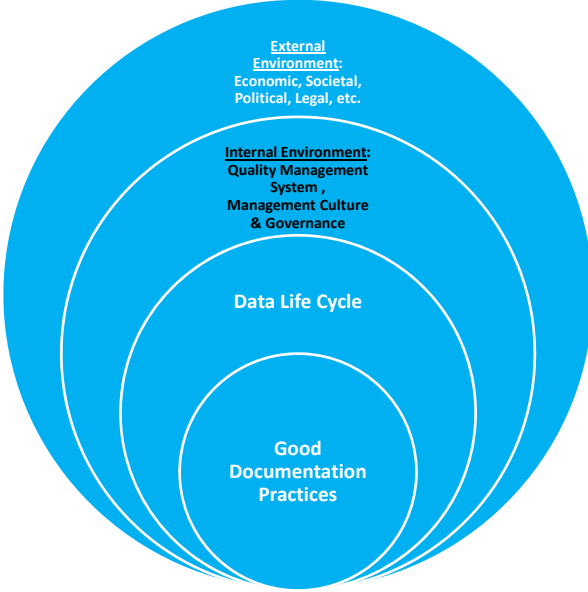
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Population of GxP Data: Meaningful Decision-Making



The graphic consists of a large circle. The left half of the circle is filled with numerous small red dots, representing a population of data. The right half of the circle is a close-up of a human eye with a green iris. A green world map is superimposed over the upper part of the eye, symbolizing global data and meaningful decision-making.

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The diagram features four concentric circles, all filled with a light blue color. From the outermost to the innermost, the layers are:

- External Environment:** Economic, Societal, Political, Legal, etc.
- Internal Environment:** Quality Management System, Management Culture & Governance
- Data Life Cycle**
- Good Documentation Practices**



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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*



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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

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“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

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

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).

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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

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